MINUTES OF 344th MEETING OF REGISTRATION BOARD HELD ON 31st DECEMBER, 2024 TO 02nd JANUARY, 2025

Drug Regulatory Authority of Pakistan
Prime Minister's National Health Complex,
Chak Shehzad, Park Road,
---------Islamabad ---------

344th meeting of Registration Board was held on 31st December 2024 – 02nd January, 2025 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad.

The meeting was chaired by Dr. Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP / Chairman, Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

The meeting was attended by the following:

1.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan. Rawalpindi.	Member
2.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Online)
4.	Mr. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member
5.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member
6.	Mr. Srtaj Khan, Representative of Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member
7.	Mr. Asad Abrar, Director DTL, Govt. of Punjab.	Member
8.	Jam Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
9.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member
10.	Mr. Babar Khan, Director, Biological Evaluation & Research Division, DRAP.	Member
11.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
12.	Dr. Ghayour Ahmed, Deputy Director, Representative of MD&MC Division, DRAP.	Member
13.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
14.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan	Co-Opted Member
15.	Dr. Shah Jahan, Representative of M/o National Food Security & Research, Islamabad.	Co-Opted Member

Mr. Nadeem Alamgir and Mr. Basharat Khan (Pharma Bureau), Mr. Jalal-ud-Din Zafar & Dr. Zafar Mustafa Jaja (PPMA) and Mr. Rashid Mahmood (PCDA) attended the meeting as observers.

ItemNo. I **Confirmation of Minutes of 343rd meeting of Registration Board.**

343rd meeting of Registration Board was held on 03rd – 05th December, 2024. Accordingly, draft minutes of the 343rd meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 343rd meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: **Registration Board unanimously confirmed minutes of 343rd meeting of Registration Board.**

ItemNo. II **Division of Pharmaceutical Evaluation & Registration**

Agenda of Mr. Ammar Ashraf Awan

Case no.: 01 Applications submitted on Form 5F by way of contract manufacturing

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21688 dated 01-09-2023 Rs.75,000/- dated 04-08-2023
	The proposed proprietary name / brand name	**Prolide 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	The status in reference regulatory authorities	USFDA approved Motegrity® 1mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 1mg tablet Manufacturer: M/s Seraph (Reg. # 119163)
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator's specifications

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
Manufacturer firm	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
Brand Name	**Prolide 1mg Tablet**

Decision: Approved.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21689 dated 01-09-2023 Rs.75,000/- dated 04-08-2023

	The proposed proprietary name / brand name	**Prolide 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…2mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	The status in reference regulatory authorities	USFDA approved Motegrity® 2mg Tablet
	For generic drugs (me-too status)	Brand Name: Prucalp 2mg tablet Manufacturer: M/s Seraph (Reg. # 119162)
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator's specifications

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Wezen Pharmaceuticals. Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat
Manufacturer firm	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
Brand Name	**Prolide 2mg Tablet**

Decision: Approved.

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Reliance Pharma.** **Plot No 8, Street No. S-8, Industrial Estate, Rawat, 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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 26023 dated 27-10-2023 Rs.75,000/- date not clear
	The proposed proprietary name / brand name	**Terboflux 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine Hcl Eq. to Terbinafine…125mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	The status in reference regulatory authorities	Lamisil Tablet (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbisil Tablet by Saffron
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	**FUNGOFINE 125mg tablet**

Decision: Approved. Firm shall submit fee for revision of title of the applicant firm before issuance of registration letter.

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Reliance Pharma.** **Plot No 8, Street No. S-8, Industrial Estate, Rawat, 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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 26024 dated 27-10-2023 Rs.75,000/- date not clear
	The proposed proprietary name / brand name	**Terboflux 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram Contains: Terbinafine Hcl…10mg
	Pharmacotherapeutic Group of (API)	Anti-Fungal
	The status in reference regulatory authorities	Lamisil Athletes Foot Cream (**TGA** Australia Approved)
	For generic drugs (me-too status)	Terbiderm cream by Atco
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	JP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	**FUNGOFINE 1% Cream**

Decision: Approved. Firm shall submit fee for revision of title of the applicant firm before issuance of registration letter.

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Pharmaceuticals** **Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 22759 dated 15-09-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Quaferric 50mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Single Dose Vial Contains: Iron as Ferric Carboxymaltose…50mg/ml
	Pharmacotherapeutic Group of (API)	Iron trivalent, parenteral preparation
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Ferinject injection of M/s LCI
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Ferinject injection
	Detail of stability batches of drug product	3 batches of 300 ampoules each
	Document for procurement of API	Loan letter form M/s English Pharma in name of M/s Wimits Pharma along with commercial invoice attested by DRAP I&E office in name of M/s English Pharma.
Evaluation by PEC[II]: Firm has submitted fee of Rs. 75,000/- vide deposit slip no. 188496673 for change of drug product manufacturer from M/s English pharmaceutical industries to M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.		
Decision: Approved by way of contract manufacturing from M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore. Registration letter will be issued upon verification of loan letter.		
6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy. No 1894 dated 20-01-2022 Rs.20,000/- dated 11-03-2020
	The proposed proprietary name / brand name	**Nu-ORS Lemon Flavor Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Sodium Chloride…2.60gm Potassium Chloride…1.50gm Tri-Sodium Citrate Dihydrate…2.90gm Dextrose Anhydrous…13.50gm
	Pharmacotherapeutic Group of (API)	Electrolyte
	The status in reference regulatory authorities	Recommended by WHO
	For generic drugs (me-too status)	Orsol sachet of M/s Kaizen

	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	BP
	Evidence of approval of manufacturing facility	GMP certificate issued on 19-04-2019 declares Sachet section
	Stability Studies of Drug Substance	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Detail of stability batches of drug product	3 batches of 200 sachets each
	Document for procurement of API	Firm has submitted Goods Declaration along with commercial invoices.

Evaluation by PEC[II]:

Observations	**Firm's response**
Submit evidence of availability of flame photometer required for analysis of drug product as per BP monograph.	Firm has submitted invoice from Western Analytical Services for the Flame Photometer dated 6-11-2019

Decision: Approved. Firm shall submit IQ, OQ & PQ reports for the Flame photometer before issuance of registration letter.

Case no.: 02 Applications submitted on Form 5F by way of self-manufacturing

7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5 Dy.No 16021 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	The proposed proprietary name / brand name	**Alpride 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Levosulpride…100mg
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	The status in reference regulatory authorities	LEVOPRAID 100 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved.
	For generic drugs (me-too status)	Sulvo tablet 100mg by M/s Medisure, Reg no. 31749
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator's specifications

Evaluation by PEC[II]:

Decision: Approved.

Case no.: 03 Applications of finished drug product import

8.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation.** **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 041 Address: **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan** Address of Godown: NA Validity: 19-11-2022. Status: Drug License By way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name, address of manufacturer(s)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 28165 dated 04-10-2022
	Details of fee submitted	Rs.150,000/- dated 23-09-2022
	The proposed proprietary name / brand name	**0.9% Sodium Chloride 900mg/100ml Ifusion for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Sodium Chloride…0.9gm
	Pharmacotherapeutic Group of (API)	Electrolyte supplements
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	--
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP no. 20210115 issued by Hubei Medical Product Administration. The certificate confirms the free sale status of the product. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection after every 5 years. Firm has also submitted copy of GMP certificate no. HB2190552 issued by issued by Hubei Province Medical Product Administration , valid till 26-11-2024 for M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei,

		China declaring scope of inspection as Large Volume Parentral
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Agent and Distributor Agreement" between M/s Sohail Corporation & M/s Tianjin King for the applied product valid till 17-06-2026
	Pharmaceutical Equivalence	Pharmaceutical equivalence has been submitted against Sodium chloride 0.9% infusion of B Braun
	Drug product stability data	Drug product stability studies has been submitted for three batches at Zone IV a conditions for both accelerated (6 months) and long term (36 months) conditions.

Evaluation by PEC^{II}:

Observations	**Firm's response**
Analytical record for the drug product stability studies shall be submitted.	Firm has submitted stability summary sheets for drug product at both accelerated and long term conditions
Valid GMP certificate of drug product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate no. HB2190552 issued by issued by Hubei Province Medical Product Administration , valid till 26-11-2024

Decision: Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

9.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation.** **Plot No. 474, Siraj Colony, Moosa Lane, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 041 Address: **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan** Address of Godown: NA Validity: 19-11-2022. Status: Drug License By way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s ShandongXier Kangtai Pharmaceutical Co., Ltd. Private Economy Garden, Xinyan Town, Yanzhou District, Jining City, Shandong China
	Name, address of manufacturer(s)	M/s ShandongXier Kangtai Pharmaceutical Co., Ltd. Private Economy Garden, Xinyan Town, Yanzhou District, Jining City, Shandong China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12289 dated 20-05-2022
	Details of fee submitted	Rs.100,000/- dated 12-04-2021 & Rs.50,000/- dated 07-06-2021
	The proposed proprietary name / brand name	**Diclofenac Sodium 75mg/3ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Diclofenac Sodium…75mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	British Pharmacopoeia
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Dicloran Injection of M/s Sami
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP/Free Sale:** Firm has submitted free sale certificate no. Y-F2002066 dated 09-09-2020 issued by Jining Yanzhou Market Supervision and Administration, China valid till 08-09-2025. Firm has also submitted copy of DML# Lu20160143 of M/s Shandong Xier Kangtai Pharmaceutical Co., Ltd. Private Economy Garden, Xinyan Town, Yanzhou District, Jining City, Shandong China issued by Shandong Provincial Drug Administration.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Agent and Distributor Agreement" between M/s ShandongXier Kangtai Pharmaceutical Co., Ltd.
	Pharmaceutical Equivalence	Pharmaceutical equivalence has been submitted against several brands Chinese origin products.
	Drug product stability data	Drug product stability studies has been submitted for three batches of 200,000 units each at Zone IV a conditions for both accelerated (6 months) and long term (36 months) conditions.

Evaluation by PEC^{II}:

Observations	**Firm's response**
Product specific sole agency agreement shall be submitted	Firm has submitted copy of legalized "Agent and Distributor Agreement" between M/s ShandongXier Kangtai Pharmaceutical Co., Ltd. & M/s Sohail Corporation including the applied product.
Analytical record for the drug product stability studies shall be submitted	Firm has submitted stability summary sheets for drug product at both accelerated and long term conditions

Decision: Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued

upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

Case no.: 04 Applications submitted on Form 5.

10.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Tofanib 5mg Tablets
	Composition	"Each Tablet Contains: Tofacitinib as Citrate …… 5mg"
	Diary No. Date of R& I & fee	Dy. No 36787 dated 06-11-2018 Rs.20,000/- Dated 06-11-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	NA
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 289th meeting: Deferred for the followings: a) Evidence of approval of required manufacturing facility for "Cytotoxic drugs" from CLB. b) Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Firm's response: a) Tofacitinib Citrate is a Immunosuppressant medication used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, and ulcerative colitis. It is a janus kinase (JAK) inhibitor. **b)** Tofanib 5mg Tablets contains Tofacitinib as Citrate as Active Pharmaceutical Ingredients is nationally available with the Name of Jakjanz Strength 5 mg Dosage Form Tablets manufactured By Atco Laboratories Limited, having registration No. 114406. **Note:** Stability data is required for applied formulation	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
11.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Tofanib 10mg Tablets
	Composition	"Each Tablet Contains: Tofacitinib as Citrate …… 10mg"
	Diary No. Date of R& I & fee	Dy. No 36788 dated 06-11-2018 Rs.20,000/- Dated 06-11-2018

	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	NA
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 289th meeting: Deferred for the followings: a) Evidence of approval of required manufacturing facility for "Cytotoxic drugs" from CLB. b) Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Firm's response: a) Tofacitinib Citrate is a medication used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, and ulcerative colitis. It is a janus kinase (JAK) inhibitor. b) Tofanib 10mg Tabletscontains Tofacitinib as Citrate as Active Pharmaceutical Ingredients is nationally available with the Name of Actinib Strength 10 mg Dosage Form Tablets manufactured By The Searle Company Limited, having registration No. 117979. **Note:** Stability data is required for applied formulation	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023 as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
12.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Naprevo 500mg /20 mg Tablets
	Composition	Each Delayed release Film Coated Tablet Contains: Naproxen…....500mg Esomeprazole Magnesium…..20mg
	Diary No. Date of R& I & fee	Dy.No. 36303 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Anti-inflammatory and Antirheumatic & PPIs
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1 x 10's, 2 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimovo Tablet 20/500 of USFDA approved
	Me-too status	Not found

	GMP status	Last GMP inspection conducted on 11-03-2017 and report concludes that firm was GMP satisfactory.
	Remarks of the Evaluator	Manufacturing method is not according to innovators product. Clarify. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5F along with differential fee.
	Decision of 293rd meeting: Deferred for the followings: 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, or else application on form-5F alongwith differential fee.	
	Firm's response: Naprevo 500/20mg Tablets contains Naproxen 500mg and Esomeprazole as magnesium trihydrate 20mg as Active Pharmaceutical Ingredients is nationally available with the Name of Nipsso MR Tablet 500mg/20mg Strength 500/20 mg Dosage Form Tablets manufactured By Weather Folds Pharmaceuticals, having registration No. 110223. **Note:** Stability data is required for applied formulation	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023 as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
13.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Bivolol 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…5mg"
	Diary No. Date of R& I & fee	Dy.No 38717 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of "M/s. Dyson Research Laboratories.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision of 295th meeting: Deferred for the followings: Deferred for either submission of 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.	

	Firm's response: Master formulation & manufacturing method for uncoated tablets along with requisite fee is submitted.	
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Nebivolol as hydrochloride…5mg"** **Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.**	
14.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories.** **41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Bivolol 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…10mg"
	Diary No. Date of R& I & fee	Dy.No 38718 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of "M/s. Dyson Research Laboratories.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision of 295th meeting: Deferred for the followings: Deferred for either submission of 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 alongwith submission of requisite fee, master formulation & manufacturing method.	
	Firm's response: Master formulation & manufacturing method for uncoated tablets along with requisite fee is submitted.	
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Nebivolol as hydrochloride…10mg"** **Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.**	
15.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories.** **41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Loxo 60mg Tablets
	Composition	"Each Tablet Contains: Loxoprofen sodium as dihydrate…60mg"
	Diary No. Date of R& I & fee	Dy. No. 39119 dated 28-11-2018 Rs.20,000/-

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	30's, 100,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA (uncoated tablet)
	Me-too status (with strength and dosage form)	Qizta Tablets of M/s Wilshire Laboratories,
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision of 295th meeting: Deferred for the followings: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.	
	Firm's response: Loxo 60mg Tablets are film coated tablets and step of coating process in manufacturing outlines is submitted.	
	Decision: Approved as per following label claim: **"Each film coated tablet contains:** **Loxoprofen sodium as dihydrate…60mg"** **Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.**	
16.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Seromet 500/85 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Naproxen sodium…500mg Sumatriptan as succinate…85mg"
	Diary No. Date of R& I & fee	Dy. No. 38715 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	NSAID/ Selective serotonin (5HT1) agonists
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	6's, 10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(film coated)
	Me-too status (with strength and dosage form)	Migrot Plus Tablet of Genix Karachi
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.

	Decision of 295th meeting: Deferred for the followings: Deferred for clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.	
	Firm's response: Seromet 500/85 mg Tablets are film coated tablets and step of coating process in manufacturing outlines is submitted.	
	Decision: Approved. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.	
17.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	TALOSIN 0.4mg Capsules
	Composition	Each Capsule contains: Tamsulosin HCl …….0.4mg
	Diary No. Date of R& I & fee	Dy. No.1429;15-3-2017 ; Rs.20,000/- (15-3-2017)
	Pharmacological Group	alpha1-adrenoceptor blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Duodart Of GSK
	GMP status	Last GMP inspection was conducted on 10-04-2017 and the report concludes: "The firm is advised to keep and maintain all the consumption scale/storage record as per SOPs and intimate the undersigned upon consumption of raw material for verification and issue of consumption certificate".
	Previous remarks of the Evaluator.	●
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-293).
	Evaluation by PEC	Source of pellets: M/s Vision Pharmaceuticals, Islamabad Analytical procedure for tamsulosin pellets, stability studies of pellets, and GMP certificate of supplier has been submitted. GMP is not within period of three years.
	Decision of 295th meeting: Deferred for the followings: Registration Board referred the case to QA & LT to conduct GMP of the firm on priority.	
	Firm's response: Firm has submitted GMP inspection report dated 03-03-2022 declaring satisfactory level of GMp compliance.	
	Decision: Approved.	
18.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name + Dosage Form and Strength	Prandlin 1mg Tablet
	Composition	Each Tablet Contains: Repaglinide……..1mg

	Dairy No. date of R &I fee	Form-5 Dy.No 41421 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other blood glucose lowering drugs, excl. insulins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Repag 1mg Tablet by Getz Pharma (Pvt)Ltd, (Reg#57891)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablet while the reference formulation is uncoated. Revise the label claim and master formulation along with submission of applicable fee.
	Decision of 296th meeting: Deferred for the followings: Deferred for revision of label claim and master formulation as per reference formulation alongwith applicable fee and GMP inspection during 3 years.	
	Firm's response: **a)** Label claim and master formulation as per reference formulation along with applicable fee is submitted. **b)** Firm has submitted GMP inspection report dated 03-03-2022 declaring satisfactory level of GMP compliance.	
	Decision: Approved. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.	
19.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name + Dosage Form and Strength	Vermeil DR 10/10mg Tablet
	Composition	Each film coated delayed Release Tablet contains: Doxylamine Succinate…10mg Pyridoxine HCl…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39886 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antihistamines
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too-status	Omit 10/10 mg Tablet by Scilife Pharma (Reg#82087)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet

		• The reference formulation is film coated delayed release tablets while the applied product manufacturing outline does not contain any such steps. Please revise the manufacturing outline as per reference formulation
	Decision of 296th meeting: Deferred for the followings: Deferred for revision of manufacturing outline as per reference formulation.	
	Firm's response: Manufacturing outline as per reference formulation is revised and submitted.	
	Decision: Approved as per innovator's specifications Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.	
20.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Zipdone 40mg Capsule
	Diary No. Date of R& I & fee	Dy.No 38145 dated 19-11-2018 Rs.12,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….40mg
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 40mg capsule of M/s Nabiqasim Industries (Reg.#055651)
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The reference product contains Ziprasidone hydrochloride monohydtrate while the applied formulaiton contains Ziprasidone hydrochloride, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision of 296th meeting: Deferred for the followings: Deferred for submission of evidence of approval of applied formulation containing "Ziprasidone Hydrochloride" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
	Firm's response: Zipdone 40mg Capsules contains Ziprasidone as HCl Master formulation revised and submitted.	
	Decision: Approved	
21.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name + Dosage Form and Strength	Cilaaz 100mg Tablet
	Composition	Each film coated Tablet Contains: Cilostazol……..100mg

	Dairy No. date of R &I fee	Form-5 Dy.No 39896 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Platelet aggregation inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PLETAL cilostazol 100 mg tablet of Otsuka Australia Pharmaceutical Pvt Ltd (TGA Approved)
	Me-too-status	Pletaal Tablets 100mg by M/s Otsuka Pakistan Ltd, (Reg#029295)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation does not contain coating. Revise the label claim and master formulation along with submission of applicable fee.
	Decision of 296th meeting: Deferred for the followings: Deferred for revision of label claim and master formulation as per reference product along with requisite fee.	
	Firm's response: Master formulation as per reference product and applicable fee submitted.	
	Decision: Approved as per following label claim: **"Each tablet contains:** **Cilostazol……..100mg"** **Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 before issuance of registration letter.**	
22.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Tibuten 90mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Ceftibuten As Dihydrate…90mg
	Diary No. Date of R& I & fee	Dy No. 38409: 30-11-2018 PKR 20,000/-: 30-11-2018 Duplicate dossier received vide Dy No. 1562 dated 17-01-2023
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed (discontinued in USFDA)
	Me-too status	Xigris suspension by Wilshire
	GMP status	Last GMP inspection dated 03-03-2022 and the report concludes satisfactory level of GMP compliance.

	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 324th meeting: Deferred for the followings: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Tibuten 90mg per 5ml Dry Suspension contains Ceftibuten As Dihydrate as Active Pharmaceutical Ingredient, is internationally available with the Name of CEDAX Strength 90mg/5ml Dosage Form Dry Suspension manufactured By SI PHARMS USA, and FDA approved the same Label and Prescribing Information. A US FDA Notice ((82 FR 16599) dated 04-05-2017 published in Federal Register declares as under: "Food and Drug Administration (FDA or Agency) has determined that CEDAX (ceftibuten dihydrate) for oral suspension, 90 milligrams (mg)/5 milliliters (mL) and 180 mg/5 mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Ceftibuten dihydrate for oral suspension, 90 mg/5 mL and 180 mg/5 mL, if all other legal and regulatory requirements are met." Federal Register :: Determination That CEDAX (Ceftibuten Dihydrate) for Oral Suspension, 90 Milligrams/5 Milliliters and 180 Milligrams/5 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness	
	Decision: Deferred for evidence of approval of required manufacturing facility i.e., "Dry powder suspension (Cephalosporin) from Central Licensing Board.	
23.	**Name and address of manufacturer / Applicant**	**"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"**
	Brand Name +Dosage Form + Strength	Tibuten 400mg Capsule
	Composition	Each Capsule Contains: Ceftibuten As Dihydrate…400mg
	Diary No. Date of R& I & fee	Dy No. 39411: 30-11-2018 PKR 20,000/-: 30-11-2018 Duplicate dossier received vide Dy No. 1559 dated 17-01-2023
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed (discontinued in USFDA)
	Me-too status	Xigris Capsule by Wilshire
	GMP status	Last GMP inspection dated 03-03-2022 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 324th meeting: Deferred for the followings: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

	Firm's response: Tibuten 400mg Capsules contains Ceftibuten As Dihydrate as Active Pharmaceutical Ingredient, is internationally available with the Name of CEDAX Strength 400 mg Dosage Form Capsules manufactured By SI PHARMS USA, and FDA approved the same Label and Prescribing Information, having same Generic, Dosage Form and Strength. Note: The referred product has been declared as "Discontinued" by US FDA
	Decision: Deferred for following: • **Clarification regarding "Discontinued:" status of the applied formulation by US FDA, whether for safety efficacy reason or otherwise.** •

Agenda of Dr. Farhadullah

Case No. 01; Routine registration applications of Human Drugs on Form 5D

24.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Rexira 1mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole……1mg"
	Diary No. Date of R& I & fee	Dy.No 38721 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Previous Decision (M-295th-RB)	Deferred for following: • 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 alongwith submission of requisite fee, master formulation & manufacturing method. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

STABILITY STUDY DATA			
Drug	Rexira 1mg Tablets		
Manufacturer of API	M/s MSN Lifesciences India		
API Lot No.	BG0061018		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TRX-046	TRX-047	TRX-048
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01-2022	10-01-2022	11-01-2022
No. of Batches	03		
Date of Submission	Dy. No. 39310 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability summary data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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
1.	Submit differential fee as the applied product is a new drug molecule
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
8.	Protocols followed for conduction of stability study shall be submitted.
9.	Method used for analysis of Finished Product shall be submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.
11.	Complete batch manufacturing record of three stability batches shall be submitted.
12.	Record of comparative dissolution data shall be submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

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

25.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.

	Brand Name +Dosage Form + Strength	Rexira 2mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole……..…2mg"
	Diary No. Date of R& I & fee	Dy.No 38722 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Previous Decision (M-295th-RB)	Deferred for following: • 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 alongwith submission of requisite fee, master formulation & manufacturing method. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

STABILITY STUDY DATA	
Drug	Rexira 2mg Tablets
Manufacturer of API	M/s MSN Lifesciences India
API Lot No.	BG0061018
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 09 months Accelerated: 06 months

Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TRX-049	TRX-050	TRX-051
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01-2022	10-01-2022	11-01-2022
No. of Batches	03		
Date of Submission	Dy. No. 39311 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability summary data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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
1.	Submit differential fee as the applied product is a new drug molecule
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
8.	Protocols followed for conduction of stability study shall be submitted.
9.	Method used for analysis of Finished Product shall be submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.
11.	Complete batch manufacturing record of three stability batches shall be submitted.
12.	Record of comparative dissolution data shall be submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

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

S. No.	Name of Firms	Name of Drugs /label Claim	Demanded Pack size	Demanded Price	Date	Remarks
26.	M/s. Ferozsons Laboratories, Nowshwra	Torix Tablets 120mg Each film coated tablet contains:- Etoricoxib.....120mg (NSAID)	10's	Rs.250.00	4-9-2009	Decision of 227th meeting of RB: Deferred till the finalization of the case by the Appellate Board.

STABILITY STUDY DATA	
Drug	Flexia 120mg tablet (Etoricoxib)
Approval status of product in Reference Regulatory Authorities	ARCOXIA 120 mg Film-coated Tablets MHRA Approved.

Me-too status (with strength and dosage form)	Starcox Tablet 120mg by M/s Getz Pharma (Reg#105294)		
Finished product Specifications	Innovator's specifications		
Manufacturer of API	M/s Aurore Life Science Pvt. Ltd., India.		
API Lot No.	ETX-60330720		
Description of Pack (Container closure system)	10's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	FATab-007	FATab-008	FATab-009
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	28-04-2021	28-04-2021	28-04-2021
No. of Batches	03		
Date of Submission	Dy. No. 35336 dated 06-12-2022.		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 294th meeting held on 09th April, 2020 decided to approve registration of Empagen 10mg tablet and Empagen 25mg tablet. Inspection date: 25th October, 2019 The report shows that: • The HPLC software is 21 CFR compliant. Firm has demonstrated audit trial reports of testing • The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#ETX-60330720) of API from M/s Aurore Life science India and M/s Ferozsons Laboratories is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from API Manufacturer provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A

<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 cGMP certificate of API manufacturer issued by Drugs control administration, Government of Telangana India valid upto 18-04-2023.</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 commercial invoice cleared dated 11-08-2020 specifying 125kg Etoricoxib. The invoice is cleared by AD (I&E) DRAP.</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>N/A
(Formulation of applied drug product is qualitatively similar to that of innovator Brand ARCOXIA 120 mg Film-coated Tablets).</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>FATab-007</td><td>1500 tablets</td><td>04-2021</td></tr>
<tr><td>FATab-008</td><td>1500 tablets</td><td>04-2021</td></tr>
<tr><td>FATab-009</td><td>1500 tablets</td><td>04-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted.
Comparative dissolution was performed against Arcoxia tablet 120mg by M/s Frosst Iberica SA Via Complutense, Spain in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.</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>Firm has submitted stability study data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</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:
<table>
<tr><th>Sr. No.</th><th>Observation</th><th>Reply by the firm</th></tr>
<tr><td>1.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.</td><td>Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Telangana India valid upto 10-06-2025.</td></tr>
</table></td></tr>
<tr><td colspan="3">Decision: Approved.</td></tr>
</table>

S. No.	Name of Firms	Name of Drugs /label Claim	Demanded Pack size	Demanded Price	Date	Remarks

27.	M/s. Ferozsons Laboratories, Nowshwra	Torix Tablets 90mg Each film coated tablet contains:- Etoricoxib.....90mg (NSAID)	10's	Rs.220.00	4-9-2009	Decision of 227th meeting of RB: Deferred till the finalization of the case by the Appellate Board.

STABILITY STUDY DATA

Drug	Flexia 90mg tablet (Etoricoxib)		
Approval status of product in Reference Regulatory Authorities	ARCOXIA 90 mg Film-coated Tablets MHRA Approved.		
Me-too status (with strength and dosage form)	Starcox Tablet 90mg by M/s Getz Pharma (Reg#105293)		
Finished product Specifications	Innovator's specifications		
Manufacturer of API	M/s Aurore Life Science Pvt. Ltd., India.		
API Lot No.	ETX-60330720		
Description of Pack (Container closure system)	10's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	FATab-001	FATab-002	FATab-003
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	28-04-2021	28-04-2021	28-04-2021
No. of Batches	03		
Date of Submission	Dy. No. 35335 dated 06-12-2022.		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 294th meeting held on 09th April, 2020 decided to approve registration of Empagen 10mg tablet and Empagen 25mg tablet. Inspection date: 25th October, 2019 The report shows that:

<table>
<tr><td></td><td></td><td>• The HPLC software is 21 CFR compliant. Firm has demonstrated audit trial reports of testing
• The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copy of COA (Batch#ETX-60330720) of API from M/s Aurore Life science India and M/s Ferozsons Laboratories 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>Method used for analysis of API from API Manufacturer provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted as per zone IV-A</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 cGMP certificate of API manufacturer issued by Drugs control administration, Government of Telangana India valid upto 18-04-2023.</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 commercial invoice cleared dated 11-08-2020 specifying 125kg Etoricoxib. The invoice is cleared by AD (I&E) DRAP.</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>N/A
(Formulation of applied drug product is qualitatively similar to that of innovator Brand ARCOXIA 90 mg Film-coated Tablets).</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>FATab-001</td><td>2500 tablets</td><td>04-2021</td></tr>
<tr><td>FATab-002</td><td>2500 tablets</td><td>04-2021</td></tr>
<tr><td>FATab-003</td><td>2500 tablets</td><td>04-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted.
Comparative dissolution was performed against Arcoxia tablet 90mg by M/s Frosst Iberica SA Via Complutense, Spain in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.</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>Firm has submitted stability study data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted.</td></tr>
</table>

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.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Telangana India valid upto 10-06-2025.

Decision: Approved.

28.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt) Ltd, Plot No.10&25, Sector 20, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Toricox 90mg Tablet
	Composition	Each film coated tablet contains: Etoricoxib……..90mg
	Diary No. Date of R& I & fee	From-5D Dy. No.9925 dated 25-07-2017 Rs. 50,000/- dated 25-07-2017
	Pharmacological Group	NSAIDs; Coxibs
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 90 mg Film-coated Tablets MHRA Approved.
	Me-too status (with strength and dosage form)	Starcox Tablet 90mg by M/s Getz Pharma (Reg#105293)
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Etoroid 90mg tablet (Etoricoxib)		
Manufacturer of API	M/s Glenmark Life Science Ltd., India.		
API Lot No.	85200045		
Description of Pack (Container closure system)	2x7's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	24DS07	24DS08	24DS09
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-2021	02-2021	02-2021

<table>
<tr><td colspan="2">Date of Initiation</td><td>02-2021</td><td>02-2021</td><td>02-2021</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">Dy. No. 12197 dated 19-05-2022.</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td colspan="2">Documents to Be Provided</td><td colspan="2">Status</td></tr>
<tr><td>1.</td><td colspan="2">Reference of previous approval of applications with stability study data of the firm.</td><td colspan="2">Not submitted</td></tr>
<tr><td>2.</td><td colspan="2">Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td colspan="2">Copy of COA (Batch#85200045) of API from M/s Glenmark Lifescience Ltd., India and M/s Aspin Pharma (Pvt) Ltd is submitted.</td></tr>
<tr><td>3.</td><td colspan="2">Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td colspan="2">Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.</td></tr>
<tr><td>4.</td><td colspan="2">Stability study data of API from API manufacturer</td><td colspan="2">Submitted as per zone IV-A</td></tr>
<tr><td>5.</td><td colspan="2">Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration, Maharashtra State India valid upto 12-01-2022.</td></tr>
<tr><td>6.</td><td colspan="2">Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Firm has submitted copy of commercial invoice cleared dated 28-09-2020 specifying 03kg Etoricoxib. The invoice is cleared by AD (I&E) DRAP.
Firm has also submitted copy of form 6 cleared dated 28-09-2020 specifying 03kg Etoricoxib. The form 6 is cleared by AD (I&E) DRAP.</td></tr>
<tr><td>7.</td><td colspan="2">Protocols followed for conduction of stability study</td><td colspan="2">Submitted.</td></tr>
<tr><td>8.</td><td colspan="2">Method used for analysis of FPP</td><td colspan="2">Submitted.</td></tr>
<tr><td>9.</td><td colspan="2">Drug-excipients compatibility studies (where applicable)</td><td colspan="2">N/A
(Formulation of applied drug product is qualitatively similar to that of innovator Brand ARCOXIA 90 mg Film-coated Tablets).</td></tr>
<tr><td>10.</td><td colspan="2">Complete batch manufacturing record of three stability batches.</td><td colspan="2">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>24DS07</td><td>2500 tablets</td><td>02-2021</td></tr>
<tr><td>24DS08</td><td>2500 tablets</td><td>02-2021</td></tr>
<tr><td>24DS09</td><td>2500 tablets</td><td>02-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td colspan="2">Record of comparative dissolution data (where applicable)</td><td colspan="2">Submitted.
Comparative dissolution was performed against Arcoxia tablet 90mg by M/s Vianex SA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.</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.	Firm has submitted stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm.	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Assay method of API by API manufacturer is not submitted	
4.	Stability study data of two batches of API at real time conditions is submitted upto 18th months while of 3rd batch upto 6 months only. Submit stability study data of API till claimed shelf life	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**
ii. **Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years**
iii. **Assay method of API by API manufacturer**
iv. **Stability study data of API at real time conditions as per zone IV-A till claimed shelf life**
v. **Valid copy of API DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**

Registration Board further decided that Registration letter shall be issued after verification of Fee challan as per decision of 285th meeting of Registration Board.

29.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt) Ltd, Plot No.10&25, Sector 20, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Toricox 120mg Tablet
	Composition	Each film coated tablet contains: Etoricoxib……..120mg
	Diary No. Date of R& I & fee	From-5D Dy. No.9926 dated 25-07-2017 Rs. 50,000/- dated 25-07-2017
	Pharmacological Group	NSAIDs; Coxibs
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 120 mg Film-coated Tablets MHRA Approved.

	Me-too status (with strength and dosage form)	Starcox Tablet 120mg by M/s Getz Pharma (Reg#105294)
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Etoroid 120mg tablet (Etoricoxib)		
Manufacturer of API	M/s Glenmark Life Science Ltd., India.		
API Lot No.	85200045		
Description of Pack (Container closure system)	2x7's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	24DS08	24DS09	24DS10
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	02-2021	02-2021	02-2021
No. of Batches	03		
Date of Submission	Dy. No. 12198 dated 19-05-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#85200045) of API from M/s Glenmark Lifescience Ltd., India and M/s Aspin Pharma (Pvt) Ltd is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration, Maharashtra State India valid upto 12-01-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-09-2020 specifying 03kg Etoricoxib. The invoice is cleared by AD (I&E) DRAP.

		Firm has also submitted copy of form 6 cleared dated 28-09-2020 specifying 03kg Etoricoxib. The form 6 is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator Brand ARCOXIA 120 mg Film-coated Tablets).
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** 24DS08 / 2500 tablets / 02-2021 24DS09 / 2500 tablets / 02-2021 24DS10 / 2500 tablets / 02-2021
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Arcoxia tablet 120mg by M/s Vianex SA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
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 stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm.	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Assay method of API by API manufacturer is not submitted	
4.	Stability study data of two batches of API at real time conditions is submitted upto 18th months while of 3rd batch upto 6 months only. Submit stability study data of API till claimed shelf life	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

ii. Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years **iii. Assay method of API by API manufacturer** **iv. Stability study data of API at real time conditions as per zone IV-A till claimed shelf life** **v. Valid copy of API DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.** **Registration Board further decided that Registration letter shall be issued after verification of:** • **Fee challan as per decision of 285th meeting of Registration Board.**

S. No.	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the	Remarks of the Evaluator.	Decision
30.	M/s. Wenovo Pharmaceuticals, Plot No. 31 & 32 Punjab Small Sundar Industrial Estate Taxila Rawalpindi.	Linavo 5 mg Tablets Each film coated tablet contains:- Linagliptin ……. 5mg (Diabetes, dipeptidyl peptidase-4 (DPP-4) inhibitor	Form 5 18-02-2014 Dy.No.196 Rs.20,000/- 18-02-2014 10x10"s As per SRO	Tradjenta (Linagliptin) USFDA approved Not provided Last inspection report 22-01-2016 For GMP certificate for export	Me too status cannot be confirmed Product deferred for comments of IPO in 253rd DRB meeting Firm has claimed Mfg Specs and the product is not present in available pharmacopoeias (USP 39& BP2013).	Decision of 267th meeting of RB; Deferred till the comments of IPO

Firms submission	The firm submitted that IPO matter was discussed and decided in 288th meeting of DRB (extract of minute attached) it is requested to consider the application
STABILITY STUDY DATA	

Drug	Linavo 5 mg Tablets (Linagliptin)		
Manufacturer of API	M/s Anhui Haikang Pharmaceutical Co., Ltd., China		
API Lot No.	21121901		
Description of Pack (Container closure system)	1x10's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	04-2022	04-2022	04-2022
No. of Batches	03		
Date of Submission	Dy. No. 37573 dated 23-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#21121901) of API from M/s Anhui Haikang Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of audit evaluation report on GMP certification in Anhui Province of API manufacturer issued by Anqing Biomedical Industry Association valid upto 09-09-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter " issuance of Linagliptin 100gm as loan for CTD Dossier" from M/s Weather Folds Pharmaceuticals in name of Wenovo Pharmaceuticals dated 05-04-2022. Firm has submitted copy of clearance certificate cleared dated 11-03-2022 specifying 05kg Linagliptin. The clearance is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.

<table>
<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>N/A
(The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator Brand).</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>T-01</td><td>1200 tablets</td><td>04-2022</td></tr>
<tr><td>T-02</td><td>1200 tablets</td><td>04-2022</td></tr>
<tr><td>T-03</td><td>1200 tablets</td><td>04-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted.
Results of comparative dissolution performed against brand leader in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.</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>Firm has submitted stability study data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</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>Not Submitted.</td></tr>
</table>

Remarks of Evaluator:

Sr. No.	Observations	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm.	
2.	Method used for analysis of API from API Manufacturer shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
5.	• Justification shall be submitted for selecting different conditions of dissolutions test in finished product specifications (medium; 6.8 phosphate buffer, apparatus 2, rpm 75rpm) than innovator product review document (medium; 0.1N HCl, apparatus 1, rpm 50rpm) • Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per innovator's product review document	
6.	• Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed • Complete record of CDP studies shall be submitted	
7.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings		
31.	Name and address of manufacturer/ Applicant	M/s Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LINA 5mg Tablet
	Composition	Each film-coated tablet contains: Linagliptin…….5 mg
	Diary No. Date of R & I & fee	Dy. No.621 dated 03-05-2012, Rs: 15000 /- dated 02-05-2012 (Challan photocopy dated 25-04-2012 provided) Dy. No. 311 dated 12-10-2015, Differential fee Rs: 35,000/- dated 12-10-2015 vide challan No.0232390 dated 12-10-2015. Dy.No.21154-R & I dated 27-07-2022, Differential fee Rs: 25,000/- vide online deposit slip No.7421014973 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor)
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRADJENTA® 5mg film-coated tablet, Boehringer Ingelheim International GmbH. (USFDA approved)
	Me-too status	Trajenta 5mg Film Coated tablet imported by M/s AGP, Karachi. Reg. No. 078139 manufactured by Boehringer Ingelheim, USA
	GMP status	GMP certificate issued on 17-01-2022 based on evaluation conducted on 13-01-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.2-5/86-Lic (Vol-II) dated 30-10-2019 for renewal of Drug Manufacturing License. • Firm has claimed manufacturer specifications. • With reference to stability study data submission as per guidelines provided in 293rd meeting of Drug Registration Board, the firm has informed vide letter RA-QR/196/0822 dated 10-08-2022 that the stability studies for the product have already been initiated and will be submitted upon completion of 6 months intervals of long term and accelerated stability data. • R & I record verified. Details incorporated in relevant column above. Firm also submitted further differential fee of Rs: 25,000/- on 20-07-2022 vide online deposit slip. 7421014973. • Patent related issues of Linagliptin containing products decided in 297th meeting of RB as: After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.
	Decision of 321st meeting of RB	• Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board.
	Decision:	

STABILITY STUDY DATA			
Drug	Lina tablet 5mg (Linagliptin)		
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China		
API Lot No.	L-L9-20210618-D01-L09-05		
Description of Pack (Container closure system)	Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	421DS01	421DS03	
Batch Size	5000 Tablets	5000 Tablets	
Manufacturing Date	08-02-2022	30-03-2022	
Date of Initiation	12-04-2022	12-04-2022	
No. of Batches	02		
Date of Submission	Dy. No. 31578 dated 03-11-2022.		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 316th meeting held on 15th-18th March, 2022 decided to approve registration of Emclide (Empagliflozin & Linagliptin) 10mg/5mg Tablets . Inspection date: 02nd December, 2021 (Forenoon) The report shows that: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copy of COA (Batch#L-L9-20210618-D01-L09-05) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China and M/s Getz Pharma Ltd 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>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted as per zone IV-A</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 DML of API manufacturer issued by Liaoning Medical Products Administration, China valid upto 20-12-2022.</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 commercial invoice cleared dated 29-09-2021 specifying 0.4kg Linagliptin. The invoice is cleared by AD (I&E) DRAP.</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>N/A
(Formulation of applied drug product is qualitatively similar to that of innovator Brand TRADJENTA 5mg Film-coated Tablets).</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>421DS01</td><td>5000 tablets</td><td>02-2022</td></tr>
<tr><td>421DS03</td><td>5000 tablets</td><td>02-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted.
Comparative dissolution was performed against Linvesta tablet 5mg by M/s Wilshire Laboratories, Pakistan in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Drug release is more than 85% so f2 factor is not calculated</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>Firm has submitted stability study data of 02 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</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:</td></tr>
</table>

Sr. No.	Observation	Reply by the firm
1.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Justification shall be submitted for not performing the test of "Enantiomeric purity" in batch analysis of drug substance by both drug substance manufacturer and drug product manufacturer	
4.	Justification shall be submitted for selecting different conditions of dissolutions test in finished product specifications (medium volume; 500ml, rpm 100rpm) than innovator product review document (medium volume; 900ml, rpm 50rpm)	
5.	Complete batch manufacturing record of only two batches is submitted (421DS01, 421DS03), clarify	
6.	• Justify the delay in initiation of stability study of batch 421DS01 of applied product • Stability study data of only two batches are submitted, clarify	

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**
ii. **Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years**
iii. **Valid copy of API DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
iv. **Performance of test of "Enantiomeric purity" in batch analysis of drug substance by drug substance manufacturer or drug product manufacturer.**
v. **Revised drug product analytical procedure with conditions of dissolution test as per innovator drug product**

32.	Name and address of manufacturer/ Applicant	M/s Highnoon Laboratories Ltd., 17.5 km, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	LINA 5mg Tablet
	Composition	Each film-coated tablet contains: Linagliptin…….5mg
	Diary No. Date of R & I & fee	From-5 Dy. No.429 dated 29-10-2014 Rs. 50,000/- dated 02-10-2013
	Pharmacological Group	Anti-diabetic (Dipeptidyl peptidase 4 inhibitor)
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRADJENTA 5mg film-coated tablet, (USFDA approved)
	Me-too status	Trajenta 5mg Film Coated tablet by M/s AGP, Karachi. (Reg. No. 078139)
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Lina tablet 5mg (Linagliptin)
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China

API Lot No.	L- 20210123-D01-L09-02		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RD-22235	RD-22236	RD-22237
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	09-2022	09-2022	09-2022
No. of Batches	03		
Date of Submission	Dated; 27-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# L- 20210123-D01-L09-02) of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China and M/s M/s Highnoon Laboratories Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Liaoning Medical Products Administration, China valid upto 17-01-2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 09-08-2021 specifying 01kg Linagliptin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Drug-excipients compatibility studies is submitted
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** | **Mfg. Date**

		RD-22235 | 08-2022 RD-22236 | 08-2022 RD-22237 | 08-2022
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Trajenta 5mg tablet by M/s Boehringer Ingelheim Germany in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Drug release is more than 85% in all three medias so f2 factor is not calculated
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 stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Justification shall be submitted for not performing the test of "Enantiomeric purity" in batch analysis of drug substance by both drug substance manufacturer and drug product manufacturer	The firm has submitted updated specifications and testing method including impurity test (s-isomer) of API manufacturer and finished product manufacturer for linagliptin.
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-06-2024.
4.	• Justification shall be submitted for selecting different conditions of dissolutions test in finished product specifications (medium volume; 500ml, rpm 100rpm) than innovator product review document (medium volume; 900ml, rpm 50rpm) • Justification shall be submitted for not including the test for loss on drying in finished product specifications as per innovator's product review document	• The firm has submitted updated specifications and testing method as per innovator's specifications including the test for loss on drying in finished product specifications.

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

33.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	Glipin tablet 6.25mg
	Composition	Each Film Coated Oral Tablet Contains: Alogliptin Benzoate Eq To Alogliptian……..6.25mg
	Diary No. Date of R & I & fee	Dy.No 13975 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Dipeptidyl peptidase 4 inhibitor
	Type of Form	Form-5D
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NESINA (25mg, 12.5mg, 6.25mg) film-coated tablet, (USFDA approved)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5 needs to be verified

STABILITY STUDY DATA

Drug	Glipin tablet 6.25mg (Alogliptin)		
Manufacturer of API	M/s Ruyuan HEC Pharm Co., Ltd., China		
API Lot No.	$AGLT_{II}$-20190943U		
Description of Pack (Container closure system)	3x10's; Alu-PVC blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ALA_t T2-21	ALA_t T3-21	ALA_t T4-21
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	02-2021	02-2021	02-2021
No. of Batches	03		
Date of Submission	Dated; 23-01-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# $AGLT_{II}$-20190943U) of API from M/s Ruyuan HEC Pharm Co., Ltd., China and M/s Neutro Pharma (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is provided by the firm.

4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for pharmaceutical products for API manufacturer issued by Shaoguan Pharmaceutical Association, China valid upto 06-01-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-10-2019 specifying 0.3kg alogliptin Benzoate. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator Nesina 6.25mg Film-coated Tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Nesina 6.25mg Tablet by M/s Takeda Pharmaceuticals USA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Drug release is more than 85% in all three medias so f2 factor is not calculated
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 stability study 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.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
The same molecule is also applied on CTD vide tracking ID BJD-R7V-S2GU

Sr. No.	Observation	Reply by the firm
1.	Submit differential fee as the applied product is a new drug molecule	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Method used for analysis of API from API Manufacturer shall be submitted	

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	

Decision: Registration Board was apprised that firm vide letter no. nil dated 19-12-2024 has requested that above product was initially submitted for registration on Form 5D dated 07-03-2019, however we have now submitted the same drug product as new application on form 5F (CTD) through the online portal via tracking ID "BJD-R7V-S2GU"

Registration Board while considering the above cited request of firm decided to declare the instant application as disposed of and the application of same formulation submitted vide tracking ID "BJD-R7V-S2GU" shall be considered on its turn.

34.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	Glipin tablet 12.5mg
	Composition	Each Film Coated Oral Tablet Contains: Alogliptin Benzoate Eq To Alogliptian……..12.5mg
	Diary No. Date of R & I & fee	Dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Dipeptidyl peptidase 4 inhibitor
	Type of Form	Form-5D
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NESINA (25mg, 12.5mg, 6.25mg) film-coated tablet, (USFDA approved)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	Record of form 5D not available. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Glipin tablet 12.5mg (Alogliptin)		
Manufacturer of API	M/s Ruyuan HEC Pharm Co., Ltd., China		
API Lot No.	$AGLT_{II}$-20190943U		
Description of Pack (Container closure system)	3x10's; Alu-PVC blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ALB_t T1-21	ALB_t T2-21	ALB_t T3-21
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	02-2021	02-2021	02-2021
No. of Batches	03		
Date of Submission	Dated; 23-01-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# $AGLT_{II}$-20190943U) of API from M/s Ruyuan HEC Pharm Co., Ltd., China and M/s Neutro Pharma (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for pharmaceutical products for API manufacturer issued by Shaoguan Pharmaceutical Association, China valid upto 06-01-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-10-2019 specifying 0.3kg alogliptin Benzoate. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator Nesina 12.5mg Film-coated Tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Nesina 12.5mg Tablet by M/s Takeda Pharmaceuticals USA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Drug release is more than 85% in all three medias so f2 factor is not calculated
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 stability study 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.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Remarks of Evaluator: The same molecule is also applied on CTD vide tracking L9D-GYP-TL1B		

Sr. No.	Observation	Reply by the firm
1.	Submit differential fee as the applied product is a new drug molecule	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Method used for analysis of API from API Manufacturer shall be submitted	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	

Decision: Registration Board was apprised that firm vide letter no. nil dated 19-12-2024 has requested that above product was initially submitted for registration on Form 5D dated 07-03-2019, however we have now submitted the same drug product as new application on form 5F (CTD) through the online portal via tracking ID "L9D-GYP-TL1B"

Registration Board while considering the above cited request of firm decided to declare the instant application as disposed of and the application of same formulation submitted vide tracking ID "L9D-GYP-TL1B" shall be considered on its turn.

35.	Name and address of manufacturer/ Applicant	M/s NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km, Ferozepure Road, Lahore.
	Brand Name + Dosage Form + Strength	Nesmet 12.5/500 mg Tablet
	Composition	Each film coated tablet contains: Alogliptin as benzoate…….……12.5mg Metformin HCl……..…500mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 101 dated 01-08-2016 Rs.50,000/- dated 01-08-2016
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KAZANO (12.5mg;500mg, 12.5mg;1gm) film-coated tablet, (USFDA approved)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Nesmet 12.5/500 mg Tablet
Manufacturer of API	Alogliptin Benzoate; M/s Shandong Sihuan Pharmaceutical Co. Ltd., China Metformin HCl; M/s Aarti Drugs Limited., India
API Lot No.	Alogliptin Benzoate; 2020090401 Metformin HCl; MEF/11010024
Description of Pack (Container closure system)	30's; Alu-Alu blister pack.
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)

Batch No.	RD/PR21-052/T1/S1	RD/PR21-052/T1/S2	RD/PR21-052/T1/S3
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	04-2021	04-2021	04-2021
No. of Batches	03		
Date of Submission	Dy No. 33100; Dated; 17-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Alogliptin Benzoate; Copy of COA (Batch# 2020090401) of API from M/s Shandong Sihuan Pharmaceutical Co. Ltd., China and M/s NovaMed Pharmaceuticals (Pvt) Ltd., is submitted. Metformin HCl; Copy of COA (Batch# MEF/11010024) of API from M/s Aarti Drugs Limited., India and M/s NovaMed Pharmaceuticals (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Alogliptin Benzoate; Firm has submitted copy of DML of API manufacturer issued by Shandong Food and Drug Administration, China valid upto 30-12-2027. Metformin HCl; Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & DrugsnControl Administration, Gujarat State India valid upto 19-03-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Alogliptin Benzoate; Firm has submitted copy of commercial invoice cleared dated 13-11-2020 specifying 170gm Alogliptin Benzoate. The invoice is cleared by AD (I&E) DRAP. Metformin HCl; Firm has submitted copy of commercial invoice cleared dated 15-02-2021 specifying 500kg Metformin HCl. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.

9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator KAZANO 12.5mg;500mg Film-coated Tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against KAZANO 12.5mg;500mg Tablets by M/s Takeda Pharmaceuticals USA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Values of f2 factor are in acceptable range
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 stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
3.	• Justification shall be submitted for not including the test for residue on ignition and enantiomer in alogliptin specification by finished product manufacturer • Justification shall be submitted for not including the test for sulphated ash in Metformin HCl specification by finished product manufacturer	• The firm submitted that test for residue on ignition and enantiomer are conducted and included in alogliptin specification. Alogliptin COA is submitted • The firm submitted that test for sulphated ash is conducted and included in Metformin HCl specification. Metformin HCl COA is submitted
4.	Stability study data of alogliptin at real time conditions from API manufacturer is submitted upto 6th months only. Stability study data till claimed shelf life shall be submitted	Stability study data of alogliptin at real time conditions from API manufacturer upto 36th months is submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer for metformin issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Control Administration, Gujarat State India valid upto 20-06-2026.
6.	• Justification shall be submitted for selecting different time of dissolution test (30min) in finished product specifications than	• The firm submitted that according to the FDA dissolution profile, the specified time point for assessing the dissolution of

	innovator's product review document (15min) • Justification shall be submitted for not including content uniformity test for alogliptin test in finished product specifications as per innovator's product review document	alogliptin-metformin tablets are 05, 10, 15, 20, and 30 minutes. The CDP report indicates more than 85% of the drug is released within 15 minutes. Hence we revised our dissolution limits in specifications. Revised finished product specifications is submitted. • The firm has submitted results of content uniformity test of three batches.

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

ii. Revision of dissolution specification as per innovator product on commercial batches

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

36.	Name and address of manufacturer/ Applicant	M/s NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km, Ferozepure Road, Lahore.
	Brand Name + Dosage Form + Strength	Nesmet 12.5/1000 mg Tablet
	Composition	Each film coated tablet contains: Alogliptin as benzoate…….……12.5mg Metformin HCl……..…1000mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 100 dated 01-08-2016 Rs.50,000/- dated 01-08-2016
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KAZANO (12.5mg;500mg, 12.5mg;1gm) film-coated tablet, (USFDA approved)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Nesmet 12.5/1000 mg Tablet		
Manufacturer of API	Alogliptin Benzoate; M/s Shandong Sihuan Pharmaceutical Co. Ltd., China Metformin HCl; M/s Aarti Drugs Limited., India		
API Lot No.	Alogliptin Benzoate; 2020090401 Metformin HCl; MEF/11010024		
Description of Pack (Container closure system)	21's; Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RD/PR21-040/T1/S1	RD/PR21-040/T1/S2	RD/PR21-040/T1/S3

Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	04-2021	04-2021	04-2021
No. of Batches	03		
Date of Submission	Dy No. 33101; Dated; 17-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Alogliptin Benzoate; Copy of COA (Batch# 2020090401) of API from M/s Shandong Sihuan Pharmaceutical Co. Ltd., China and M/s NovaMed Pharmaceuticals (Pvt) Ltd., is submitted. Metformin HCl; Copy of COA (Batch# MEF/11010024) of API from M/s Aarti Drugs Limited., India and M/s NovaMed Pharmaceuticals (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Alogliptin Benzoate; Firm has submitted copy of DML of API manufacturer issued by Shandong Food and Drug Administration, China valid upto 30-12-2027. Metformin HCl; Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & DrugsnControl Administration, Gujarat State India valid upto 19-03-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Alogliptin Benzoate; Firm has submitted copy of commercial invoice cleared dated 13-11-2020 specifying 170gm Alogliptin Benzoate. The invoice is cleared by AD (I&E) DRAP. Metformin HCl; Firm has submitted copy of commercial invoice cleared dated 15-02-2021 specifying 500kg Metformin HCl. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.

9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator KAZANO 12.5mg;1000mg Film-coated Tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against KAZANO 12.5mg;1000mg Tablets by M/s Takeda Pharmaceuticals USA in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Values of f2 factor are in acceptable range
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 stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
3.	• Justification shall be submitted for not including the test for residue on ignition and enantiomer in alogliptin specification by finished product manufacturer • Justification shall be submitted for not including the test for sulphated ash in Metformin HCl specification by finished product manufacturer	• The firm submitted that test for residue on ignition and enantiomer are conducted and included in alogliptin specification. Alogliptin COA is submitted • The firm submitted that test for sulphated ash is conducted and included in Metformin HCl specification. Metformin HCl COA is submitted
4.	Stability study data of alogliptin at real time conditions from API manufacturer is submitted upto 6^{th} months only. Stability study data till claimed shelf life shall be submitted	Stability study data of alogliptin at real time conditions from API manufacturer upto 36^{th} months is submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer for metformin issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Control Administration, Gujarat State India valid upto 20-06-2026.
6.	• Justification shall be submitted for selecting different time of dissolution test	• The firm submitted that according to the FDA dissolution profile, the specified time point for

	(30min) in finished product specifications than innovator's product review document (15min) • Justification shall be submitted for not including content uniformity test for alogliptin test in finished product specifications as per innovator's product review document	assessing the dissolution of alogliptin-metformin tablets are 05, 10, 15, 20, and 30 minutes. The CDP report indicates more than 85% of the drug is released within 15 minutes. Hence we revised our dissolution limits in specifications. Revised finished product specifications is submitted. • The firm has submitted results of content uniformity test of three batches.
7.	• Clarify the difference in batch number of trial batches in BMR (RD/PR21-040/T1/S1, RD/PR21-040/T1/S2, RD/PR21-040/T1/S3) and stability summary sheets (RD/PR20-040/T1/S1, RD/PR20-040/T1/S2, RD/PR20-040/T1/S3)	The firm has submitted stability study protocols and report of trial batches containing batch numbers as per submitted BMR.

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

ii. **Revision of dissolution specification as per innovator product on commercial batches**

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

37.	Name and address of manufacturer/ Applicant	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	**Prelin CR Tablets 330mg**
	Composition	Each Extended Release Film Coated Tablet Contains: Pregabalin……330mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 5083 dated 06-02-2019 Rs.50,000/- dated 04-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specs
	Pack size & Demanded Price	14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330mg) USFDA Approved.
	Me-too status	Not Available
	GMP status	
	Remarks of the Evaluator	Main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	**Prelin CR Tablets 330mg**
Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan Duqiao, Linhai, Zhejiang, China
API Lot No.	D5248-21-176R
Description of Pack (Container closure system)	(2x7's); Alu-Alu blister pack.
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%

Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3 (months) Real Time: 0, 3 (months)		
Batch No.	NPD-T-1966-S	NPD-T-1976-S	NPD-T-1977-S
Batch Size	1500 tablets	5000 tablets	5000 tablets
Manufacturing Date	26-05-2022	07-06-2022	07-06-2022
Date of Initiation	17-06-2022	17-06-2022	17-06-2022
No. of Batches	03		
Date of Submission	Dy No. 28531; Dated; 07-10-2022		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 297th meeting held on 12th-15th January, 2021 decided to approve registration of Pirfedow tablet 267mg. Inspection date: 04th January, 2020 The report shows that: • The HPLC software is 21 CFR compliant. Firm has complete audit trial reports on testing • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through 21CFR compliant data logging sofware
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#D5248-21-176R) from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Martin Dow Limited., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substance exported to EU issued by Deputy Director, Zhejiang Medical Produccts Administration, China valid upto 25-10-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 29-06-2021 specifying 100kg Pregabalin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.

9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator LYRICA CR 300mg extended-release tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Lyrica 330mg CR tablet by M/s Pfizer in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Values of f2 factor are in acceptable range
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 stability study 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.	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.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 02nd&15th-08-2024.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate (EudraGMP) of API manufacturer issued by Italian Medicine Agency valid upto 11-04-2027.
3.	Stability study data of applied product at 6th month time point shall be submitted	Stability study data of applied product at 6th month time point is submitted

Decision: Approved.

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

38.	Name and address of manufacturer/ Applicant	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	**Prelin CR Tablet 165mg**
	Composition	Each Film Coated Extended Release Tablet Contains: Pregabalin…….165mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 5082 dated 06-02-2019 Rs.50,000/- dated 04-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specs
	Pack size & Demanded Price	14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330mg) USFDA Approved.
	Me-too status	Not Available

	GMP status	
	Remarks of the Evaluator	Main list file. Form 5D needs to be verified

STABILITY STUDY DATA			
Drug	**Prelin CR Tablet 165mg**		
Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan Duqiao, Linhai, Zhejiang, China		
API Lot No.	D5248-21-176R		
Description of Pack (Container closure system)	(2x7's); Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	NPD-T-1845-S	NPD-T-1883-S	NPD-T-1884-S
Batch Size	1500 tablets	5000 tablets	5000 tablets
Manufacturing Date	01-02-2022	24-02-2022	24-02-2022
Date of Initiation	11-03-2022	11-03-2022	11-03-2022
No. of Batches	03		
Date of Submission	Dy No. 18956; Dated; 29-06-2022		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 297th meeting held on 12th-15th January, 2021 decided to approve registration of Pirfedow tablet 267mg. Inspection date: 04th January, 2020 The report shows that: • The HPLC software is 21 CFR compliant. Firm has complete audit trial reports on testing • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through 21CFR compliant data logging sofware
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#D5248-21-176R) from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Martin Dow Limited., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substance exported to EU issued by Deputy Director, Zhejiang Medical Produccts Administration, China valid upto 25-10-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 29-06-2021 specifying 100kg Pregabalin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator LYRICA CR 165mg extended-release tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Lyrica 165mg CR tablet by M/s Pfizer in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Values of f2 factor are in acceptable range
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 stability study 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.	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.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 02nd&15th-08-2024.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate (EudraGMP) of API manufacturer issued by Italian Medicine Agency valid upto 11-04-2027.

Decision: Approved.

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

39.	Name and address of manufacturer/ Applicant	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	**Prelin CR Tablets 82.5mg**
	Composition	Each Extended-Release Film Coated tablet contains:

		Pregabalin……82.5mg.
	Diary No. Date of R & I & fee	Form-5D Dy. No. 5081 dated 06-02-2019 PKR 50,000/- dated 04-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specs
	Pack size & Demanded Price	14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330mg) USFDA Approved.
	Me-too status	Not Available
	GMP status	
	Remarks of the Evaluator	Main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	**Prelin CR Tablets 82.5mg**		
Manufacturer of API	Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan Duqiao, Linhai, Zhejiang, China		
API Lot No.	2108000062		
Description of Pack (Container closure system)	(2x7's); Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	NPD-T-1844-S	NPD-T-1881-S	NPD-T-1882-S
Batch Size	1500 tablets	5000 tablets	5000 tablets
Manufacturing Date	01-02-2022	23-02-2022	23-02-2022
Date of Initiation	11-03-2022	11-03-2022	11-03-2022
No. of Batches	03		
Date of Submission	Dy No. 18955; Dated; 29-06-2022		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 297th meeting held on 12th-15th January, 2021 decided to approve registration of Pirfedow tablet 267mg. Inspection date: 04th January, 2020 The report shows that: • The HPLC software is 21 CFR compliant. Firm has complete audit trial reports on testing • Adequate monitoring and control are available for stability chamber. Chambers are controlled

		and monitored through 21CFR compliant data logging sofware
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#D5248-21-176R) from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Martin Dow Limited., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of written confirmation for active substance exported to EU issued by Deputy Director, Zhejiang Medical Produccts Administration, China valid upto 25-10-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 29-06-2021 specifying 100kg Pregabalin. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator LYRICA CR 82.5mg extended-release tablets).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Comparative dissolution was performed against Lyrica 82.5mg CR tablet by M/s Pfizer in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Values of f2 factor are in acceptable range
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 stability study 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.	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.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 02nd&15th-08-2024.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate (EudraGMP) of API manufacturer issued by Italian Medicine Agency valid upto 11-04-2027.
3.	Stability study data of three batches of 165mg strength of applied product is submitted instead of 82.5mg strength at 3rd month time point, clarify	Stability study data of three batches of applied product 82.5mg strength at 3rd month time point is submitted.

Decision: Approved.
Registration Board further decided that Registration letter shall be issued after verification of:
Fee challan as per decision of 285th meeting of Registration Board.

40.	Name and address of manufacturer/ Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	**Zeegap 20mg/ml Oral Solution**
	Composition	Each ml Contains: Pregabalin…….20mg
	Diary No. Date of R & I & fee	Form-5F Dy.No 25887 dated 26-10-2023 Rs.75,000/- dated 03-10-2023
	Pharmacological Group	Analgesics; Gabapentinoids
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specs
	Pack size & Demanded Price	14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA ORAL SOLUTION 20mg/ml (USFDA Approved)
	Me-too status	Not Available
	GMP status	
	Remarks of the Evaluator	
	Submission of submission of stability data	12-05-2023

Remarks of Evaluator:
The same formulation has been applied by firm on Form 5F: Dy. No. 25887: 26-10-2023 and has been considered (approved) in 343rd meeting of Registration Board

Decision: Registration Board rejected the instant application as the same molecule has already been approved in 343rd meeting of Registration Board.

41.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	**Ludil 0.02% Opthalmic Solution**
	Composition	Each ml Contains: Netarsudil Dimesylate Eq. To Netarsudil…0.20mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 31547 dated 18-09-2018 Rs.50,000/- dated 18-09-2018 (copy of duplicate receiving submitted)
	Pharmacological Group	Antiglaucoma preparations and miotics
	Type of Form	Form 5-D
	Finished product Specification	In house specifications
	Pack size & Demanded Price	5ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	RHOPRESSA (netarsudil ophthalmic solution) 0.02%, for topical ophthalmic use USFDA Approved.
	Me-too status	Not Available
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA			
Drug	**Ludil 0.02% Opthalmic Solution**		
Manufacturer of API	M/s Yibin Hongguang Pharmaceutical Co., Ltd., China		
API Lot No.	MS204901-200901		
Description of Pack (Container closure system)	1x5ml; LDPE container in carton		
Stability Storage Condition	Real time: 5°C±3° C Accelerated: 25 °C ± 2 °C / 60% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR-043	TR-044	TR-045
Batch Size	1500ml/600 bottles	1500ml/600 bottles	1500ml/600 bottles
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	12-04-2021	12-04-2021	12-04-2021
No. of Batches	03		
Date of Submission	Dated; 01-04-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#MS204901-200901) from M/s Yibin Hongguang Pharmaceutical Co., Ltd., China and M/s Helix Pharma Pvt Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from d Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Sichuan Medical Product Administration, China valid upto 29-12-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 cleared dated 18-11-2020 specifying 07gm Netarsudil Dimesylate. The form 6 is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator

		RHOPRESSA (netarsudil ophthalmic solution) 0.02%).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	N/A
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 stability study 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.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP shall be submitted	
4.	Method used for analysis of API from API Manufacturer is not submitted	
5.	Stability study data of API from API manufacturer at real time conditions till 18months is submitted. Stability study data of API from API manufacturer at real time conditions till claimed shelf life shall be submitted.	
6.	• Justification shall be submitted for selecting limits of pH test as 4.5-5.2 and osmolality as 171mOsmol/kg-1711mOsmol/kg instead of pH approximately 5 and osmolality of approximately 295mOsmol/kg as per innovator product review document • Justification shall be submitted for not including the antimicrobial preservative test and leachable extractable in finished product specifications as per innovator's product review document	
7.	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

Decision: Deferred for submission of following:

i. **Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years**
ii. **Copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP**
iii. **Method used for analysis of API from API Manufacturer**
iv. **Stability study data of API from API manufacturer at real time conditions till claimed shelf life**
v. **Justification for selecting limits osmolality as 171mOsmol/kg-1711mOsmol/kg instead of 295mOsmol/kg as per innovator product review document**
vi. **Justification for not including the test of antimicrobial preservative and leachable extractable in finished product specifications as per innovator's product review document**

42.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	Neutaxo 5/80mg tablet
	Composition	Each Tablet Contains: Nebivolol as HCl…….5mg Valsartan…….80mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 13419 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form-5D
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYVALSON (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, (USFDA approved ***Discontinued) (NDA)*** VYDUO (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, USFDA approved (ANDA)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA			
Drug	Neutaxo 5/80mg tablet		
Manufacturer of API	Nebivolol HCl; M/s Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd., China Valsartan; M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China		
API Lot No.	Nebivolol HCl; NBB-1903003-1M Valsartan; C5607-21-039W		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	NVA_t T2-22	NVA_t T3-22	NVA_t T4-22
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		
Date of Submission	Dy No. 27123 Dated; 26-09-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Nebivolol HCl; Copy of COA (Batch# NBB-1903003-1M) of API from M/s Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd., China and M/s Neutro Pharma (Pvt) Ltd., is submitted. Valsartan; Copy of COA (Batch# C5607-21-039W) of API from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Neutro Pharma (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nebivolol HCl; Firm has submitted copy of audit report on GMP certificate in nantong jiangsu of API manufacturer issued by Jiangsu Nantong pharmaceutical association valid upto 31-01-2023. Valsartan; Firm has submitted copy of DML of API manufacturer issued by Zhejiang Medical product association valid upto 12-01-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Nebivolol HCl; Firm has submitted copy of commercial invoice cleared dated 03-10-2019 specifying 0.1kg Nebivolol HCl. The invoice is cleared by AD (I&E) DRAP. Valsartan; Firm has submitted copy of commercial invoice cleared dated 26-08-2021 specifying 3600g Valsartan. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of innovator BYVALSON (nebivolol and valsartan) 5mg;80mg tablets film-coated table.
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted.

		Comparative dissolution was performed against Byvalson 5mg/80mg Tabtet by M/s Allergan USA Inc in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. Drug release is more than 85% in all three medias so f2 factor is not calculated
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 stability study 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.	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.	You have applied for uncoated tablet while reference formulation is film coated. Revise the label claim as per reference formulation along with submission of applicable fee.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Justify the difference in mobile phase composition of assay test and HPLC method (isocratic) of valsartan by drug product manufacturer than drug substance manufacturer (gradient)	
5.	Approval of API/ DML/GMP certificate of API manufacturer for Nebivolol HCl issued by concerned regulatory authority of country of origin shall be submitted	
6.	Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document	
7.	Submit details of innovator's product including batch number, manufacturing date and expiry date against which CDP studies were performed	

Decision: Approved.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Revision of the label claim from uncoated tablet to film coated tablet as per reference formulation along with submission of applicable fee.**
ii. **Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years**
iii. **Revision of drug substance analytical procedure of Valsartan as per the Pharmacopoeial monograph.**
iv. **Valid copy of API DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
v. **Inclusion of test for content uniformity in finished product specifications as per innovator's product review document**
vi. **Details of innovator's product including batch number, manufacturing date and expiry date against which CDP studies were performed**

Registration Board further decided that Registration letter shall be issued after verification of:

- **Fee challan as per decision of 285th meeting of Registration Board.**

43.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Seikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Velamer-C 0.8g Sachet
	Composition	Each Sachet contains: Sevelamer Carbonate…….0.8g
	Diary No. Date of R& I & fee	Dy.No 8626 dated 08-03-2018 Rs.50,000/- 07-03-2018
	Pharmacological Group	Phosphate removing agent
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	15's, 60's, 90's,: As per SRO
	Approval status of product in Reference Regulator Authorities	Renvela Approved by US FDA
	Me-too status	
	GMP status	

STABILITY STUDY DATA			
Drug	Velamer-C 0.8g Sachet		
Name of Manufacturer	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Seikhupura Road, Lahore		
Manufacturer of API	M/S Century Pharmaceuticals Ltd, India		
API Lot No.	08528001-SLC		
Description of Pack (Container closure system)	Sachet		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 65% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)		
Batch No.	Vel-SH-0.8-001-19	Vel-SH-0.8-002-19	Vel-SH-0.8-003-19
Batch Size	360gm	360gm	360gm
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	07-10-2019	07-10-2019	07-10-2019
No. of Batches	03		
Date of Submission	29-08-2020 (21597)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Not submitted</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC) from M/S Century Pharmaceuticals Ltd, India is submitted
Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC)) from M/S Neutro Pharma 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>Yes</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches</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>Copy of GMP certificate (Certificate No# 20011803) for M/s Century Pharmaceuticals Limited, 103-106, GDC Halol-389350, Dist- Panchmahal issued Food and Drug Control Adminstration Gandhinagar, Gujrat stat, India is submitted, valid upto 08-01-2023</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Commercial Invoice No: CPLEXp1800043 Dated: 30-06-2018 from M/S Century Pharmaceuticals Limited, is submitted attested by AD(Lahore) dated ; 04-07-2018 for Sevelamer Carbonate quantity 4Kg Batch no # 08528001-SLC</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Velamer-C 0.8mg Sachet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>Vel-SH-0.8-001-19</td><td>360g</td><td>02-10-2019</td></tr>
<tr><td>Vel-SH-0.8-002-19</td><td>360g</td><td>03-10-2019</td></tr>
<tr><td>Vel-SH-0.8-003-19</td><td>360g</td><td>03-10-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>NA</td></tr>
</table>

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

S.#	Shortcomings communicated	Reply
1.	Certificate of Analysis of API from API Manufacturer Provided of different batch than batch No mentioned in commercial invoice. Clarify.	COA of API from API manufacturer of relevant batch No submitted.
2.	Submit Certificate of Analysis of API from Finished Product manufacturer.	COA from finished product manufacturer submitted
3.	Submit Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin as submitted GMP certificate is invalid.	Valid GMP certificate submitted. Valid until 08-01-2023
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Submitted but test for Sevelamer carbonate Assay is titratable amines by potentiometric titration in reference product which is not performed by both API manufacturer and drug product manufacturer. Phosphate binding capacity (by UV) and carbonate content is performed by both API manufacturer and drug product manufacturer
5.	Stability study data of API from API manufacturer.	Submitted but in 48 months of stability studies Phosphate binding capacity and carbonate content
6.	Complete batch manufacturing record of three stability batches.	Submitted
7.	Provide reference finished pharmaceuticals specifications including Phosphate Binding Capacity and assay of Sevelamer carbonate.	Not submitted.

Previous Decision (M-313th-RB): Deferred for Scientific justification for not performing test of Titratable amines as required by reference product (i.e. Renvela 0.8g & 2.4g powder for oral suspension) approved by US FDA, EMA and TGA Australia.

Firm's response: Firm has submitted stability study data of new batches. The details are given below;

STABILITY STUDY DATA	
Drug	Velamer-C 0.8g Sachet
Manufacturer of API	M/S Century Pharmaceuticals Ltd, India
API Lot No.	08528001-SLC
Description of Pack	Sachet

(Container closure system)			
Stability Storage Condition	Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 65% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0,3,6 (06month) Real Time: 0,3,6 (06month)		
Batch No.	SCAs T4-21	SCAs T5-21	SCAs T6-21
Batch Size	200 sachets	200 sachets	200 sachets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		
Date of Submission	25-08-2022 (24069)		

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	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC) from M/s Century Pharmaceuticals Ltd, India is M/s Neutro Pharma is submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by issued Food and Drug Control Adminstration Gandhinagar, Gujrat stat, India valid upto 10-03-2024
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No: CPLEXp1800043 Dated: 30-06-2018 from M/S Century Pharmaceuticals Limited, is submitted attested by AD(Lahore) dated; 04-07-2018 for Sevelamer Carbonate quantity 4Kg Batch no # 08528001-SLC
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA

10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	NA
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-04-2022.
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate of API manufacturer issued by issued Food and Drugs Control Administration Gandhinagar, Gujrat stat, India valid upto 31-03-2026
4.	Justification shall be submitted for not including the test for loss on drying, in finished product specifications as per innovator's product review document	Firm has submitted revised finished product specifications in which the test for loss on drying has been included.
5.	Stability study summary data sheets of batch No. SCAs T6-21 is not submitted	Stability study summary data sheets of batch No. SCAs T6-21 is submitted

Decision: Approved with innovator's specifications.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

44.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Seikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Velamer-C 2.4g Sachet
	Composition	Each Sachet contains: Sevelamer Carbonate…….2.4g
	Diary No. Date of R& I & fee	Dy.No 8627 dated 08-03-2018 Rs.50,000/- 07-03-2018

	Pharmacological Group	Phosphate removing agent
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	15's, 60's, 90's,: As per SRO
	Approval status of product in Reference Regulator Authorities	Renvela Approved by US FDA
	Me-too status	
	GMP status	

STABILITY STUDY DATA			
Drug	Velamer-C 2.4g Sachet		
Name of Manufacturer	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Seikhupura Road, Lahore		
Manufacturer of API	M/S Century Pharmaceuticals Ltd, India		
API Lot No.	08528001-SLC		
Description of Pack (Container closure system)	Sachet		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 65% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)		
Batch No.	Vel-SH-2.4-001-19	Vel-SH-2.4-002-19	Vel-SH-2.4-003-19
Batch Size	300 g	300 g	300 g
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	07-10-2019	07-10-2019	07-10-2019
No. of Batches	03		
Date of Submission	29-08-2020 (21598)		

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	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC) from M/S Century Pharmaceuticals Ltd, India is submitted Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC)) from M/S Neutro Pharma is submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches</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>Copy of GMP certificate (Certificate No# S-GMP/1803664) for M/s Century Pharmaceuticals Limited, 103-106, GDC Halol-389350, Dist-Panchmahal issued Food and Drug Control Adminstration Gandhinagar, Gujrat stat, India is submitted, valid upto 04-03-2020</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Commercial Invoice No: CPLEXp1800043 Dated: 30-06-2018 from M/S Century Pharmaceuticals Limited, is submitted attested by AD(Lahore) dated ; 04-07-2018 for Sevelamer Carbonate quantity 4Kg Batch no # 08528001-SLC</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>NA</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Velamer-C 2.4mg Sachet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>Vel-SH-2.4-001-19</td><td>360gm</td><td>02-10-2019</td></tr>
<tr><td>Vel-SH-2.4-002-19</td><td>360gm</td><td>04-10-2019</td></tr>
<tr><td>Vel-SH-2.4-003-19</td><td>360gm</td><td>04-10-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>NA</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Not 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>Not submitted</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR</td></tr>
<tr><td>S.#</td><td>Shortcomings communicated</td><td>Reply</td></tr>
<tr><td>1.</td><td>Certificate of Analysis of API from API Manufacturer Provided of different batch</td><td>COA of API from API manufacturer of relevant batch No submitted.</td></tr>
</table>

	than batch No mentioned in commercial invoice. Clarify.	
2.	Submit Certificate of Analysis of API from Finished Product manufacturer.	COA from finished product manufacturer submitted
3.	Submit Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin as submitted GMP certificate is invalid.	Valid GMP certificate submitted. Valid until 08-01-2023
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Submitted but test for Sevelamer carbonate Assay is titratable amines by potentiometric titration in reference product which is not performed by both API manufacturer and drug product manufacturer. Phosphate binding capacity (by UV) and carbonate content is performed by both API manufacturer and drug product manufacturer
5.	Stability study data of API from API manufacturer.	Submitted but in 48 months of stability studies Phosphate binding capacity and carbonate content
6.	Complete batch manufacturing record of three stability batches.	Submitted
7.	Provide reference finished pharmaceuticals specifications including Phosphate Binding Capacity and assay of Sevelamer carbonate.	Not submitted.
8.	Batch size mentioned is 300 gm and fill weight of sachet 5 gm, while sample size in stability sheets mentioned is 110 sachet. Clarify.	Actual quantity of batch is 360gm and fill weight is 2.70gm. so calculated no of sachet is 133. As mentioned in Trial cards and BMR.

Previous Decision (M-313th-RB): Deferred for Scientific justification for not performing test of Titratable amines as required by reference product (i.e. Renvela 0.8g & 2.4g powder for oral suspension) approved by US FDA, EMA and TGA Australia.

Firm's response: Firm has submitted stability study data of new batches. The details are given below;

STABILITY STUDY DATA	
Drug	Velamer-C 2.4g Sachet
Manufacturer of API	M/S Century Pharmaceuticals Ltd, India
API Lot No.	08528001-SLC
Description of Pack (Container closure system)	Sachet
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 65% ± 5% RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated:0,3,6 (06month) Real Time: 0,3,6 (06month)		
Batch No.	SCBs T4-21	SCBs T5-21	SCBs T6-21
Batch Size	200 sachets	200 sachets	200 sachets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		
Date of Submission	25-08-2022 (24068)		

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	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Sevelamer Carbonate (Batch#08528001-SLC) from M/s Century Pharmaceuticals Ltd, India is M/s Neutro Pharma is submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by issued Food and Drug Control Adminstration Gandhinagar, Gujrat stat, India valid upto 10-03-2024
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No: CPLEXp1800043 Dated: 30-06-2018 from M/S Century Pharmaceuticals Limited, is submitted attested by AD(Lahore) dated; 04-07-2018 for Sevelamer Carbonate quantity 4Kg Batch no # 08528001-SLC
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	NA
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-04-2022.
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	Firm has submitted copy of cGMP certificate of API manufacturer issued by issued Food and Drugs Control Administration Gandhinagar, Gujrat stat, India valid upto 31-03-2026
4.	Justification shall be submitted for not including the test for loss on drying, in finished product specifications as per innovator's product review document	Firm has submitted revised finished product specifications in which the test for loss on drying has been included.
5.	Stability study summary data sheets of batch No. SCAs T6-21 is not submitted	Stability study summary data sheets of batch No. SCBs T6-21 is submitted

Decision: Approved with innovator's specifications.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

45.	Name and address of manufacturer/ Applicant	M/s Weather Folds Pharmaceuticals., Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	VasNeb 5/80mg tablet
	Composition	Each film coated tablet contains: Nevbivolol……..5mg Valsartan……80mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 359 dated 30-09-2016 Rs.50,000/- dated 30-09-2016
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form-5D
	Finished product Specification	Inhouse specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYVALSON (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, (USFDA approved ***Discontinued) (NDA)*** VYDUO (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, USFDA approved (ANDA)
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Nabeval 5/80mg tablet		
Manufacturer of API	Nebivolol HCl; M/s Hema Pharmaceuticals Pvt. Ltd., India Valsartan; M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China		
API Lot No.	Nebivolol HCl; 21NB0004 Valsartan; 10252-210202		
Description of Pack (Container closure system)	3x10's; Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-101	T-102	T-103
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	08-2021	08-2021	08-2021
No. of Batches	03		
Date of Submission	Dy No. 19915 Dated; 07-07-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Nebivolol HCl; Copy of COA (Batch#21NB0004) of API from M/s Hema Pharmaceuticals Pvt. Ltd., India and M/s Weather Folds Pharmaceuticals., is submitted. Valsartan; Copy of COA (Batch# 10252-210202) of API from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China and M/s Weather Folds Pharmaceuticals., is submitted.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is provided by the firm.
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nebivolol HCl; Firm has submitted copy of certificate of license to manufacture for sale of drugs of API manufacturer issued by food and drugs control administration Gujarat state India valid upto 31-12-2021. Valsartan; Firm has submitted copy of DML of API manufacturer issued by Zhejiang province food and drug administration valid upto 16-06-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Nebivolol HCl; Firm has submitted copy of form 6 cleared dated 18-06-2021 specifying 0.05kg Nebivolol HCl. The form 6 is cleared by AD (I&E) DRAP. Valsartan; Firm has submitted copy of commercial invoice cleared dated 09-03-2021 specifying 0.5kg Valsartan. The invoice is cleared by AD (I&E) DRAP. Firm has submitted copy of form 6 cleared dated 09-03-2021 specifying 0.5kg Valsartan. The form6 is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator Brand).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against brand leader in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
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 stability study 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.	The firm submitted that HPLC software does not comply with 21CFR and audit trials on product testing. So data is not submitted

14. c	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.	You have applied for label claim without considering the salt form of nebivolol. Revise the label claim as per reference formulation along with submission of applicable fee.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Justification shall be submitted for not performing the test for residue on ignition and chiral purity (D-isomer and L-isomer) for nebivolol by finished product manufacturer as per API manufacturer	
5.	Method used for analysis of API nebivolol from Finished Product Manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer for Nebivolol HCl issued by concerned regulatory authority of country of origin shall be submitted	
7.	Copy of commercial invoice or clearance certificate for the procurement of API nebivolol with approval from DRAP shall be submitted	
8.	Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document	
9.	• Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed • Complete record of CDP studies shall be submitted	

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

46.	Name and address of manufacturer/ Applicant	M/s Wnsfeild Pharmaceuticals, Plot No.122, Block-A, Phase V, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Nebival 5/80mg tablet
	Composition	Each film coated tablet contains: Nebivolol……5mg valsartan …….80mg
	Diary No. Date of R & I & fee	From-5 Dy. No.2102 dated 07-12-2016 Rs. 50,000/- dated 07-12-2016
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form-5D
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYVALSON (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, (USFDA approved ***Discontinued) (NDA)*** VYDUO (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, USFDA approved (ANDA)
	Me-too status	Could not be confirmed

	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA			
Drug	Nebival 5/80mg tablet		
Manufacturer of API	Nebivolol HCl; Valsartan;		
API Lot No.	Nebivolol HCl; Valsartan;		
Description of Pack (Container closure system)	3x10's; Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	SV-01	SV-02	SV-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	05-01-2020	05-01-2020	05-01-2020
No. of Batches	03		
Date of Submission	Dy No. 27284 Dated; 04-10-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Nebivolol HCl; Not submitted. Valsartan; Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nebivolol HCl; Not submitted. Valsartan; Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Nebivolol HCl; Not submitted. Valsartan; Not submitted.

7.	Protocols followed for conduction of stability study	Not submitted. .
8.	Method used for analysis of FPP	Not submitted. .
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not submitted.
14. c	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	You have applied for label claim without considering the salt form of nebivolol. Revise the label claim as per reference formulation along with submission of applicable fee.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted.	
12.	Record of comparative dissolution data shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

15.	Clarification shall be submitted as date of initiation of stability study in stability summary sheets is prior to the manufacturing of trial batches	

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

47.	Name and address of manufacturer/ Applicant	M/s Dynatis Pakistan Pvt Ltd., Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TICOL Tablet 90 mg
	Composition	Each Film Coated Tablet Contains: Ticagrelor…….90mg
	Diary No. Date of R & I & fee	Dy. No 12373 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antithrombotic agent
	Type of Form	Form-5
	Finished product Specification	Innovator specification.
	Pack size & Demanded Price	30's, as per SRO
	Approval status of product in Reference Regulatory Authorities	BRILINTA 90mg Tablets by M/s AstraZeneca Pharmaceuticals, USFDA Approved.
	Me-too status	Anplag 90mg Tablet, PharmEvo(Pvt) Ltd, R. No. 089382
	GMP status	Last GMP inspection is conducted on 26-03-2021 and GMP certificate has been issued to firm on 01-07-2021.
	Remarks of the Evaluator	Stability study data is required as per the guidelines approved in 293RD meeting of Registration Board
	Previous Decision (M-317th-RB)	Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Ticol 90mg Tablet		
Manufacturer of API	M/s Nantong Chanyoo Pharmacetechl Co., Ltd., China		
API Lot No.	RD-TG-202005061		
Description of Pack (Container closure system)	1x10's; Alu-PVC blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 18 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18 (months)		
Batch No.	TDK-002	TDK-003	TDK-004
Batch Size	2500 tablet	2500 tablet	2500 tablet
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Date of Submission	Dy No. 17839 Dated; 20-06-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#RD-TG-202005061) from M/s Nantong Chanyoo Pharmacetechl Co., Ltd., China and M/s Dynatis Pakistan Pvt Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Jiangsu Drug Administration, China valid upto 02-12-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 13-07-2020 specifying 1.5kg Ticagrelor. The invoice is cleared by AD (I&E) DRAP. Invoice is also submitted from M/s Changzhou pharmaceutical factory
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product Brilianta).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against Brillinta 90mg tablet by M/s Astrazeneca UK in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8 and QC release media. Drug release is more than 85% so f2 factor is not calculated.
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 stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	

3.	Analytical method for API is submitted from M/s Changzhou pharmaceutical factory which is different from API manufacturer (COA and copy of cGMP is submitted from chanyoo)	
4.	Stability study for API is submitted from M/s Changzhou pharmaceutical factory which is different from API manufacturer (COA and copy of cGMP is submitted from chanyoo)	
5.	Justification shall be submitted for selecting different chromatographic conditions of assay test of finished product than BP monograph Justification shall be submitted for selecting different time of dissolution test (75min) in finished product specifications than BP monograph (45min)	
6.	Justification shall be submitted selecting different limits of assay test for finished drug product (90-110%) than BP monograph (95-105%)	

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

48.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals., Plot # 31& 32 Punjab Small Industrial Estate Taxila
	Brand Name + Dosage Form + Strength	Weglor 90mg tablet
	Composition	Each Film Coated Tablet Contains: Ticagrelor……..…90mg
	Diary No. Date of R & I & fee	Dy No. 14191: 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	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.
	Previous Decision (M-323rd-RB)	Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Tacvo 90mg Tablet
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China
API Lot No.	20210402T
Description of Pack (Container closure system)	1x10's; Alu-alu blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
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	1200 tablet	1200 tablet	1200 tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		
Date of Submission	Dy No. 37574 Dated; 23-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#20210402T) from M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 cleared dated 11-10-2021 specifying 0.5kg Ticagrelor. The form 6 is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against brand leader in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
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 stability study 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.	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)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP shall be submitted	
7.	Justification shall be submitted for selecting different chromatographic conditions of assay test of finished product than BP monograph	
8.	• Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed • Complete record of CDP studies shall be submitted	
9.	Compliance Record of HPLC software 21CFR shall be submitted.	
10.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

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

49.	Name and address of manufacturer / Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Angiclor Tablet 90mg
	Composition	Each Film Coated Tablet Contains: Ticagrelor…….90mg
	Diary No. Date of R& I & fee	Dy.No 14862 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Virata tablet of M/s Sami Pharma
	GMP status	GMP certificate was issued based on inspection conducted on 29th October 2020.
	Remarks of the Evaluator II:	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. Frim's reply: We have submitted 06 months stability data (Accelerated & Real Time) of said product on 19th July,2022

	Previous Decision (M-323rd-RB)	Deferred for evaluation of submitted stability studies data on its turn

STABILITY STUDY DATA			
Drug	Angiclor Tablet 90mg		
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20200401T		
Description of Pack (Container closure system)	2x10's; Alu-alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR-058	TR-059	TR-060
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	23-08-2021	23-08-2021	23-08-2021
No. of Batches	03		
Date of Submission	Dy No. 20418 Dated; 19-07-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#20200401T) from M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from d Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of pharmaceutical production license of API manufacturer issued by Jiangxi Province FDA, China valid upto 15-02-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 04-01-2021 specifying 0.7kg Ticagrelor. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A

		(The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product Brillinta).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against Virata 90mg tablet by M/s CCL Pharma in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
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 stability study 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.	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)	Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	• Justification shall be submitted for selecting different time of dissolution test (45 &60min) in finished product specifications than BP monograph (45min) • Justification shall be submitted for selecting different chromatographic conditions of assay test of finished product than BP monograph	
6.	Submit details of comparator product including manufacturing date and expiry date against which CDP studies were performed	
7.	Compliance Record of HPLC software 21CFR shall be submitted	
8.	• Justify the delay in initiation of stability study of applied product as the trial batches are manufactured on 06-2021 and stability study is initiated on 23-08-2021 • Stability summary data sheets for batch no. TR-059 at real time conditions is not submitted	

Decision: Approved with BP specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

	ii. Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years **iii. Certificate of Analysis of API from Finished Product manufacturer** **iv. Valid copy of API DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.** **v. Details of comparator product including manufacturing date and expiry date against which CDP studies were performed** **vi. Stability summary data sheets for batch no. TR-059 at real time conditions**	
50.	Name and address of manufacturer/ Applicant	M/s Saffron pharmaceuticals (Pvt.) Limited, 19 Km, Sheikhupura Road, Faisalabad.
	Brand Name + Dosage Form + Strength	CAGRELOR 90mg Tablets
	Composition	Each film-coated tablet contains: - Ticagrelor……..90mg
	Diary No. Date of R & I & fee	Dy. No. 5791 dated 28-06-2012, Rs. 8,000/- dated 28-06-2012 (Fee challan copy not provided), Dy.No. 745 dated 14-03-2019 Differential fee Rs. 12,000/- vide challan No.0740777 dated 11-03-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Platelet aggregation inhibitor excluding heparin
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	BRILINTA® (ticagrelor) 60mg, 90mg film-coated tablets (US FDA approved)
	Me-too status	ACS Tablet 90mg of M/s Genome pharmaceuticals, Hattar. Registration No. 098704
	GMP status	GMP certificate dated 15-10-2018 issued based on evaluation conducted on 03-10-2018.
	Remarks of the Evaluator (PEC-XVII)	Tablet Section (General) mentioned in GMP certificate dated 15-10-2018. Provide stability study data as per guidelines of 293rd meeting of Registration Board along with submission of applicable fee. The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial.
	Previous Decision (M-323rd-RB)	Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board within 6 months.

STABILITY STUDY DATA

Drug	CAGRELOR 90mg Tablets
Manufacturer of API	M/s Nantong Chanyoo Pharmaceutical Co., Ltd., China
API Lot No.	RD-TG-201711241
Description of Pack (Container closure system)	2x10's; Alu-alu blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
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.	T-002	T-003	T-004
Batch Size	2300 tablets	2300 tablets	2300 tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	09-08-2018	09-08-2018	09-08-2018
No. of Batches	03		
Date of Submission	Dy No. 35144 Dated; 05-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#RD-TG-202005061) from M/s Nantong Chanyoo Pharmaceutical Co., Ltd., China and M/s Saffron pharmaceuticals (Pvt.) Limited., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Jiangsu Drug Administration, China valid upto 02-12-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 08-02-2018 specifying 0.75kg Ticagrelor. The invoice is cleared by AD (I&E) DRAP. Invoice is submitted from M/s Changzhou pharmaceutical factory
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Method used for analysis of API from API Manufacturer shall be submitted	
4.	• Justification shall be submitted for selecting different limit of assay test (90-110% in finished product specifications than BP monograph (95-105%) • Justification shall be submitted for selecting different chromatographic conditions of assay test of finished product than BP monograph	
5.	Stability study data of API from API manufacturer shall be submitted	
6.	Drug-excipients compatibility studies (where applicable) shall be submitted	
7.	Record of comparative dissolution data shall be submitted	
8.	• Justify the delay in initiation of stability study of applied product as the trial batches are manufactured on 05-2018 and stability study is initiated on 09-08-2018 • Stability study data documents including chromatograms, Raw data sheets, COA of applied product at accelerated conditions is not submitted	
9.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	

Decision: Deferred for submission of following:

i. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**
ii. **Valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years**
iii. **Method used for analysis of API from API Manufacturer**
iv. **Justification for selecting different limit of assay test (90-110% in finished product specifications than BP monograph (95-105%)**
v. **Justification for selecting different chromatographic conditions of assay test of finished product than BP monograph**
vi. **Stability study data of API from API manufacturer**
vii. **Drug-excipients compatibility studies**
viii. **Record of comparative dissolution data**
ix. **Justification for the delay in initiation of stability study of applied product as the trial batches are manufactured on 05-2018 and stability study is initiated on 09-08-2018**
x. **Stability study data documents including chromatograms, Raw data sheets, COA of applied product at accelerated conditions.**

51.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma., 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Pentadol 100mg tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol as HCl……..…100mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 11613 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other opioids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications

	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA 50mg, 75mg, 100mg film-coated tablets (US FDA approved)
	Me-too status	Tapento IR 100mg Tablet by M/s SAMI Pharmaceuticals (Registration No. 109990)
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Pentadol 100mg Tablet		
Manufacturer of API	M/s Precise Chemipharma Pvt. Ltd., India		
API Lot No.	6009122016		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TP-01	TP-02	TP-03
Batch Size	666 tablets	666 tablets	666 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		
Date of Submission	Dy No. 4385 Dated; 16-02-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#6009122016) from M/s Precise Chemipharma Pvt. Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	
5.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted	
6.	• Justification shall be submitted for selecting the value of Q in dissolution specifications NLT 70% instead of NLT 75% as per the decision of registration board • Justify the dissolution time of 60minutes since the applied product is immediate release dosage form	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted	
8.	Complete batch manufacturing record of three stability batches shall be submitted	
9.	Record of comparative dissolution data shall be submitted	
10.	• The expiry date mentioned on COA of API is Nov 2019 while manufacturing date of trial batches are 09-2021. Clarification is required weather same API was used in manufacturing of trial batches? • The batch number of API mentioned in stability summary sheets is different than that mentioned in the submitted COA, clarify • Clarification shall be submitted since the dissolution medium mentioned in analytical method is phosphate buffer pH 6.8 while 0.1N HCl in stability summary sheets	
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings		
52.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma., 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Pentadol 50mg tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol as HCl……..…50mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 11615 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other opioids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA 50mg, 75mg, 100mg film-coated tablets (US FDA approved)
	Me-too status	Tapento IR 50mg Tablet by M/s SAMI Pharmaceuticals (Registration No. 109989)
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Pentadol 50mg Tablet		
Manufacturer of API	M/s Precise Chemipharma Pvt. Ltd., India		
API Lot No.	6009122016		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TP-01	TP-02	TP-03
Batch Size	666 tablets	666 tablets	666 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		
Date of Submission	Dy No. 4383 Dated; 16-02-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#6009122016) from M/s Precise Chemipharma Pvt. Ltd., is submitted.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	
5.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted	
6.	• Justification shall be submitted for selecting the value of Q in dissolution specifications NLT 70% instead of NLT 75% as per the decision of registration board • Justify the dissolution time of 60minutes since the applied product is immediate release dosage form	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted	

8.	Complete batch manufacturing record of three stability batches shall be submitted	
9.	Record of comparative dissolution data shall be submitted	
10.	• The expiry date mentioned on COA of API is Nov 2019 while manufacturing date of trial batches are 09-2021. Clarification is required weather same API was used in manufacturing of trial batches? • The batch number of API mentioned in stability summary sheets is different than that mentioned in the submitted COA, clarify • Clarification shall be submitted since the dissolution medium mentioned in analytical method is phosphate buffer pH 6.8 while 0.1N HCl in stability summary sheets	
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

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

53.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd., 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Silosyn 4mg Capsule
	Composition	Each capsule contains: Silodosin……..4mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 252 dated 13-01-2016 Rs.50,000/- dated 13-01-2016
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	RAPAFLO (4mg, 8mg) capsules USFDA Approved
	Me-too status	Siloon Capsule 4mg by M/s Genix Pharma (Registration No. 107783)
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Dosin 4mg capsule		
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China		
API Lot No.	13000-190502-02		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T01	T02	T03

Batch Size	1000 capsule	1000 capsule	1000 capsule
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	11-2019	11-2019	11-2019
No. of Batches	03		
Date of Submission	Dated; 12-07-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#13000-190502-02) from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China and M/s Dyson Research Laboratories is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter dated 08-05-2019 "permission to import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability study" specifying 45gm silodosin issued by AD (I&E) DRAP Lahore.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product RAPAFLO 4mg capsule.
10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Certificate of compliance of HPLC software 21CFR is 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	
4.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted	
5.	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, rpm, time and limits (0.1N HCl, 900ml, 50rpm and NLT 80% in 15min)	
6.	Record of comparative dissolution data shall be submitted	
7.	Audit trail reports on product testing shall be submitted	

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

54.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd., 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Silosyn 8mg Capsule
	Composition	Each capsule contains: Silodosin……..8mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 251 dated 13-01-2016 Rs.50,000/- dated 13-01-2016
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	RAPAFLO (4mg, 8mg) capsules USFDA Approved
	Me-too status	Siloon Capsule 8mg by M/s Genix Pharma (Registration No. 107784)
	GMP status	
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Dosin 8mg capsule
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China
API Lot No.	13000-190502-02
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T01	T02	T03
Batch Size	1000 capsule	1000 capsule	1000 capsule
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	11-2019	11-2019	11-2019
No. of Batches	03		
Date of Submission	Dated; 12-07-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#13000-190502-02) from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China and M/s Dyson Research Laboratories is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter dated 08-05-2019 "permission to import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability study" specifying 45gm silodosin issued by AD (I&E) DRAP Lahore.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product RAPAFLO 8mg capsule.
10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	
4.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted	
5.	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, rpm, time and limits (0.1N HCl, 900ml, 50rpm and NLT 80% in 15min)	
6.	Record of comparative dissolution data shall be submitted	

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

55.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd., Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Colistim Injection 150mg
	Composition	Each vial contains: Colistimethate (as sodium) powder for reconstitution ……150mg
	Diary No. Date of R& I & fee	Diary No: 24091 , 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate for injection150mg/vial by M/s X-Gen Pharmaceutical USA (USFDA Approved)
	Me-too status	Colistat by Medisure (Reg. No. 076160) (Formulation is not same as for applied product)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Previous remarks of the Evaluator.	• Me-too status not confirmed from available database.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith

		registration number, brand name and name of firm **(M-278)**.
	Evaluation by PEC	The firm has submitted revised Form-5 with following label claim: Each vial contains: Colistimethate sodium (lyophilized powder)……2 MIU Fee of Rs. 20,000/- (deposit slip # 0805249) dated 05-03-2020 has been submitted for change in strength of applied formulation. **International availability**: Approved in MHRA **Me-too status:** Not confirmed The firm has been granted GMP certificate based on inspection conducted on 25-07-2019.
	Previous Decision (M-295th-RB)	Deferred for submission of stability studies data as per decision of 278th meeting of Registration Board.

STABILITY STUDY DATA

Drug	Colistim Injection 2MIU		
Manufacturer of API	M/s Sumar Biotech LLP India		
API Lot No.	SBL/SRD/COS/22/90/048		
Description of Pack (Container closure system)	Clear glass vial, type I		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	E001	E002	E003
Batch Size	264 Vials	264 Vials	264 Vials
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	08-2022	08-2022	08-2022
No. of Batches	03		
Date of Submission	Dy No. 8790 Dated; 30-03-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#SBL/SRD/COS/22/90/048) from M/s Sumar Biotech LLP India and M/s Pharmasol (Pvt) Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-B
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs

		Control Administration, Gujarat State India valid upto 24-08-2024. Firm has also submitted copy of DML of API manufacturer issued by Food & Drugs Control Administration, Gujarat State India valid upto 17-08-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate cleared dated 19-07-2022 specifying 01kg Colistimethate Sodium. The clearance certificate is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	N/A
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 stability study data of 03 batches supported by attested respective documents like Raw data sheets, COA, etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:
The same molecule is also applied on CTD vide tracking ID 5NA-539-J56E

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	N/A
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 24-09-2024 and 25-09-2024.
3.	Method used for analysis of API from API Manufacturer shall be submitted	Method used for analysis of API from API Manufacturer is submitted
4.	Stability study data of API at real time conditions from API manufacturer is submitted upto 6th months only. Stability study data till claimed shelf life shall be submitted	Stability study data of API at real time conditions from API manufacturer upto 24th months is submitted.
5.	Stability study data of applied product at real time conditions is not submitted	Stability study data of applied product at real time conditions is submitted

Decision: Approved.
Registration Board further decided that the same formulation also applied on CTD vide tracking ID 5NA-539-J56E by the firm may be considered as disposed of.

56.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma., 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Ivaprolol 50/5 mg Tablet
	Composition	Each Tablet Contains: Metoprolol Tartrate……50mg Ivabradine as HCl……..…5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 748 dated 07-01-2019 Rs.20,000/- dated 07-01-2019
	Pharmacological Group	Beta blocking agents, other combinations
	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	
	Me-too status	Implicor 5/25 Film Coated Tablet by M/s Servier Research and Pharmaceuticals Pakistan (Registration No. 99006)
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Ivaset-M 50/5 mg Tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 12 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 09, 12 (months)		
Batch No.	T-091	T-092	T-093
Batch Size	1333 tablets	1333 tablets	1333 tablets
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	12-05-2020	12-05-2020	12-05-2020
No. of Batches	03		
Date of Submission	Dated; 06-08-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted

4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability summary data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

The same molecule is also applied on CTD Format and Deferred in 329th meeting of RB.

Sr. No.	Observation	Reply by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

12.	Data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

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

57.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma., 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Ivaprolol 50/7.5 mg Tablet
	Composition	Each Tablet Contains: Metoprolol Tartrate……50mg Ivabradine as HCl……..…7.5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 749 dated 07-01-2019 Rs.20,000/- dated 07-01-2019
	Pharmacological Group	Beta blocking agents, other combinations
	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	
	Me-too status	Implicor 7.5/50 Film Coated Tablet by M/s Servier Research and Pharmaceuticals Pakistan (Registration No. 99495)
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Ivaset-M 50/7.5 mg Tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 12 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 09, 12 (months)		
Batch No.	T-094	T-095	T-096
Batch Size	1333 tablets	1333 tablets	1333 tablets
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	12-05-2020	12-05-2020	12-05-2020
No. of Batches	03		
Date of Submission	Dated; 06-08-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability summary data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	

6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

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

58.	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	Kandina8+5mg tablet
	Composition	Each tablet contains: Candesartan……8mg Amlodipine…….5mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 19 dated 03-10-2014 Rs.50,000/- dated 03-10-2014
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Not available
	GMP status	
	Remarks of the Evaluator.	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Kandina8+5mg tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	22PD-0287-24-SB	22PD-0285-22-SB	22PD-0286-23-SB
Batch Size	2500 tablets	2500 tablets	2500 tablets

Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	30-07-2022	30-07-2022	30-07-2022
No. of Batches	03		
Date of Submission	Dated; 24-02-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted	Unisia Combination Tablets HD PMDA Japan approved

2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	Candesartan cilexetil Copy of COA (Batch#5668-21-188) of API from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Pharmevo Private Limited., is submitted. Amlodipine Besylate Copy of COA (Batch#AMB/172/12/21) of API from M/s Prudence Pharma Chem India and M/s Pharmevo Private Limited., is submitted.
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.	Submitted as per zone IV-A
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Candesartan cilexetil Firm has submitted copy of DML (certificate#20000311) of API manufacturer issued by Zhejiang Medical Products Administration China valid upto 12-01-2025. Amlodipine Besylate Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Control Administration, Gujarat State India valid upto 26-05-2024.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Candesartan cilexetil Firm has submitted copy of commercial invoice cleared dated 14-12-2021 specifying 25kg Candesartan Cilexetil. The invoice is cleared by AD (I&E) DRAP. Amlodipine Besylate Firm has submitted copy of commercial invoice cleared dated 07-01-2022 specifying 200kg Amlodipine. The invoice is cleared by AD (I&E) DRAP.
8.	Protocols followed for conduction of stability study shall be submitted	Submitted.
9.	Method used for analysis of Finished Product shall be submitted.	Submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	N/A (Firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product).
11.	Complete batch manufacturing record of three stability batches shall be submitted.	Complete batch manufacturing record of three stability batches is submitted.
12.	Record of comparative dissolution data shall be submitted.	Submitted. Comparative dissolution was performed against Unisia 8/5mg tablet by M/s Takeda Pharma Osaka, Japan in HCl Buffer pH 1.2, acetate

		buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted.

Decision: Approved with following label claim:
Each tablet contains:
Candesartan cilexetil ……8mg
Amlodipine as besylate…….5mg
Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 75000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per S.R.O. 1324(l)2024 dated 30-08-2024

59.	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	Kandina8+2.5mg tablet
	Composition	Each tablet contains: Candesartan……8mg Amlodipine…….2.5mg
	Diary No. Date of R& I & fee	Form-5D Dy.No…….. dated 29-04-2016 Rs.50,000/- dated 28-04-2016
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Not available
	GMP status	
	Remarks of the Evaluator.	Stability list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	Kandina8+2.5mg tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	22PD-0288-07-SB	22PD-0289-08-SB	22PD-0290-09-SB
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2022	07-2022	07-2022

Date of Initiation	30-07-2022	30-07-2022	30-07-2022
No. of Batches	03		
Date of Submission	Dated; 24-02-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study 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.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be submitted	Unisia Combination Tablets LD PMDA Japan approved
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A

3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	Candesartan cilexetil Copy of COA (Batch#5668-21-188) of API from M/s Zhejiang Huahai Pharmaceutical Co., Ltd., China and M/s Pharmevo Private Limited., is submitted. Amlodipine Besylate Copy of COA (Batch#AMB/172/12/21) of API from M/s Prudence Pharma Chem India and M/s Pharmevo Private Limited., is submitted.
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer is submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.	Submitted as per zone IV-A
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Candesartan cilexetil Firm has submitted copy of DML (certificate#20000311) of API manufacturer issued by Zhejiang Medical Products Administration China valid upto 12-01-2025. Amlodipine Besylate Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Control Administration, Gujarat State India valid upto 26-05-2024.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Candesartan cilexetil Firm has submitted copy of commercial invoice cleared dated 14-12-2021 specifying 25kg Candesartan Cilexetil. The invoice is cleared by AD (I&E) DRAP. Amlodipine Besylate Firm has submitted copy of commercial invoice cleared dated 07-01-2022 specifying 200kg Amlodipine. The invoice is cleared by AD (I&E) DRAP.
8.	Protocols followed for conduction of stability study shall be submitted	Submitted.
9.	Method used for analysis of Finished Product shall be submitted.	Submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	N/A (Firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product).
11.	Complete batch manufacturing record of three stability batches shall be submitted.	Complete batch manufacturing record of three stability batches is submitted.
12.	Record of comparative dissolution data shall be submitted.	Submitted. Comparative dissolution was performed against Unisia 8/2.5mg tablet by M/s Takeda Pharma Osaka, Japan in HCl Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH

		6.8. The values of f2 factor are in acceptable range.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted.

Decision: Approved with following label claim:
Each tablet contains:
Candesartan cilexetil ……8mg
Amlodipine as besylate…….2.5mg
Registration Board further decided that Registration letter will be issued after submission of following:
Fee of Rs. 75000/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per S.R.O. 1324(l)2024 dated 30-08-2024

60.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd., 19 Km Sheikhupura Road, Faisalabad"
	Brand Name +Dosage Form + Strength	Trifort DS Tablet
	Composition	"Each Film Coated Tablet Contains: Tramadol HCL…75mg Paracetamol…650mg"
	Diary No. Date of R& I & fee	Dy.No 6328 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.
	Me-too status	Could not be confirmed in applied strength.
	GMP status	08-10-2019 Recommendations: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of Cgmp certificate, un respect of all approved sections.
	Remarks of the Evaluator (V)	• 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.
	Decision in 295th Meeting: Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

	Evaluation by PEC-V: a) Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Tramadol/Paracetamol 75 mg / 650 mg tablets MHRA Approved (Uncoated Tablet) b) Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Tono Flex by M/s Sami (094798) Conclusion: The firm has film coated tablet whereas the applied formulation is approved in MHRA as uncoated tablet. Approved in ANSM as film coated tablet.
	Previous Decision (M-297th-RB): Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Trifort DS Tablet		
Approval status of product in Reference Regulatory Authorities.	Tramadol/paracetamol cinfa 75 mg/650 mg film-coated tablets CIMA Spain aprroved		
Manufacturer of API	Tramadol HCl; M/s Surya Lifesciences Ltd., India Paracetamol; M/s Hebei Jiheng (Group) Pharmaceuticals Co., Ltd., China		
API Lot No.	Tramadol HCl; SLL/TDM/0619018 Paracetamol; 012101080		
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%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-002	T-003	T-004
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	10-2021	12-2021	12-2021
Date of Initiation	16-12-2021	19-01-2022	21-01-2022
No. of Batches	03		
Date of Submission	Dy No. 22943 Dated; 15-08-2022		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 293rd meeting held on 06th-08th January, 2020

		decided to approve registration of Elixa 2.5mg tablet and Elixa 5mg tablet. Inspection date: 08th October, 2019 The report shows that: • Firm has data based lab solution software on the Schimadzu HPLCs details of which are as under; o Schimadzu Lab solution (Equipment ID; QC-75) o Schimadzu LC solution (Equipment ID; QC-101) • The date and time were properly locked. The firm has defined the rights of manager and analyst separately. The audit trial feature of the system was active. The firm was advised to develop control for deletion of file from the system. • Firm has demonstrated audit trial reports for the submitted stability studies data. Also the relevant log books were verified for the performance of stability studies • The firm has demonstrated chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers. Record of digital data logger for both chambers used in accelerated and real time stability studies were demonstrated.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Tramadol HCl; Copy of COA (Batch#SLL/TDM/0619018) from M/s Supriya Lifesciences Ltd., India and M/s Saffron Pharmaceuticals., is submitted. Paracetamol; Copy of COA (Batch#012101080) from M/s Hebei Jiheng (Group) Pharmaceuticals Co., Ltd., China and M/s Saffron Pharmaceuticals., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Tramadol HCl; Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration M.S, Mumbai India valid upto 23-11-2024. Paracetamol; Firm has submitted copy of Drug product license of API manufacturer issued by Hebei Drug Administration, China valid upto 30-08-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Tramadol HCl; Firm has submitted copy of commercial invoice cleared dated 27-06-2019 specifying 200kg

		Tramadol HCl. The invoice is cleared by AD (I&E) DRAP. Paracetamol; Firm has submitted copy of commercial invoice cleared dated 30-04-2021 specifying 500kg Paracetamol. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Complete batch manufacturing record of three stability batches is submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 03 batches supported by attested respective documents like Raw data sheets, COA, etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
2.	Method used for analysis of API from API Manufacturer shall be submitted	
3.	Approval of API/ DML/GMP certificate of API manufacturer for tramadol issued by concerned regulatory authority of country of origin shall be submitted	
4.	Justify the use of ethanol in applied formulation	
5.	Record of comparative dissolution data shall be submitted	
6.	• Justify the delay in initiation of stability study of applied product • Stability summary data sheets of batch No T-003 and T-004 of applied product is not submitted • Stability study data of batch No T-003 and T-004 at 3rd month time point real time conditions of applied product is not submitted	
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	

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

61.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	**Otoxel otic Solution**
	Composition	Each ml Of Otic Solution Contains:

		Ciprofloxacin HCl……..…3.0mg (0.3%) Fluocinolone Acetonide…..…0.25mg (0.025%)
	Diary No. Date of R & I & fee	Form-5D Dy.No 25396 dated 21-12-2017 Rs.50,000 dated 20-12-2017
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of Form	Form 5-D
	Finished product Specification	In house specifications
	Pack size & Demanded Price	5ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	OTOVEL (ciprofloxacin and fluocinolone acetonide) 0.3%;0.025% otic solution USFDA Approved.
	Me-too status	Not Available
	GMP status	
	Remarks of the Evaluator	PEC main list file. Form 5D needs to be verified

STABILITY STUDY DATA

Drug	**Otoxel otic Solution**		
Manufacturer of API	Fluocinolone Acetonide: M/s Farmabios S.P.A. Via Pavia, 1,27027 Gropello Cairoli, Italy Ciprfloxacin HCl; M/s Pharmagen Limited Pakistan		
API Lot No.	Fluocinolone Acetonide: 2151NM1 Ciprofloxacin HCl; 00510011/040/2019		
Description of Pack (Container closure system)	1x5ml; LDPE container 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: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12, 18, 24 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000ml/192 bottles	1000ml/192 bottles	1000ml/192 bottles
Manufacturing Date	06-2019	06-2019	06-2019
Date of Initiation	01-07-2019	01-07-2019	01-07-2019
No. of Batches	03		
Date of Submission	Dated; 28-11-2022		

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.	The firm has referred to previous inspection for verification of authenticity of stability data of their product on the basis of which Registration Board in its 307th meeting held on 08th-10th June, 2021 decided to approve registration of C-zyn ophthalmic solution 0.24%. Inspection date: 01st September, 2020

		The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. Audit trail on the testing reports of "c-zyn opthalmoc solution 0.24%" has available On upgraded HPLC 21 CFR. • Adequate monitoring and control are available for stability chamber. The firm has installed software for recording the temperature / humidity of chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Fluocinolone Acetonide: Copy of COA (Batch#2151NM1) from M/s Farmabios S.P.A. Via Pavia, 1,27027 Gropello Cairoli, Italy is submitted. Ciprofloxacin HCl; Copy of COA (Batch#00510011/040/2019) from M/s Pharmagen Limited Pakistan and M/s Helix Pharma Pvt Ltd., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Method used for analysis of API from Finished Product Manufacturer is submitted
4.	Stability study data of API from API manufacturer	Ciprofloxacin HCl; Submitted as per zone IV-A Fluocinolone Acetonide: Submitted at 25ºC±2/RH 60º±5%
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ciprofloxacin HCl; Firm has submitted copy of cGMP certificate of API manufacturer issued by DRAP valid upto 21-06-2022. Fluocinolone Acetonide: Firm has submitted copy of cGMP certificate of API manufacturer issued by AIFA Italy valid upto 11-06-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Fluocinolone Acetonide: Firm has submitted copy of form 6 cleared dated 15-11-2018 specifying 200gm Fluocinolone Acetonide. The form 6 is cleared by AD (I&E) DRAP. Firm has also submitted copy of commercial invoice cleared dated 15-11-2018 specifying 200gm Fluocinolone Acetonide. The invoice is cleared by AD (I&E) DRAP. Ciprofloxacin HCl;
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (Formulation of applied drug product is qualitatively similar to that of reference product

		Cetraxal plus otic solution by M/s Aspire Pharma UK.
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	N/A
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 stability study 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.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:
The formulation does not contain any preservative.

Sr. No.	Observation	Reply by the firm
1.	You have applied for label claim without considering the salt form of Ciprofloxacin. Revise the label claim as per reference formulation along with submission of applicable fee.	
2.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
3.	Certificate of Analysis of API for Fluocinolone Acetonide from Finished Product manufacturer shall be submitted	
4.	Approval of API/ DML/GMP certificate of API manufacturer for Ciprofloxacin and Fluocinolone Acetonide issued by concerned regulatory authority of country of origin shall be submitted	
5.	Documents for the procurement of API ciprofloxacin HCl shall be submitted	
6.	Method used for analysis of API from API Manufacturer is not submitted	
7.	Stability study data of API fluocinolone acetonide from API manufacturer at zone IV-A conditions shall be submitted.	
8.	• Clarification is required as the pack size of reference product is single-dose 0.25 mL vials. Fourteen single-dose vials are packaged in a protective foil pouch contained in a carton while you have applied for 5ml volume in LDPE bottle. • Clarification shall be submitted for maintaining the sterility throughout the shelf life without using the preservatives.	
9.	Provide evidence of applied formulation in multiple dose container	
10.	Justification shall be submitted for not including the test for osmolality, viscosity, particulate matter and weight loss as per innovator's product review document	

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

Agenda of Mr. Adil Saeed

Form 5F case;

62.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat. (DML No. 000778)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22601 dated 14-09-2023
	Details of fee submitted	PKR 30,000/- : 172955320
	The proposed proprietary name / brand name	**ORATANE 40mg Softgel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains; Isotretinoin……40mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne ATC Code: D10BA01
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	ISOTRETINOIN 40 MG SOFT CAPSULES, ISOTRETINOIN MYLAN 40 MG CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Maxinoin 40mg capsule M/s Maxitech.
	Proposed Pack size	30's

EVALUATION OF DATA

GMP status of the firm	Copy of GMP certificate valid till 07.08.2025 is submitted
Evidence of approval of manufacturing facility	Firm has submitted copy of renewal letter No. 1-54/2009-Lic(Vol-I) dated 06.03.2024 wherein softgel Section General is mentioned.
Name and address of API manufacturer.	M/s Chongqing Huapont Shengchem Pharmaceutical Co. Ltd. No. 666 Rongjun Road, Nanjin Avenue Henchuan District Chongqing China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Maxinoin 40mg Softgel capsule Batch No. 008G03D manufactured by Maxitech Pharma (Pvt.) Ltd. Firm has submitted CDP results of their product against the same product. F2 values at all pH are above 90

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			
API Lot No.	ISTR-20210701		
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.	015T22	013T22	014T22
Batch Size	600 capsules	600 capsules	600 capsules
Manufacturing Date	11.2022	11.2022	11.2022
Date of Initiation	09.11.2022	07.11.2022	08.11.2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
Reference of previous approval of applications with stability study data of the firm (if any)	NA		
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 Chongqing FDA valid till 06.06.2023.		
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of attested invoice mentioning 1kg Isotretinoin		
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.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system		
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 (No IX):			
Decision: Approved.			

Stability Cases:

63.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot No. 10& 25 Sector 20, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	DAGLI-M 5mg / 850mg Tablet
	Composition	Each film coated tablet contains:

		Dapagliflozin propanediol monohydrate eq. to Dapagliflozin…….. 5mg Metformin hydrochloride……..850mg
	Diary No. Date of R& I & fee	Dy. No. 37594 dated 13.11.2018, Fee Rs: 50,000/- dated 17.10.2018 vide deposit slip No. 0742422. (Duplicate dossier submitted vide Dy. No. 28765 dated 11.10.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Not mentioned
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	XIGDUO 5 MG/850 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Dapa-Met 5/850 M/s Hilton
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	DAGLI-M 5mg/850mg		
Manufacturer of API	**Dapagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam		
API Lot No.	**Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/19081515		
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.	076DS01	076DS02	076DS03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	11.2021	11.2021	11.2021
Date of Initiation	09.12.2021	09.12.2021	09.12.2021
No. of Batches	03		
Date of Submission	Dy. No. 28765 dated 11.10.2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>NA</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted.
<u>Dapagliflozin Propanediol Monohydrate:</u> DG-20201201-D03-DG06-01
Metformin HCl: MEF/19081515</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 both 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.</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><u>Dapagliflozin:</u> 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.
<u>Metformin HCl:</u> Not submitted.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td><u>Dapagliflozin</u>: AD attested invoice mentioning 0.6kg drug substance, attested on 07.05.2021 is submitted. Batch No. DG-20201201-D03-DG06-01
<u>Metformin HCl:</u> Copy of AD attested invoice mentioning 500kg drug substance, attested on 22.08.2019 is submitted. Batch No. MEF/19081515</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>076DS01</td><td>2500 tablets</td><td>11.2021</td></tr>
<tr><td>076DS02</td><td>2500 tablets</td><td>11.2021</td></tr>
<tr><td>076DS03</td><td>2500 tablets</td><td>11.2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has performed CDP against product Xigduo 5mg/850mg Batch No. Z7576A, manufactured by M/s Astra Zeneca.
pH 1.2: F2 55%, 53%
pH 4.5: F2 53%, 92 %
pH 6.8: F2 53%, 51%</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)	Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply of Firm
1.	Application Form is not submitted. Only annexures are attached. Copy of fee deposit slip is also not attached.	Firm has submitted their response vide letter No. ASP-RA/330/12/2024 dated 26.12.2024. Copy of fee deposit slip is submitted. R&I verified. Form-5D Dy.No 37594 dated 13-11-2018
2.	Label claim and specifications applied are not mentioned anywhere in the application.	Copy of Form 5D is submitted. In-House specifications were applied.
3.	Copy OF GMP certificate/ DML of manufacturer of Metformin HCl is required.	Copy of DML issued by F&DCA Gujrat State India, valid till 20.03.2029 is submitted.
4.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 02.05.2027 is submitted.

Decision: Approved with Innovator Specifications. Registration Registration Letter shall be issued after submission of fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.

64.	Name and address of manufacturer / Applicant	M/s Aspin Pharma (Pvt.) Ltd. Plot No. 10& 25 Sector 20, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	DAGLI-M 5mg / 1000mg Tablet
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin…….. 5mg Metformin hydrochloride……..1000mg
	Diary No. Date of R& I & fee	Dy. No. 37595 dated 13.11.2018, Fee Rs: 50,000/- dated 17.10.2018_vide deposit slip No. 0742423. (Duplicate dossier submitted vide Dy. No. 28766 dated 11.10.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Not mentioned
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	XIGDUO 5 MG/1000 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Dapa-Met 5/1000 M/s Hilton

	GMP status	Not submitted.		
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		DAGLI-M 5mg / 1000mg Tablet		
Manufacturer of API		**Dapagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam		
API Lot No.		**Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/19081515		
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 ℃ ± 2 ℃ / 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.		276DS01	276DS02	276DS03
Batch Size		2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date		11.2021	11.2021	11.2021
Date of Initiation		09.12.2021	09.12.2021	09.12.2021
No. of Batches		03		
Date of Submission		Dy. No. 28766 dated 11.10.2022		
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	NA		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/19081515		
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 both 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.		

5.	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 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. **Metformin HCl:** Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin**: AD attested invoice mentioning 0.6kg drug substance, attested on 07.05.2021 is submitted. Batch No. DG-20201201-D03-DG06-01 **Metformin HCl:** Copy of AD attested invoice mentioning 500kg drug substance, attested on 22.08.2019 is submitted. Batch No. MEF/19081515
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** 276DS01 / 2500 tablets / 11.2021 276DS02 / 2500 tablets / 11.2021 276DS03 / 2500 tablets / 11.2021
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Xigduo 5mg/1000mg Batch No. Z7577A, manufactured by M/s Astra Zeneca. pH 1.2: F2 51%, 50% pH 4.5: F2 52%, 52 % pH 6.8: F2 85%, 97%
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
1.	Application Form is not submitted. Only annexures are attached.	Firm has submitted their response vide letter No. ASP-RA/330/12/2024 dated 26.12.2024.

	Copy of fee deposit slip is also not attached.	Copy of fee deposit slip is submitted. R&I verified. Form-5D Dy.No 37595 dated 13-11-2018
2.	Label claim and specifications applied are not mentioned anywhere in the application.	Copy of Form 5D is submitted. In-House specifications were applied.
3.	Copy OF GMP certificate/ DML of manufacturer of Metformin HCl is required.	Copy of DML issued by F&DCA Gujrat State India, valid till 20.03.2029 is submitted.
4.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 02.05.2027 is submitted.

Decision: Approved with Innovator Specifications. Registration Letter shall be issued after submission of fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.

65.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Ltd.F/423 S.I.T.E. Karachi (DML No. 000457
	Brand Name +Dosage Form + Strength	IZOLOL Eye DROPS
	Composition	Each ml Contains: Brinzolamide……10mg Timolol Maleate eq. to timolol …5mg
	Diary No. Date of R& I & fee	Dy. No. 14756 dated 07.03.2019, Fee Rs: 50,000/- dated 06.03.2019 vide deposit slip No. 0837548. Stability: Dy. No. 35840 dated 09.12.2022
	Pharmacological Group	brinzolamide, combinations S01EC54
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	5ml 1's
	Approval status of product in Reference Regulator Authorities	BRINZOLAMIDE/TIMOLOL ACCORD 10MG/ML + 5MG/ML EYE DROPS SUSPENSION MHRA Approved.
	Me-too status	
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	IZOLOL Eye DROPS
Manufacturer of API	**Brinzolamide** : DUKE CHEM SAU AV. MARE DE DEU DE Montserrat 93-99 POL. IND. Sant Pere Molanta Olerdola, Barceloma Spain. **Timolol maleate:** Taijin Minxiang Biomedical Inc No. 24 Fangang Road Shuanggang Industrial Zone Tianjin City China.
API Lot No.	**Brinzolamide** : 332702000 **Timolol maleate:** 032C210107
Description of Pack (Container closure system)	LDPE Eye drop Bottle
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	EXP-OP-294	PLT-OP-015	PLT-OP-016
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	14.12.2021	14.12.2021	14.12.2021
Date of Initiation	26.01.2022	26.01.2022	26.01.2022
No. of Batches	03		
Date of Submission	Dy. No. 35840 dated 09.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Brinzolamide** : 332702000 **Timolol maleate:** 032C210107
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Brinzolamide** : **Timolol maleate:**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Brinzolamide** : Copy of invoice mentioning 150 grams API, attested on 22.09.2021 is submitted **Timolol maleate:** Copy of invoice mentioning 5kg API attested on 09.02.2021 is submitted.
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 03 stability Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed pharmaceutical equivalence against Azarga Eye drops Batch No. 20I02SB mfg by Alcon

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
1.	Copies of GMP certificate/ DML of both drug substance manufacturers are required.
2.	Water loss studies are not part of stability studies.

Decision: Approved. Registration Letter shall be issued after submission of following;

- **Copy of GMP/DML of both drug substance manufacturers.**
- **Water loss studies for the container closure used as primary packaging.**
- **Fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.**

66.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Ltd.F/423 S.I.T.E. Karachi (DML No. 000457
	Brand Name +Dosage Form + Strength	BRINZOL Ophthalmic Suspension
	Composition	Each ml of contains: Brinzolamide …..10mg Brimonidine tratrate…..2mg
	Diary No. Date of R& I & fee	From-5 Dy. No.242 dated 08-06-2015 50,000/- dated 08-06-2015. Stability: Dy. No. 26937 dated 23.09.2022
	Pharmacological Group	brinzolamide, combinations S01EC54
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	5ml 1's
	Approval status of product in Reference Regulator Authorities	BRINZOLAMIDE/TIMOLOL ACCORD 10MG/ML + 5MG/ML EYE DROPS SUSPENSION MHRA Approved.
	Me-too status	
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	IZOLOL Eye DROPS
Manufacturer of API	**Brinzolamide** : DUKE CHEM SAU AV. MARE DE DEU DE Montserrat 93-99 POL. IND. Sant Pere Molanta Olerdola, Barceloma Spain.

	Brimonidine Tartrate: M/s Laurus Labs Limited (Unit-1) Plot No. 21 JN Pharma City Parawada mandal Visakhapatnam District Andhra Pradesh India.		
API Lot No.	**Brinzolamide** : 332702000 **Brimonidine Tartrate:** ABTVSP10031020		
Description of Pack (Container closure system)	LDPE Eye drop Bottle		
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.	EXP-OP-293	PLT-OP-013	PLT-OP-014
Batch Size	100 bottles	200 bottles	200 bottles
Manufacturing Date	11.2021	12.2021	12.2021
Date of Initiation	12.2022	01.2022	01.2022
No. of Batches	03		
Date of Submission	Dy. No. 26937 dated 23.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Brinzolamide** : 332702000 **Brimonidine Tartrate:**.ABTVSP10031020
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Brinzolamide** : Copy of GMP certificate issued by DG Regulacio Sanitaria Barcelona Spain is submitted. **Brimonidine Tartrate:** Copy of GMP certificate issued by DCA Andhra Pradesh valid till 09.01.2023 I submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Brinzolamide** : Copy of invoice mentioning 150 grams API, attested on 22.09.2021 is submitted **Brimonidine Tartrate:**.Copy of invoice mentioning 5kg API attested on 09.02.2021 is submitted.

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 03 stability Batches:
11.	Record of comparative dissolution data (where applicable)	
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
1.	Pharmaceutical equivalence studies data is not submitted
2.	Water loss studies are not part of stability studies.

Decision: Approved. Registration Letter shall be issued after submission of following;

- **Copy of GMP/DML of both drug substance manufacturers.**
- **Water loss studies for the container closure used as primary packaging.**
- **Fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.**

67.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Ltd.F/423 S.I.T.E. Karachi (DML No. 000457
	Brand Name +Dosage Form + Strength	Eyecef Ophthalmic Solution 0.25%
	Composition	Each ml contains: Alcaftadine…..2.5mg
	Diary No. Date of R& I & fee	From-5 Dy. No. 1333 dated 27-06-2016 50,000/- dated 27-06-2016 Stability:16.01.2023
	Pharmacological Group	Other antiallergics S01GX11
	Type of Form	Form 5
	Finished product Specifications	Suppliers Specifications
	Pack size & Demanded Price	3ml Rs. 550/- 5ml Rs. 850/-

	Approval status of product in Reference Regulator Authorities	Lastacaft USFDA Approved.
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Eyecef Ophthalmic Solution 0.25%		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
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.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	16.01.2023		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted
7.	Protocols followed for conduction of stability study	Not Submitted
8.	Method used for analysis of FPP	Not Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not Submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted
11.	Record of comparative dissolution data (where applicable)	Not Submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Finished product specifications are mentioned as Suppliers specifications, clarification is required.
2.	Method used for analysis of API along with COA. / COA of drug substance by both drug product manufacturer and drug substance manufacturers are required.
3.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
4.	Protocols followed for conduction of stability study and details of tests are required
5.	Stability Summary sheets are required.
6.	Documents confirming import of API etc.
7.	(AD Attested invoices or clearance certificates)
8.	Complete batch manufacturing record of three stability batches is required.
9.	Method used for analysis of FPP is required.
10.	Reports of stability studies of API from manufacturer of is required.
11.	Analysis reports for excipients used is required.
12.	Pharmaceutical equivalence studies are required.

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

68.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road,Karachi.
	Brand Name +Dosage Form + Strength	Xab 2.5mg tablets
	Composition	Each film coated tablet contains: Apixaban……..…..2.5 mg

	Diary No. Date of R& I & fee	Dy. No.220; 09-09-2014; Rs.20,000/- (04-09-2014) Fee of Rs. 10,000/- submitted vide slip No. 07926591 dated 23.12.2022
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer‘s specifications
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	Eliquis (approved in USFDA)
	Me-too status	Not provided
	GMP status	Last GMP inspection conducted on 26-01-2017 and the report concludes that the firm is considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	□ Approved in USFDA with box warning □ Shortcomings: □ Application on form-5D with differential fee □ Complete stability studies data as per zone IV-A conditions
.	Decision of 274th RB	Deferred for submission of □ complete stability studies data as per zone IV-A conditions □ application on form 5D with differential fee

STABILITY STUDY DATA			
Drug	Xab 2.5mg tablets		
Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Louyang Town Wujin District Changzhou Jiangsu China		
API Lot No.	ZSAP210201		
Description of Pack (Container closure system)	Alu Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	21SB(A)-179-01	21SB(A)-180-02	21SB(A)-181-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	11.10.2021	11.10.2021	11.10.2021
No. of Batches	03		
Date of Submission	Dy. No. 38206 dated 28.12.2022		
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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. ZSAP210201
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML issued by Jiangsu Drug Administration valid till 20.09.2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.5kg rug substance attested on 22.03.2021 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Eliquid Tablet 2.5mg Batch No. ABR2431. pH 1.2: F2 83.2% pH 4.5: F2 85% pH 6.8: F2 88.8%
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
1.	Form 5D is not attached	Firm has submitted copy of Form 5D vide letter No. RA/264/24 dated 27.12.2024

Decision: Approved with Innovator Specifications. Registration Letter shall be issued after submission of fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.

69.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road,Karachi.
	Brand Name +Dosage Form + Strength	Xab 5mg tablets
	Composition	Each film coated tablet contains: Apixaban……..…..5 mg
	Diary No. Date of R& I & fee	Dy. No.221; 09-09-2014; Rs.20,000/- (04-09-2014) Fee of Rs. 10,000/- submitted vide slip No. 099261007896 dated 23.12.2022
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer‘s specifications
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	Eliquis (approved in USFDA)
	Me-too status	Not provided
	GMP status	Last GMP inspection conducted on 26-01-2017 and the report concludes that the firm is considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	□ Approved in USFDA with box warning □ Shortcomings: □ Application on form-5D with differential fee □ Complete stability studies data as per zone IV-A conditions
.	Decision of 274th RB	Deferred for submission of □ complete stability studies data as per zone IV-A conditions □ application on form 5D with differential fee

STABILITY STUDY DATA

Drug	Xab 5mg tablets
Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Louyang Town Wujin District Changzhou Jiangsu China
API Lot No.	ZSAP210201
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%

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)-176-01	21SB(A)-177-02	21SB(A)-178-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	09.08.2021	09.08.2021	09.08.2021
No. of Batches	03		
Date of Submission	Dy. No. 38207 dated 28.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. ZSAP210201
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML issued by Jiangsu Drug Administration valid till 20.09.2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.5kg rug substance attested on 22.03.2021 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Eliquid Tablet 5mg Batch No. ABR1639. pH 1.2: F2 66% pH 4.5: F2 76%

		pH 6.8: F2 78%
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
2.	Form 5D is not attached	Firm has submitted copy of Form 5D vide letter No. RA/264/24 dated 27.12.2024

Decision: Approved with Innovator Specifications. Registration Letter shall be issued after submission of fee of Rs. 9000/- as per SRO 1324(I)/2024 dated 30.08.2024 for preregistration variation.

70.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road,Karachi.
	Brand Name +Dosage Form + Strength	APRAST 10mg Tablet
	Composition	Each film coated tablet contains: Apremilast……..…..10 mg
	Diary No. Date of R& I & fee	From-5 Dy. No.3318 dated 19-05-2017 Rs. 50,000/- dated 18-05-2017 Stability dy. No. 27402 dated 27.09.2022
	Pharmacological Group	Selective immunosuppressants ATC Code: L04AA32
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	APREMILAST 10 MG 20 MG 30 MG FILM-COATED TABLETS MHRA Approved. Initiation pack Carton with PVC/Al foil blisters containing 27 tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg).
	Me-too status	Apezla 10mg 20 mg 30mg M/s Ferozsons
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	APRAST 10mg Tablet		
Manufacturer of API	M/s Ruyuan HEC Pharm Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City Guangdong China.		
API Lot No.	ZSAP210201		
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%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	21SB(A)-161-01	21SB(A)-162-02	21SB(A)-163-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	05.08.2021	05.08.2021	05.08.2021
No. of Batches	03		
Date of Submission	Dy. No. 27402 dated 27.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. S110B-RD202101201F1
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP issued by Shaoguan FDA valid till 04.12.2021 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.15kg drug substance attested on 15.03.2021 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Otezla Tablet 10mg Batch No. JBS01. pH 1.2: F2 71.7% pH 4.5: F2 more than 85% in 15 min pH 6.8: F2 more than 85% in 15 min
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
1.	Form 5D is not attached
2.	GMP certificate of drug product manufacturer is required.
3.	As per BMR pack size is mentioned as 1 x14's. Please give details of blister size and justify how it is in accordance with treatment plan or innovator product.
4.	Why batch number of reference product (JBS01) is same for all 3 strengths

Decision: Approved. The Registration Letter shall be issued as per pack size details decided in 321st meeting of Registration Board for Apremilast tablet product.

71.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road,Karachi.
	Brand Name +Dosage Form + Strength	APRAST 20mg Tablet
	Composition	Each film coated tablet contains: Apremilast……..…..20 mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 3316 dated 19-05-2017 Rs.50,000/- dated 19-05-2017 Stability dy. No. 27756 dated 30.09.2022
	Pharmacological Group	Selective immunosuppressants ATC Code: L04AA32
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	Not mentioned

	Approval status of product in Reference Regulator Authorities	APREMILAST 10 MG 20 MG 30 MG FILM-COATED TABLETS MHRA Approved. Initiation pack Carton with PVC/Al foil blisters containing 27 tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg).
	Me-too status	Apezla 10mg 20 mg 30mg M/s Ferozsons
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	APRAST 10mg Tablet		
Manufacturer of API	M/s Ruyuan HEC Pharm Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City Guangdong China.		
API Lot No.	ZSAP210201		
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%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	21SB(A)-164-01	21SB(A)-165-02	21SB(A)-166-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	05.08.2021	05.08.2021	05.08.2021
No. of Batches	03		
Date of Submission	Dy. No.27756 dated 30.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. S110B-RD202101201F1
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP issued by Shaoguan FDA valid till 04.12.2021 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.15kg drug substance attested on 15.03.2021 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Otezla Tablet 20mg Batch No. JBS01. pH 1.2: F2 67% pH 4.5: F2 more than 85% in 15 min pH 6.8: F2 more than 85% in 15 min
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
1.	Form 5D is not attached
2.	GMP certificate of drug product manufacturer is required.
3.	As per BMR pack size is mentioned as 1 x14's. Please give details of blister size and justify how it is in accordance with treatment plan or innovator product.
4.	Why batch number of reference product (JBS01) is same for all 3 strengths

Decision: Approved. The Registration Letter shall be issued as per pack size details decided in 321st meeting of Registration Board for Apremilast tablet product.

72.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road,Karachi.
	Brand Name +Dosage Form + Strength	APRAST 30mg Tablet

	Composition	Each film coated tablet contains: Apremilast……..…..30 mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 3315 dated 19-05-2017 Rs.50,000/- dated 18-05-2017 Stability dy. No. 28645 dated 10.10.2022
	Pharmacological Group	Selective immunosuppressants ATC Code: L04AA32
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	Not mentioned
	Approval status of product in Reference Regulator Authorities	APREMILAST 10 MG 20 MG 30 MG FILM-COATED TABLETS MHRA Approved. Initiation pack Carton with PVC/Al foil blisters containing 27 tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg).
	Me-too status	Apezla 10mg 20 mg 30mg M/s Ferozsons
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	APRAST 30mg Tablet		
Manufacturer of API	M/s Ruyuan HEC Pharm Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City Guangdong China.		
API Lot No.	ZSAP210201		
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%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	21SB(A)-164-01	21SB(A)-165-02	21SB(A)-166-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	05.08.2021	05.08.2021	05.08.2021
No. of Batches	03		
Date of Submission	Dy. No. 28645 dated 10.10.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. S110B-RD202101201F1
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP issued by Shaoguan FDA valid till 04.12.2021 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.15kg drug substance attested on 15.03.2021 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Otezla Tablet 30mg Batch No. JBS01. pH 1.2: F2 68% pH 4.5: F2 more than 85% in 15 min pH 6.8: F2 more than 85% in 15 min
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
1.	Form 5D is not attached
2.	GMP certificate of drug product manufacturer is required.
3.	Why batch number of reference product (JBS01) is same for all 3 strengths

Decision: Approved. The Registration Letter shall be issued as per pack size details decided in 321st meeting of Registration Board for Apremilast tablet product.

73.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	GVIAS-S 50mg/10mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin phosphate Monhydrate eq. to Sitagliptin……..…50mg Simvastatin……10mg
	Diary No. Date of R& I & fee	Dy. 262 dated 16.09.2014 Fee Rs. 50,000/- slip No. 0065444. Stability dy. No. 28645 dated 22.09.2022
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors A10BH51
	Type of Form	Form 5D
	Finished product Specifications	
	Pack size & Demanded Price	10's 20's 30's
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	GVIAS-S 50mg/10mg Tablet
Manufacturer of API	**Sitagliptin:** M/s Shangyu Jingxin Pharmaceutical Co. Ltd. No. 31 Wesan Road Hangzhou Bay, Shangyu Economic and Technological Development area China **Simvastatin:** M/s Fuxin Long Rui Pharmaceutical Co Ltd. Fluoride Industrial Park, Fuxin M/s Shangyu Jingxin Pharmaceutical Co. Ltd. No 31 Weisan Road Hangzhou Bay Shangyu Economic and Technological Development area China.
API Lot No.	**Sitagliptin:** L-GWC-20210921-D07-GWC **Simvastatin:** DK40-2004071
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%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	22SB(B)-378-01	22SB(B)-379-02	22SB(B)-380-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01.2022	01.2022	01.2022
Date of Initiation	07.02.2022	07.02.2022	07.02.2022
No. of Batches	03		
Date of Submission	Dy. No. 28645 dated 10.10.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Sitagliptin:** L-GWC-20210921-D07-GWC **Simvastatin:** DK40-2004071
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** **Simvastatin:** Copy of GMP issued by CFDA valid till 05.05..2024 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin:** Copy of invoice mentioning 350kg drug substance attested on 31.01.2022 is submitted. **Simvastatin:** Copy of AD attested invoice mentioning 2kg API, attested on 15.07.2020 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be supported by attested respective documents like	Submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
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
1.	Verifiable RRA reference is required. USFDA reference is discontinued.	Firm has submitted their response vide letter No. RA/265/24 dated 27.12.2024. Firm has submitted a reference of TGA Australia (ARTG No. 191482; 191478; 191481; 191476; 191474; 191477; 191475; 191479; and 191480. **The submitted evidence is not verifiable from TGA website.**
2.	Pharmaceutical equivalence and CDP is not performed	Firm has submitted Pharmaceutical equivalence and CDP against product Juvisync Batch No. P045523, performed in 2022.

Decision: Deferred for submission of evidence of approval of applied formulation by any of the refernce regulatory authorities adopted by registration Board in its 275th meeting, since the submitted reference was not verifiable.

74.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	GVIAS-S 100mg/20mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin phosphate Monhydrate eq. to Sitagliptin……..…100mg Simvastatin……20mg
	Diary No. Date of R& I & fee	Dy. 261 dated 16.09.2014 Fee Rs. 50,000/- slip No. 0065446. Stability dy. No. 28655 dated 22.09.2022
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors A10BH51
	Type of Form	Form 5D
	Finished product Specifications	
	Pack size & Demanded Price	10's 20's 30's
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	

	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		GVIAS-S 100mg/20mg Tablet		
Manufacturer of API		**Sitagliptin:** M/s Shangyu Jingxin Pharmaceutical Co. Ltd. No. 31 Wesan Road Hangzhou Bay, Shangyu Economic and Technological Development area China **Simvastatin:** M/s Fuxin Long Rui Pharmaceutical Co Ltd. Fluoride Industrial Park, Fuxin M/s Shangyu Jingxin Pharmaceutical Co. Ltd. No 31 Weisan Road Hangzhou Bay Shangyu Economic and Technological Development area China.		
API Lot No.		**Sitagliptin:** L-GWC-20210921-D07-GWC **Simvastatin:** DK40-2004071		
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%		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.		22SB(B)-381-01	22SB(B)-382-02	22SB(B)-383-03
Batch Size		1500 tablets	1500 tablets	1500 tablets
Manufacturing Date		01.2022	01.2022	01.2022
Date of Initiation		11.02.2022	11.02.2022	11.02.2022
No. of Batches		03		
Date of Submission		Dy. No. 28655 dated 10.10.2022		
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	NA		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Sitagliptin:** L-GWC-20210921-D07-GWC **Simvastatin:** DK40-2004071		
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 both 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.		

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** **Simvastatin:** Copy of GMP issued by CFDA valid till 05.05..2024 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin:** Copy of invoice mentioning 350kg drug substance attested on 31.01.2022 is submitted. **Simvastatin:** Copy of AD attested invoice mentioning 2kg API, attested on 15.07.2020 is submitted.
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 above mentioned 03 Batches:
11.	Record of comparative dissolution data (where applicable)	
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
3.	Verifiable RRA reference is required. USFDA reference is discontinued.	Firm has submitted their response vide letter No. RA/265/24 dated 27.12.2024. Firm has submitted a reference of TGA Australia (ARTG No. 191482; 191478; 191481; 191476; 191474; 191477; 191475; 191479; and 191480. **The submitted evidence is not verifiable from TGA website.**
4.	Pharmaceutical equivalence and CDP is not performed	Firm has submitted Pharmaceutical equivalence and CDP against product Juvisync 100mg/20mg Batch No. P045522, performed in 2022.

Decision: Deferred for submission of evidence of approval of applied formulation by any of tehrefernce regulatory authorities adpted by registration Board in its 275th meeting, since the submitted reference was not verifiable.

75.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.

	Brand Name +Dosage Form + Strength	Asinap 5mg Tablet
	Composition	Each Sublingual tablet Contains: Asenapine Maleate eq. to Asenapine…….5 mg
	Diary No. Date of R& I & fee	Dy. No 11973 dated 06-03-2019; Rs.50,000/- dated 06-03- 2019.
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
Decision of 321st RB: Deferred for submission of Stability study data as per guidelines provided in 293rd meeting of Registration Board.		
The firm had submitted CTD dossier of the same product vide Dy No. 22957 dated 19.09.2023. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
76.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Asinap 10mg Tablet
	Composition	Each Sublingual tablet Contains: Asenapine Maleate eq. to Asenapine…….10 mg
	Diary No. Date of R& I & fee	Dy. No 11974 dated 06-03-2019; Rs.50,000/- dated 06-03-2019.
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
Decision of 321st RB: Deferred for following **• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **• Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.** **• Form-5 Annexure as per prescribed format of Drug (L, R&A) rules 1976**		

The firm had submitted CTD dossier of the same product vide Dy No. 22958 dated 19.09.2023. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
77.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Fludip-M XR 5/1000 mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…5mg Metformin Hydrochloride…1000mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 31741 dated 24-09-2018 Rs.50,000/- dated 24-09-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
The firm had submitted CTD dossier of the same product vide Dy No. 24543 dated 09.10.2023 by name of Daglozin-M XR. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
78.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Fludip-M XR 10/1000 mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…10mg Metformin Hydrochloride…1000mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 31743 dated 24-09-2018 Rs.50,000/- dated 24-09-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

The firm had submitted CTD dossier of the same product vide Dy No. 23150 dated 20.09.2023 by name of Daglozin-M XR. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
79.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Fludip-M XR 10/1000 mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin……5mg Metformin Hydrochloride…500mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 31740 dated 24-09-2018 Rs.50,000/- dated 24-09-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
The firm had submitted CTD dossier of the same product vide Dy No. 24542 dated 09.10.2023 by name of Daglozin-M XR. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
80.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd., 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Fludip-M XR 10/1000 mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…10mg Metformin Hydrochloride…500mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 31742 dated 24-09-2018 Rs.50,000/- dated 24-09-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	20's,60's, As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

The firm had submitted CTD dossier of the same product vide Dy No. 23150 dated 20.09.2023 by name of Daglozin-M XR. It was considered and approved in 343rd meeting of the Registration board.		
Decision: The Board rejected the case, based on the fact that same formulation is already approved in the name of the applicant		
81.	Name and address of manufacturer / Applicant	M/s Helix Pharma (Pvt.) Ltd. Hakimsons House, A-56, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	COMBITO Ophthalmic Suspension 1% / 0.2%
	Composition	Each ml contains: Brinzolamide…10mg Brimonidine Tartrate…2mg
	Diary No. Date of R& I & fee	Form 5-D Diary No. 1422 dated 22/07/2013 Rs. 150,000/- As per PRC for 8 ml.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	The firm has claimed Manufacturer's Specifications.
	Pack size & Demanded Price	5ml, 8ml
	Approval status of product in Reference Regulator Authorities	SIMBRINZA by M/s Novartis Pharms Corp, USA.
	Me-too status	
	GMP status	GMP compliant dated 09-02-2016.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	<u>COMBITO Ophthalmic Suspension 1% / 0.2%</u> <u>(Brinzolamide + Brimonidine Tartrate)</u>		
Manufacturer of API	**<u>Brinzolamide USP Micronized:</u>** M/s Century Pharmaceuticals Ltd. India. Brimonidine Tartarate Ph. Eur: M/s Unichem Laboratories Ltd. India.		
API Lot No.	**<u>Brinzolamide USP Micronized:</u>** 07111004-BA **Brimonidine Tartarate Ph. Eur:** RBMTP60001		
Description of Pack (Container closure system)	5ml LDPE Bottle.		
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.	TF 001	TF 003	TF 003
Batch Size	01 Liter/ 181 bottles	01 Liter/ 181 bottles	01 Liter/ 181 bottles

Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	20-01-2017	20-01-2017	20-01-2017
No. of Batches	03		
Date of Submission	25-08-2017 (Dy. No. 13359) Submitted complete stability data upto 2 years vide Dy No. 9097 dt: 11.04.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Yes
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Century Pharmaceuticals Ltd. India: Copy of GMP Certificate issued by Food and Drug Control Administration, India is submitted. M/s Unichem Laboratories Ltd. India: Copy of GMP Certificate issued by Food and Drug Administration (Maharashtra) India is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Brinzolamide USP Micronized: ADC (Karachi) issued license to import API (Brinzolamide USP Micronized) from M/s Century Pharmaceuticals Ltd. India is submitted. Brimonidine Tartarate Ph. Eur: ADC (Karachi) issued license to import API (Brimonidine Tartarate Ph. Eur) from M/s Unichem Laboratories Ltd. India is submitted.
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.	Yes

11.	Record of comparative dissolution data (where applicable)	NA
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:

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

Decision of 274th RB: Registration Board decided to constitute the following panel for onsite investigation to confirm genuineness/ authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.

- Dr.Rafeeq Alam Khan, Meritorious Professor
- Director DTL Karachi
- Dr. Saif ur Rehman Khattak, FGA, CDL, Karachi.

Current application: Firm has stated that due to some reasons firm couldn't coordinate the inspection, now they are submitting stability data of same batches for the whole claimed shelf life that is 24 months.

Decision: Registration Board while considering the stability data, submitted as per requirements for Stability study data and exemption from onsite inspection checklist, approved in 293rd meeting of Registration Board, decided to approve the instant application.

82.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories (Pvt.) Ltd., 26 km Lahore-Sharikpur Road, Sheikhupura (Tablet general).
	Brand Name +Dosage Form + Strength	Mcbriet 534mg Tablets.
	Composition	Each Film Coated Tablet Contains: Pirfenidone ……..…534mg
	Diary No. Date of R& I & fee	Dy. No. 41658 dated 07-12-2018; Rs. 50,000/- 07-12-2018. Stability: 25568 dt. 08.09.2022
	Pharmacological Group	Immunosuppressants (L04)
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulator Authorities	Esbriet film coated tablets (534mg), TGA approved.
	Me-too status	Could not be confirmed/not provided
	GMP status	Could not be confirmed.

	Remarks of the Evaluator	□ Latest GMP certificate/Inspection report conducted within last three years could not be confirmed. □ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

Decision of 312th RB: Deferred for the following:
□ Latest GMP certificate/Inspection report conducted within last three years.
□ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Mcbriet 534mg Tablets.		
Manufacturer of API	M/s laurus Labs limited Plot No. 18, Jawaharlal Nehru Pharma City Parawada Visakhapatnam Nehru Pharma City Andhra Pradesh India.		
API Lot No.	APFDVSP30100521		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	MFT-PB-01	MFT-PB-02	MFT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	12.12.2021	12.12.2021	12.12.2021
No. of Batches	03		
Date of Submission	Dy. No. : 25568 dt. 08.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	
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
3.	Copy of GMP certificate of drug product manufacturer is required.
4.	Copy of GMP certificate of drug substance manufacturer is required.
5.	Pharmaceutical equivalence and CDP is not performed
6.	AD attested invoice is required.

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

83.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories (Pvt.) Ltd., 26 km Lahore-Sharikpur Road, Sheikhupura (Tablet general).
	Brand Name +Dosage Form + Strength	Mcbriet 267mg Tablets.
	Composition	Each Film Coated Tablet Contains: Pirfenidone ……..…267mg
	Diary No. Date of R& I & fee	Dy. No. 41656 dated 07-12-2018; Rs. 50,000/- 07-12-2018. Stability: 25568 dt. 08.09.2022
	Pharmacological Group	Immunosuppressants (L04)
	Type of Form	Form 5D.

	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulator Authorities	Esbriet film coated tablets (267mg), TGA approved.
	Me-too status	Could not be confirmed/not provided
	GMP status	Could not be confirmed.
	Remarks of the Evaluator	□ Latest GMP certificate/Inspection report conducted within last three years could not be confirmed. □ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

Decision of 312th RB: Deferred for the following:
□ Latest GMP certificate/Inspection report conducted within last three years.
□ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Mcbriet 267mg Tablets.		
Manufacturer of API	M/s laurus Labs limited Plot No. 18, Jawaharlal Nehru Pharma City Parawada Visakhapatnam Nehru Pharma City Andhra Pradesh India.		
API Lot No.	APFDVSP30100521		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	MTT-PB-01	MTT-PB-02	MTT-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	12.12.2021	12.12.2021	12.12.2021
No. of Batches	03		
Date of Submission	Dy. No. : 25566 dt. 08.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted

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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	
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
1.	Copy of GMP certificate of drug product manufacturer is required.
2.	Copy of GMP certificate of drug substance manufacturer is required.
3.	Pharmaceutical equivalence and CDP is not performed
4.	AD attested invoice is required.

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

84.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories (Pvt.) Ltd., 26 km Lahore-Sharikpur Road, Sheikhupura (Tablet general).
	Brand Name +Dosage Form + Strength	Mcbriet 801mg Tablets.

	Composition	Each Film Coated Tablet Contains: Pirfenidone ……..…801mg
	Diary No. Date of R& I & fee	Dy. No. 41659 dated 07-12-2018; Rs. 50,000/- 07-12-2018. Stability: 25507 dt. 08.09.2022
	Pharmacological Group	Immunosuppressants (L04)
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulator Authorities	Esbriet film coated tablets (801mg), TGA approved.
	Me-too status	Could not be confirmed/not provided
	GMP status	Could not be confirmed.
	Remarks of the Evaluator	□ Latest GMP certificate/Inspection report conducted within last three years could not be confirmed. □ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

Decision of 312th RB: Deferred for the following:
□ Latest GMP certificate/Inspection report conducted within last three years.
□ Stability studies data as per the guidelines approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Mcbriet 801mg Tablets.		
Manufacturer of API	M/s laurus Labs limited Plot No. 18, Jawaharlal Nehru Pharma City Parawada Visakhapatnam Nehru Pharma City Andhra Pradesh India.		
API Lot No.	APFDVSP30100521		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	MET-PB-01	MET-PB-02	MET-PB-03
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	12.2021	12.2021	12.2021
Date of Initiation	12.12.2021	12.12.2021	12.12.2021
No. of Batches	03		
Date of Submission	Dy. No. : 25566 dt. 08.09.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	
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
1.	Copy of GMP certificate of drug product manufacturer is required.
2.	Copy of GMP certificate of drug substance manufacturer is required.

3.	Pharmaceutical equivalence and CDP is not performed	
4.	AD attested invoice is required.	
Decision: Deferred for submission of reply to above cited shortcomings.		
85.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 5/500 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin…… 5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38729 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39304 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo-M XR 5/500 mg Tablet		
Manufacturer of API	**Dapagliflozin:** M/s. **Metformin HCl:** M/s		
API Lot No.	**Dapagliflozin:** D5290-22-005 **Metformin HCl:** MEF/11030557		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-019	TDM-020	TDM-021
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39304 dt. 29.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** **Metformin HCl:**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** **Metformin HCl:**
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
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

1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

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

86.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 10/500 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin…10mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38730 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39306 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo-M XR 10/500 mg Tablet
Manufacturer of API	**Dapagliflozin:** M/s. **Metformin HCl:** M/s
API Lot No.	**Dapagliflozin:** D5290-22-005 **Metformin HCl:** MEF/11030557
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%
Time Period	Real time: 9 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-022	TDM-023	TDM-024
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39306 dt. 29.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** **Metformin HCl:**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** **Metformin HCl:**
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
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
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

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

87.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 5/1000 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38731 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39305 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo-M XR 10/500 mg Tablet
Manufacturer of API	**Dapagliflozin:** M/s.

	Metformin HCl: M/s		
API Lot No.	**Dapagliflozin:** D5290-22-005 **Metformin HCl:** MEF/11030557		
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%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-025	TDM-026	TDM-027
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39305 dt. 29.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** **Metformin HCl:**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** **Metformin HCl:**
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	

9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
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
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

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

88.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 10/1000 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin…10mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38732 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39307 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Daplo-M XR 10/1000 mg Tablet		
Manufacturer of API	**Dapagliflozin:** M/s. **Metformin HCl:** M/s		
API Lot No.	**Dapagliflozin:** D5290-22-005 **Metformin HCl:** MEF/11030557		
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%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-028	TDM-029	TDM-030
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39305 dt. 29.12.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** **Metformin HCl:**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** **Metformin HCl:**
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
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
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

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

89.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	Nupreced 200mcg/2ml Injection

	Composition	Each 2ml ampoule contains:- Dexmedetomidine Hydrochloride….200mcg
	Diary No. Date of R& I & fee	Dy.No. 17-05-13 Fee Rs.60,000/-+ Rs. 90,000(28-05-13)
	Pharmacological Group	(Sedative) e alpha2-adrenergic agonist ATC Code: N05CM18
	Type of Form	Form 5D.
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	2ml ampoule, Rs. 5500/-
	Approval status of product in Reference Regulator Authorities	Precedex USFDA Approved.
	Me-too status	Fee submitted for NDP
	GMP status	Not submitted.
	Remarks of the Evaluator	**Previous Decision (M-239):** Deferred for confirmation of availability of formulation in FDA, EMA,Australia and Japan **(M-239)** **Previous Decision (M-241):** The request of firm was deferred for opinion of following experts. Head. Department of ICU, MH, Rawalpindi. Head. Department of Anesthesia, PIMS, Islamabad. Brig. Dr.Muhammad Aslam khan **Previous Decision (M-249):** The firm has the submitted that the third expert nominated by the Board is **Head of Department of ICU,Rawalpindi , is also Brig. Dr. Muhammad Aslam Khan** who has already provided expert opinion and both the experts has commented as under:-

Name of Expert	Comments
Prof. M. Iqbal Memon	1. Said drug is already in practice worldwide and few centers in Pakistan. 2. On page 14 there is typographical mistake showing that said firm not checked before submission on serial No. 1. It is not Lidocaine but Dexmedatomidine HCl as active ingredient. Calculation from gram to microgram may be revisited according to their statement of manufacturing step (25L to 206 litres). 3. Said firm has not mentioned about the country of import for raw material and how quality of that material will be maintained during transport to Pakistan. 4. Are they going to check the efficacy drug in animal lab?
Brig. Dr. Muhammad Aslam khan	Dexmedetomidine is a highly selective, centrally acting alpha- 2-agonist with anxiolytic, sedative, and some analgesic effects. It has no deleterious effects

	on respiratory drive. According to the approved product information from the United States Food and Drug Administration (FDA), dexmedetomidine is indicated for initial sedation of mechanically ventilated patients for up to 24 hours. Its indications include sedation of initially-intubated and medicinally-ventilated patients during treatment in an intensive care setting. Procedural sedation prior to and/ or during awake fiber optic intubation; sedation prior to and/ or during surgical or other procedures of non-intubated patients. Dexmedetomidine may be less likely to cause delirium, than sedative agents in the ICU. It will be a useful addition in the armamentarium of the intensivist unit and anesthetists. In view of the above I recommend this drug for registration at an affordable price

Registration Board discussed and agreed to above expert opinions. However, the Board advised firm to submit laboratory scale scientifically rational stability data for above registration application. **(M-249)**

Decision of 294th RB: Deferred for submission of submission of valid GMP certificate of API manufacturer issued by regulatory authority of country of origin.

Request by firm: Please refer to our already applied dossier namely Nupreced for Registration purpose. In this regard, we would like to inform you that the firm want to withdraw the previously submitted stability data of Nupreced Injection and we are also committed that firm will have resubmitted new stability data along with all required documents under 278th meeting of Registration board. We are humbly requested to kindly consider our request for withdraw previously submitted stability data in upcoming agenda.

Decision of 307th RB; Registration Board acceded firm's request and deferred for submission of stability data as per requirement decided in 293rd meeting.

STABILITY STUDY DATA

Drug	Nupreced 200MCG/2ML Injection		
Manufacturer of API	M/s Shandong Chenghui Shuangda Pharmaceutical Co. Ltd. Economic Development Zone, Pingyuan County Dezhou City Shandong China.		
API Lot No.	**21101203**		
Description of Pack (Container closure system)	Clear Glass Ampoule		
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.	DMAi T1-22	DMAi T2-22	DMAi T3-22
Batch Size	2000 Injection	2000 Injection	2000 Injection
Manufacturing Date	03.2022	03.2022	03.2022
Date of Initiation	25.03.2022	11.04.2022	11.04.2022
No. of Batches	03		
Date of Submission	Dy. No. 28765 dated 18.11.2022		

<table>
<tr><th colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</th></tr>
<tr><th>Sr. No.</th><th>Documents to Be Provided</th><th>Status</th></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>NA</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted.
21101203</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 both 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.</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>Submitted one is issued by association.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of AD attested invoice mentioning 5g drug substance, attested on 17.1.2022 is submitted. Batch No. D21101203</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>DMAi T1-22</td><td>2000 In</td><td>03.2022</td></tr>
<tr><td>DMAi T2-22</td><td>2000 In</td><td>03.2022</td></tr>
<tr><td>DMAi T3-22</td><td>2000 In</td><td>03.2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Pharmaceutical equivalence is performed against product Precedex 200mcg/2ml injection manufactured by Hospira USA</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>
</table>

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
13.	Copy OF GMP certificate/ DML of drug substance manufacture issued by relevant regulatory body is required.	Firm has submitted their response vide letter No. NP/5D-023 dated 28.12.2024. Copy of DML No. Lu20170365 issued by Shandong Drug Administration valid till 11.10.2027 is submitted.
14.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.

Decision: Approved.

90.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	GLIFO MET 5mg + 850mg Tablets
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin…….. 5mg Metformin hydrochloride……..850mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 13973 dated 07-03-2019 Rs.50,000/- dated 07-03-2019 slip No. 0844974. Stability Dy No. 12196 dated 19.05.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	XIGDUO 5 MG/850 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Dapa-Met 5/850 M/s Hilton
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	GILFO 5mg + 850mg Tablets
Manufacturer of API	**Dapagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam
API Lot No.	**Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/18122461

Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	DMAi T2-21	DMAi T3-21	DMAi T4-21
Batch Size	3000 tabs	3000 tabs	3000 tabs
Manufacturing Date	08.2021	08.2021	08.2021
Date of Initiation	17.08.2021	17.08.2021	17.08.2021
No. of Batches	03		
Date of Submission	Dy No. 12196 dated 19.05.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/19081515
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 both 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.
5.	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 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. **Metformin HCl:** Copy of GMP certificate issued by F&DCA Gujrat valid till 19.03.2023 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin**: AD attested invoice mentioning 0.85kg drug substance, attested on 11.03.2021 is submitted. Batch No. DG-20201201-D03-DG06-01

		Metformin HCl: Copy of AD attested invoice mentioning 50kg drug substance, attested on 01.03.2019 is submitted. Batch No. MEF/18122461
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 3 batches mentioned above.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Xigduo 5mg/850mg batch No. 2574A, manufactured by M/s Astra Zeneca. pH 1.2: F2 above 85% in 15min, -do- pH 4.5: F2 63%, 67 % pH 6.8: F2 above 85% in 15min, -do-
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
1.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.

Decision: Approved.

91.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	GILFO MET 5mg + 1000mg Tablets
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin…….. 5mg Metformin hydrochloride……..1000mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 13968 dated 07-03-2019 Rs.50,000/- dated 07-03-2019 vide slip No. 0844969.

		Stability Dy No. 12195 dated 19.05.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	XIGDUO 5 MG/1000 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Dapa-Met 5/1000 M/s Hilton
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	GILFO 5mg + 850mg Tablets		
Manufacturer of API	**Dapagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam		
API Lot No.	**Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/18122461		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	DMBi T2-21	DMBi T3-21	DMBi T4-21
Batch Size	3000 tabs	3000 tabs	3000 tabs
Manufacturing Date	08.2021	08.2021	08.2021
Date of Initiation	17.08.2021	17.08.2021	17.08.2021
No. of Batches	03		
Date of Submission	Dy No. 12195 dated 19.05.2022		

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	NA

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted. **Dapagliflozin Propanediol Monohydrate:** DG-20201201-D03-DG06-01 **Metformin HCl:** MEF/19081515
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 both 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.
5.	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 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. **Metformin HCl:** Copy of GMP certificate issued by F&DCA Gujrat valid till 19.03.2023 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin**: AD attested invoice mentioning 0.85kg drug substance, attested on 11.03.2021 is submitted. Batch No. DG-20201201-D03-DG06-01 **Metformin HCl:** Copy of AD attested invoice mentioning 50kg drug substance, attested on 01.03.2019 is submitted. Batch No. MEF/18122461
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 3 batches mentioned above.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Xigduo 5mg/1000mg batch No. X188A, manufactured by M/s Astra Zeneca. pH 1.2: F2 above 85% in 15min, -do- pH 4.5: F2 59%, 63 % pH 6.8: F2 above 85% in 15min, -do-
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
1.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.

Decision: Approved.

92.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	AZILSAN 40mg Tablet
	Composition	Each film coated tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan……..40mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 13969 dated 07-03-2019 Rs.50,000/- dated 07-03-2019 vide slip No. 0844970 Stability Dy No. 22944 dated 15.08.2022
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain C09CA09
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	EDARBI 40mg USFDA Approved.
	Me-too status	Azilaan Tablet M/s Horizon
	GMP status	Not submitted.
	Remarks of the Evaluator	Product present in stability list presented in 329th RB

STABILITY STUDY DATA

Drug	AZILSAN 40mg Tablet
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Block No. 251/ P252/P253 to 255 256 P258 P276 P277 28 P 279 to 282, 283 P284 P GIDC Gujrat India.
API Lot No.	20AK00001
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%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	AZAt T1-21	AZAt T2-21	AZAt T3-21
Batch Size	2500 tabs	2500 tabs	2500 tabs
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	19.10.2021	19.10.2021	19.10.2021
No. of Batches	03		
Date of Submission	Dy No. 12195 dated 19.05.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	20AK00001
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by F&DCA Gujrat valid till 29.05.2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice mentioning 0.5kg drug substance attested on 27.01.2020 is submitted.
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 3 batches mentioned above.

11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product EDARBI 40mg Tablet batch No. 11696408, manufactured by M/s Takeda pH 1.2: F2 97% pH 4.5: F2 96% pH 6.8: F2 99%
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
1.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.

Decision: Approved.

93.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	Rajumat 50/500mg XR tablets
	Composition	Each film coated tablet contains: Sitagliptin as phosphate monohydrate …. 50mg Metformin hydrochloride (Extended release) …….. 500mg
	Diary No. Date of R& I & fee	30-11-2010 (Duplicate dossier) Rs. 8,000/- (30-11-2010) Rs. 12,000/- (to be verified) Dy No. 18307 dated 23.06.2022 (Stability)
	Pharmacological Group	DPP4 inhibitor/Biguanide
	Type of Form	Form 5
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	14’s, 10’s,28’s & 30’s; as per SRO
	Approval status of product in Reference Regulator Authorities	Approved by USFDA
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084649)
	GMP status	Last GMP inspection report dated 18-07-2017 concluding that firm has maintained fair level of compliance.

	Remarks of the Evaluator	Submit stability studies as per directions of Registration Board, decided in its 278th meeting
.	Decision of 284th RB	Deferred for evidence of fee of Rs. 12,000/- & submission of stability studies data as per directions of 278th meeting of Registration Board.

STABILITY STUDY DATA			
Drug	Rajumat 50/500mg XR tablets		
Manufacturer of API	**Sitagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam		
API Lot No.	**Sitagliptin;** HM-20201223-D04-M06-03 **Metformin HCl:** MEF/18122461		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	SMAt T2-21	SMAt T3-21	SMAt T4-21
Batch Size	3000 tabs	3000 tabs	3000 tabs
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	16.09.2021	26.09.2021	30.09.2021
No. of Batches	03		
Date of Submission	Dy No. 18307 dated 23.06.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Sitagliptin;** HM-20201223-D04-M06-03 **Metformin HCl:** MEF/18122461
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 both 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.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** 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. **Metformin HCl:** Copy of GMP certificate issued by F&DCA Gujrat valid till 19.03.2023 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin**: AD attested invoice mentioning 230kg drug substance, attested on 11.03.2021 is submitted. Batch No. HM-20201223-D04-M06-03 **Metformin HCl:** Copy of AD attested invoice mentioning 50kg drug substance, attested on 01.03.2019 is submitted. Batch No. MEF/18122461
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 3 batches mentioned above.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product JANUMET 50/500 batch No. T020153 mfg by Merck Sharp & Dohme pH 1.2: F2 70%, 71% pH 4.5: F2 66%, more than 85% in 15 min pH 6.8: F2 more than 85% in 15 min, -do-
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

1.	Fee is not submitted as per previous decision of RB. Form 5D is also not submitted.	The firm has submitted their response vide letter No. NP/5D-026 dated 28.12.2024. New filled and signed Form 5D are submitted. **Evidence of fee is not submitted.**
2.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.
3.	The CDP is done against Non-extended release product and dissolution profile indicate that Metformin Core is not modified release, Whereas application is of XR product.	The firm has stated that it was a mistake writing XR in brand name. The application was intended for normal release film coated tablet. The firm has requested to consider their application as a normal formulation. **The new Form5D submitted still have XR in the brand name of product.**

Decision: Registration Board on the basis of submitted drug product stability data approved the instant application as per following label claim:

"Each film coated tablet contains:
Sitagliptin as phosphate monohydrate …. 50mg
Metformin hydrochloride …….. 500mg"

Registration Letter shall be issued upon submission of following:

- **Fee of Rs. /- 37,000 for pre-registration variations of label claim as per SRO1324 (I)/2024 dated 30-08-2024.**
- **Original receipt of submission of fee of Rs. 12,000/- within 6 months of publication of minutes of instant meeting on DRAP website.**

94.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	Rajumat 50/1000mg XR tablets
	Composition	Each film coated tablet contains: Sitagliptin as phosphate monohydrate …. 50mg Metformin hydrochloride (Extended release) …….. 1000mg
	Diary No. Date of R& I & fee	30-11-2010 (Duplicate dossier) Rs. 8,000/- (30-11-2010) Rs. 12,000/- (to be verified) Dy No. 18306 dated 23.06.2022 (Stability)
	Pharmacological Group	DPP4 inhibitor/Biguanide
	Type of Form	Form 5
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	14's, 10's,28's & 30's; as per SRO
	Approval status of product in Reference Regulator Authorities	Approved by USFDA
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084649)
	GMP status	Last GMP inspection report dated 18-07-2017 concluding that firm has maintained fair level of compliance.

	Remarks of the Evaluator	Submit stability studies as per directions of Registration Board, decided in its 278th meeting
.	Decision of 284th RB	**Deferred for evidence of fee of Rs. 12,000/- & submission of stability studies data as per directions of 278th meeting of Registration Board.**

STABILITY STUDY DATA

Drug	Rajumat 50/500mg XR tablets		
Manufacturer of API	**Sitagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam		
API Lot No.	**Sitagliptin;** HM-20201223-D04-M06-03 **Metformin HCl:** MEF/18122461		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	SMBt T1-21	SMBt T2-21	SMBt T3-21
Batch Size	3000 tabs	3000 tabs	3000 tabs
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	20.09.2021	20.09.2021	20.09.2021
No. of Batches	03		
Date of Submission	Dy No. 18306 dated 23.06.2022		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Sitagliptin;** HM-20201223-D04-M06-03 **Metformin HCl:** MEF/18122461
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 both 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.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** 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. **Metformin HCl:** Copy of GMP certificate issued by F&DCA Gujrat valid till 19.03.2023 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin**: AD attested invoice mentioning 230kg drug substance, attested on 11.03.2021 is submitted. Batch No. HM-20201223-D04-M06-03 **Metformin HCl:** Copy of AD attested invoice mentioning 50kg drug substance, attested on 01.03.2019 is submitted. Batch No. MEF/18122461
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 3 batches mentioned above.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product JANUMET 50/1000 batch No. T030594 mfg by Merck Sharp & Dohme pH 1.2: F2 72%, 70% pH 4.5: F2 58%, more than 85% in 15 min pH 6.8: F2 more than 85% in 15 min, -do-
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

1.	Fee is not submitted as per previous decision of RB. Form 5D is also not submitted.	The firm has submitted their response vide letter No. NP/5D-026 dated 28.12.2024. New filled and signed Form 5D are submitted. **Evidence of fee is not submitted.**
2.	Copy of GMP certificate of drug product manufacturer is required.	Copy of GMP certificate valid till 13.04.2025 is submitted.
3.	The CDP is done against Non-extended release product and dissolution profile indicate that Metformin Core is not modified release, Whereas application is of XR product.	The firm has stated that it was a mistake writing XR in brand name. The application was intended for normal release film coated tablet. The firm has requested to consider their application as a normal formulation. **The new Form5D submitted still have XR in the brand name of product.**

Decision: Registration Board on the basis of submitted drug product stability data approved the instant application as per following label claim:

"Each film coated tablet contains:
Sitagliptin as phosphate monohydrate …. 50mg
Metformin hydrochloride …….. 1000mg"

Registration Letter shall be issued upon submission of following:

- **Fee of Rs. /- 37,000 for pre-registration variations of label claim as per SRO1324 (I)/2024 dated 30-08-2024.**
- **Original receipt of submission of fee of Rs. 12,000/- within 6 months of publication of minutes of instant meeting on DRAP website.**

95.	Name and address of manufacturer / Applicant	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
	Brand Name +Dosage Form + Strength	Carbiz 200mg Tablets
	Composition	Each Tablet Contains: Eslicarbazepine Acetate…200mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 13422 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Carboxamide derivatives ATC Code: N03AF04
	Type of Form	Form 5D
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulator Authorities	Eslicarbazepine Ascend 200 mg tablets MHRA Approved.
	Me-too status	
	GMP status	Last GMP inspection report dated 18-07-2017 concluding that firm has maintained fair level of compliance.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Carbiz 200mg Tablets

Manufacturer of API	M/s CTX LIFESCIENCES PVT. LTD Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA		
API Lot No.	20EP00001		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	EAA T2-22	EAA T3-22	EAA T4-22
Batch Size	100,000 tabs	100,000 tabs	100,000 tabs
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	19.07.2021	19.07.2021	19.07.2021
No. of Batches	03		
Date of Submission	27-02-2023		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	SUBMITTED 20EP00001
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by F&DCA Gujrat valid till 21.01.2024 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of AD attested invoice mentioning 1kg drug substance, attested on 27.01.2020 is submitted.
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 3 batches mentioned above.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Aptiom 200mg Tablet batch No. 47261 mfg by Suovion Pharmaceuticals Inc. pH 1.2: F2 81% pH 4.5: F2 more than 85% in 15 min pH 6.8: F2 82%
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:		
Decision: Approved.		
96.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceutical (Pvt.) Ltd. 28-KM Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	AXHERT/AXBET XR 50mg/500mg Tablets
	Composition	Each film coated extended release tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin……50mg Metformin HCl(Extended release)……500mg
	Diary No. Date of R& I & fee	Form-5D dated 04.11.2016 Rs.50,000/- dated 03.11.2016 Stability: 11116 dt. 09.05.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD07
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Approved by USFDA
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084649)
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	AXHERT XR 50mg/500mg Tablets		
Manufacturer of API	**Sitagliptin:** M/s Zhejiang Yentai Pharmaceutical Co. Ltd. No.1 Donghai 4th Avenue Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City Zhejiang China. **Metformin HCl:** M/s AARTI Drugs Ltd. Plot No. 211 & 213 GIDC Sarigam Valsad Gujrat India.		
API Lot No.	**Sitagliptin:** 1827-0001-20090 **Metformin HCl:** MEF/19123234		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RD/PR20-005/T1/S1	RD/PR20-005/T1/S2	RD/PR20-005/T1/S3
Batch Size	2000 tabs	2000 tabs	2000 tabs
Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	09.04.2021	09.04.2021	09.04.2021
No. of Batches	03		
Date of Submission	Dy. No. : 11116 dt. 09.05.2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sitagliptin:** . **Metformin HCl:** Copy of GMP certificate issued by F&DCA Gujrat valid till 19.03.2023 is submitted.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sitagliptin**: AD attested invoice mentioning 25kg drug substance, attested on 17.12.2020 is submitted. **Metformin HCl:** Copy of AD attested invoice mentioning 1500kg drug substance, attested on 08.01.2020 is submitted.
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Tagipmet XR 50/500 Batch No. 213093 mfg by M/s Highnoon. Dissolution profile is comparable at all 3 pH values.
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
1.	Copy of GMP certificate of drug product manufacturer is required.	The firm has submitted their response vide letter No. NMP/DRAP/EX01/2024 dated 26.12.2024. Copy of GMP certificate valid till 06.11.2026 is submitted.
2.	Copy of DML of manufacturer of Sitagliptin is required.	Copy of DML valid till 31.05.2027 issued by Zhejiang Medical Products Administration is submitted.

Decision: Approved.

97.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Trapeze Plus XR Tablets 100mg/1000mg
	Composition	Each extended release tablet contains: Sitagliptin as phosphate monohydrate……100mg Metformin HCl……..1000mg
	Diary No. Date of R& I & fee	Dy.No 42026 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic

	Type of Form	Form 5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	7"s, 2x 7"s, 1x 10"s & 10x 6"s & as per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Tagipmet XR 100/1000 Tablet Highnoon Laboratories Limited, 17.5 km Multan Road, Lahore 084651
	GMP status	17-10-2018 the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial. Stability data is required for this applied molecule.

Decision of 295th RB: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.

STABILITY STUDY DATA

Drug	Trapeze Plus XR Tablets 100mg/1000mg		
Manufacturer of API	Metformin: Sitagliptin:		
API Lot No.	**Metformin:** **Sitagliptin:**		
Description of Pack (Container closure system)	LDPE Bottle.		
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.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01.2022	01.2022	01.2022
Date of Initiation	02.02.2022	02.02.2022	02.02.2022
No. of Batches	03		
Date of Submission	25-08-2017 (Dy. No. 13359) Submitted complete stability data upto 2 years vide Dy No. 9097 dt: 11.04.2022		

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	NA

2.	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	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	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Metformin: Sitagliptin:
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Metformin: Sitagliptin:.
7.	Protocols followed for conduction of stability study	
8.	Method used for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation:

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.

7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.
10.	Record of comparative dissolution data is required.

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

98.	Name and address of manufacturer / Applicant	M/s S.J. & G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E Karachi.
	Brand Name +Dosage Form + Strength	Ates-P 200mg/500mg tablet
	Composition	Each film coated tablet contains: Ibuprofen…….200mg Paracetamol……..…500mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 19301 dated 27-10-2017 Rs.50,000/- dated 27-10-2017 Stability: 8789 dt. 30.03.2023
	Pharmacological Group	Paracetamol, combinations excl. psycholeptics ATC Code: N02BE51
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	IBUPROFEN/PARACETAMOL 200/500 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	PROVAS DUO M/s Sami
	GMP status	Copy of GMP certificate valid till 28.05.2025 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ates-P 200mg/500mg tablet		
Manufacturer of API	**Ibuprofen:** M/s Hubei Biocause Heilen Pharmaceutical Co. Ltd. 122 Yangwan Road Jingmen Hubei China. **Paracetamol:** M/s Pharmagen Limited Pakistan		
API Lot No.	**Ibuprofen:** C100-2004161M **Paracetamol:** 00510911/002/2021		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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.	ATE 200 500 TBDS 007	ATE 200 500 TBDS 008	ATE 200 500 TBDS 009

Batch Size	450 tablets	450 tablets	450 tablets
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	14.10.2022	14.10.2022	14.10.2022
No. of Batches	03		
Date of Submission	Dy. No. : 8789 dt. 30.03.2023		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** Copy of GMP certificate issued by DRAP Lahore is submitted. **Ibuprofen:** Written confirmation for export to Europe issued by Hubei Medical Products Administration valid till 27.08.2023
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Local purchase **Ibuprofen:** AD attested invoice of 4kg API is submitted.
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Nuromol 200mg/500mg Tablets Batch No. JW942 Mfg Reckitt Benckiser UK.

		Dissolution profile is comparable at all 3 pH values.
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:		
Decision: Approved.		

99.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceutical (Pvt.) ltd. Plot No. 129, Sundar Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	SOFOS 400mg Tablet
	Composition	Each film coated tablet contains Sofosbuvir……400 mg
	Diary No. Date of R& I & fee	Dy. _____ dt. ____ fee Rs. _____ Application is mentioned in list presented before the Board in its 329th meeting. Stability: 8857 dt. 18.03.2021
	Pharmacological Group	(Nucleotide Analog NS5B Polymerase Inhibitor)
	Type of Form	Form 5D.
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	10's
	Approval status of product in Reference Regulator Authorities	SOVALDI 400MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Sovaldi 400mg
	GMP status	Copy of GMP certificate valid till 02.04.2026 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	SOFOS 400mg Tablet
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co. Ltd. Tonghai Si Road, Yangkou Chemical industrial park, Rudong Coastal economic development zone Nantong Jiangsu China.
API Lot No.	
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TSF001	TSF002	TSF003
Batch Size	2000 tabs	2000 tabs	2000 tabs
Manufacturing Date	04.2020	04.2020	04.2020
Date of Initiation	20.07.2020	20.07.2020	20.07.2020
No. of Batches	03		
Date of Submission	Dy. No. : 88157 dt. 18.03.2021		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not 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	Not Submitted
5.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of AD attested invoice mentioning 6kg Sofosbuvir is submitted. Attested on 08.01.19
6.	Protocols followed for conduction of stability study	Submitted
7.	Method used for analysis of FPP	Submitted
8.	Drug-excipients compatibility studies (where applicable)	Submitted
9.	Complete batch manufacturing record of three stability batches.	Submitted
10.	Record of comparative dissolution data (where applicable)	CDP is performed against product Sovaldi 400mg Batch No. VVDFD, CDP is comparable at all 3 pH values.
11.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

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

Remarks of Evaluator:

Sr. No.	Observation
1.	Evidence of initial submission and fee submission is required.
2.	COA of drug substance from both drug product and substance manufacturer is required.
3.	Differential fee is required along with revision of label claim as per innovator product.
4.	Detailed testing method of finished drug product is required.
5.	Stability study data of API from API manufacturer

Decision: Deferred for submission of reply to above cited shortcomings along with the evidence of submission of Form 5D dossier.

100.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceutical (Pvt.) ltd. Plot No. 129, Sundar Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	MAXVIR 100mg/400mg Tablet
	Composition	Each film coated tablet contains Sofosbuvir……400 mg Velpatasvir ….100mg
	Diary No. Date of R& I & fee	Dy. _____ dt. ____ fee Rs. _____ Application is mentioned in list presented before the Board in its 329th meeting Stability: 88158 dt. 18.03.2021
	Pharmacological Group	(Nucleotide Analog NS5B Polymerase Inhibitor)
	Type of Form	Form 5D.
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	10's
	Approval status of product in Reference Regulator Authorities	EPCLUSA 400 MG / 100 MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	MAXVIR 100mg/400mg Tablet
Manufacturer of API	Sofosbuvir & Velpartasvir: M/s Nantong Chanyoo Pharmatech Co. Ltd. No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong coastal economic development zone Nantong Jiangsu China.
API Lot No.	
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH

	Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TVP001	TVP002	TVP003
Batch Size	1600 tabs	1600 tabs	1600 tabs
Manufacturing Date	06.2020	06.2020	06.2020
Date of Initiation	11.07.2020	11.07.2020	11.07.2020
No. of Batches	03		
Date of Submission	Dy. No. : 88158 dt. 18.03.2021		

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	NA
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not 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	Not Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of AD attested invoice mentioning 6kg Sofosbuvir & 1kg Velpatasvir Copovidone is submitted. Attested on 08.01.19
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product EPCLUSA 400mg/100mg Tablet Batch No. CBZKTD. CDP is comparable with reference product.
12.	Data of 03 batches will be supported by attested respective documents like	Submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
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
1.	Evidence of initial submission and fee submission is required.
2.	Copies of BMR of trial batches are required
3.	Differential fee is required.
4.	Label claim needs revision as per innovator product.
5.	COA of both drug substances from both drug product and substance manufacturer is required.
6.	Stability study data of API from API manufacturer

Decision: Deferred for submission of reply to above cited shortcomings along with the evidence of submission of Form 5D dossier.

101.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No.122, Block A, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	WINOVIR Tablet 400 mg
	Composition	Each film coated tablet contains Sofosbuvir……400 mg
	Diary No. Date of R& I & fee	15-07-2014 Rs 50,000/- Rs 85,000/ Stability: 25824 dt. 13.09.2022
	Pharmacological Group	(Nucleotide Analog NS5B Polymerase Inhibitor)
	Type of Form	Form 5D.
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	10’s
	Approval status of product in Reference Regulator Authorities	SOVALDI 400MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Sovaldi 400mg
	GMP status	Copy of GMP certificate valid till 26.09.2020 is submitted
	Remarks of the Evaluator	

Decision of 253rd RB: Board decided to defer all the cases till provision of scientifically rationale lab scale stability data in accordance with the guidelines approved by the Board in 251st meeting.

STABILITY STUDY DATA

Drug	WINOVIR Tablet 400 mg		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co. Ltd. No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong coastal economic development zone Nantong Jiangsu China.		
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	SF-01	SF-02	SF-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	09.2021	09.2021	09.2021
Date of Initiation	18.09.2021	18.09.2021	18.09.2021
No. of Batches	03		
Date of Submission	Dy. No. : 8789 dt. 30.03.2023		

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	NA
2.	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	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 both 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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice mentioning 1.8kg Sofosbuvir Form VI is submitted.
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.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has performed CDP against product Nuromol 200mg/500mg Tablets Batch No. JW942 Mfg Reckitt Benckiser UK. Dissolution profile is comparable at all 3 pH values.
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
1.	Justify use of polymorphic Form VI in manufacturing of trial batches.	The firm has submitted their response vide letter No. nil dated 26.12.2024. The firm has submitted monograph of International Pharmacopoeia wherein its mentioned that Sofosbuvir does exhibit polymorphism.
2.	COA of drug substance by drug substance manufacturer and drug product manufacturer is required.	COA of batch No. 1911002 is submitted.
3.	Pharmaceutical equivalence and CDP is not performed	Firm has submitted pharmaceutical equivalence against Sofiget 400mg tablet manufactured by M/s Getz pharma batch No. 401F86, mfg 12.2021. At all 3 pH values, release profile is comparable.

Decision: Approve with International Pharmacopoeia Specifications (Ph.Int.). Registration Letter shall be issued after submission of fee of Rs. 9000/- for preregistration variation as per SRO1324 (I)/2024 dated 30-08-2024.

Agenda of Mr. Shahid Nawaz

102.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi (Liquid/Oral hygiene (Mouth wash) semi solid & Tooth paste).

	Brand Name +Dosage Form + Strength	Baclo Syrup 5mg/5ml.
	Composition	Each ml Contains: Baclofen ……..…5mg
	Diary No. Date of R& I & fee	Dy. No. 12975 dated 05-03-2019; Rs.20,000/- 05-03-2019.
	Pharmacological Group	Muscle relaxant, centrally acting agent.
	Type of Form	Form-5.
	Finished product Specifications	Innovator's specifications.
	Pack size & Demanded Price	60ml, 90ml, 120ml & As per SRO.
	Approval status of product in Reference Regulator Authorities	Lioresal® liquid contains 5mg/5ml baclofen, MHRA approved.
	Me-too status	Could not be confirmed.
	GMP status	Same as above.
	Remarks of the Evaluator	Evidence of approval of applied formulation/me too already registered by DRAP with brand name, Reg. No. and name of the firm.
	Decision of 307th meeting of Registration Board.	Deferred for Evidence of approval of applied formulation/me too already registered by DRAP with brand name, Reg. No. and name of the firm.

STABILITY STUDY DATA

Drug	Baclo Syrup 5mg/5ml.		
Manufacturer of API	M/s Reine Lifesciences, Plot No. 5901, GIDC Estate, Ankleshwar, District-Bharuch, Gujrat, India.		
API Lot No.	Baclofen: BLF19001.		
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%		
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.	TF-03	TF-04	TF-05
Batch Size	1 litre (14 bottles).	1 litre (14 bottles).	1 litre (14 bottles).
Manufacturing Date	10-2019	11-2019	11-2019
Date of Initiation	11.2019	11.2019	11.2019
No. of Batches	03		
Date of Submission	Dy. No. 266 dated 04-01-2022.		

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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR Compliant. ii. Firm has demonstrated Audit trail reports of testing.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. BLF19001, Mfg. date 01-2019) of the drug substance (Baclofen) from M/s Reine Lifesciences, India. Firm has also submitted COA from the drug product manufacturer with same batch Number and manufacturing date etc.
17.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Only from drug product manufacturer is submitted.
18.	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 18 months.
19.	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/1705115 issued to M/s Reine Lifesciences, India issued by F&DCA Gujrat State India valid from 29-05-2017 to 28-05-2019.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of FedEx document with ship date of 24-01-2019 mentioning Baclofen free sample without commercial value only for testing purpose. However, no clearance certificate is provided by the firm for import with approval from DRAP.
21.	Protocols followed for conduction of stability study	Submitted.
22.	Method used for analysis of FPP	Submitted.
23.	Drug-excipients compatibility studies (where applicable)	Not submitted.
24.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of 03 Batches:
25.	Record of comparative dissolution data (where applicable)	Not applicable.
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

28.	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
5.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of FedEx document with ship date of 24-01-2019 mentioning Baclofen free sample without commercial value only for testing purpose.
6.	valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of GMP certificate No. S-GMP & GLP/21062628 issued to M/s Reine Lifesciences, India issued by F&DCA Gujrat State India valid from 25-06-2023 to 24-06-2025.
7.	COAs of the finished product has mentioned assay of Ibuprofen. Clarification shall be submitted,	Firm has submitted that they mistakenly mentioned Ibuprofen on COA. They also submitted corrected COA.
8.	Method used for analysis of API from API Manufacturer shall be submitted.	Submitted.
9.	Stability study data of drug substance at accelerated condition shall be submitted.	Submitted.
10.	• Justification for not performing general test of oral liquid dosage forms mentioned in BP general monographs i.e. pH, deliverable volume etc. • Justification shall be submitted for using different assay parameters in the assay test from that of the BP monograph. i.e. injection volume, Flow rate, wavelength etc. • Justify the batch size with respect to the stability studies till claimed shelf life.	Firm has submitted that they have performed these tests at the time of analysis but not added in the COA of the finished product. Now they submitted revised COAs with inclusion of these tests. Firm has submitted that they followed USP monograph for finished product. Firm has submitted that 1 litre trial batch was produced, each bottle containing 50ml of the solution, resulting in approximately 20 bottles. 12 bottles were placed in chamber for real time stability testing and 07 were allocated in accelerated stability testing chamber. According to ICH guidelines, approximately six bottles are needed for real time testing and two for accelerated testing per testing interval. Therefore, the number of bottles placed in the chamber is sufficient for require testing.

Decision: Approved with BP specifications.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

103.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Revonap 375/20mg Tablet.

	Composition	Each Modified Release Tablet contains: Naproxen ……375mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Diary No. Date of R& I & fee	From-5 Dy. No. 1751 dated 02-12-2016 Rs. 50,000/- dated: 01-12-2016 (From PEC list. Form 5D in duplicate submitted.)
	Pharmacological Group	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Type of Form	Form-5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	TGA approved.
	Me-too status	N/A.
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.

STABILITY STUDY DATA

Drug	Revonap 375/20mg Tablet.		
Manufacturer of API	Esomeprazole Magnesium: M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India. Naproxen: M/s Divi's Laboratories Limited, Unit-I, Lingujigudem Village, Choutupal Mandal, Nalgonda district, Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Peach colour, round, biconvex tablet plain on both sides.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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.	TF-02	TF-03	TF-04
Batch Size	1000 tablets.	1000 tablets.	1000 tablets.
Manufacturing Date	25-04-2017	04-05-2017	04-05-2017
Date of Initiation	15-05-2017	15-05-2017	15-05-2017
No. of Batches	03		

Date of Submission	Dy. No. 37998 dated 27-12-2022.	
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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR Compliant. ii. 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 (Batch No. ESM/1604139, Mfg. date 01-2017 for Esomeprazole and COA (B. No. M-1601117, Mfg. date 10-2016) for Naproxen respectively) of both the drug substances from respective manufacturers is submitted. COAs from drug product manufacturer with same batch number is also 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	Firm has submitted stability studies of both the drug substances from drug substance manufacturers at zone Iva condition.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Esomeprazole Magnesium: Firm has submitted copy of certificate No. 60625/TS/2021 dated 27-10-2016 in the name of M/s Metrochem API Private Limited Unit-I, issued by DCA, Telangana valid till 26-10-2017. Naproxen: Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of mutual agreement between M/s kaizan pharma and m/s Platinum pharma wherein they agreed to provide raw material (active & in-actives) to each other only for research and development purpose upon request. Naproxen: Firm has submitted copy of commercial invoice No. 5117500752 dated 30-11-2016 mentioning 1000kg of Naproxen, B. No. M-1601117 from M/s Divi's laboratories limited India to M/s Platinum pharma. Esomeprazole Magnesium: Firm has submitted copy of commercial invoice No. AE017 dated 30-04-2016 mentioning 10kgs of Esomeprazole Magnesium, B. No. ESM/1604139. However, neither of the invoice is attested by DRAP.
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 submitted that they follow the qualitative composition of innovator product.
10.	Complete batch manufacturing record of three stability batches.	Complete record for following three batches is submitted; TF-02, TF-03 & TF-04.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against Vimivo tablets of Astrazenica. However, results are not in tabulated form nor any F2 values are submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 5117500752 dated 30-11-2016 mentioning 1000kg of Naproxen, B. No. M-1601117 from M/s Divi's laboratories limited India to M/s Platinum pharma. Esomeprazole Magnesium: Firm has submitted copy of commercial invoice No. AE017 dated 30-04-2016 mentioning 10kgs of Esomeprazole Magnesium, B. No. ESM/1604139. However, neither of the invoice is attested by DRAP. Firm has also submitted copy of airway bills and form 3 and form 7.
2.	Record of comparative dissolution data (where applicable) in tabulated form with values of F2 shall be submitted.	Firm has submitted CDP studies against the innovator product i.e. Vimovo Tablets manufactured by M/s AstraZeneca.
3.	valid DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of GMP certificate valid till 26-10-2023.

Decision: Approved. Registration letter will be issued after submission of valid copy of GMP certificate of the drug substance manufacturer (Metrochem API Pvt. Ltd., Unit-I) issued by relevant/concerned regulatory authority.

104.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Revonap 500/20mg Tablet.
	Composition	Each Modified Release Tablet contains: Naproxen ……500mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Diary No. Date of R& I & fee	From-5 Dy. No. 1752 dated 02-12-2016. Rs. 50,000/- dated: 01-12-2016. (From PEC list. Form 5D duplicate copy submitted)
	Pharmacological Group	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Type of Form	Form-5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	TGA approved.
	Me-too status	N/A.
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.

STABILITY STUDY DATA

Drug	Revonap 500/20mg Tablet.		
Manufacturer of API	Esomeprazole Magnesium: M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India. Naproxen: M/s Divi's Laboratories Limited, Unit-I, Lingujigudem Village, Choutupal Mandal, Nalgonda district, Telangana State, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Peach colour, round, biconvex tablet plain on both sides.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
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.	TF-07	TF-08	TF-07
Batch Size	3000 tablets.	3000 tablets.	3000 tablets.

Manufacturing Date	25-09-2020	07-10-2020	07-10-2020
Date of Initiation	06-10-2020	16-10-2020	16-10-2020
No. of Batches	03		
Date of Submission	Dy. No. 37999 dated 27-12-2022.		

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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR Compliant. ii. 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 (Batch No. ESM/1604139, Mfg. date 01-2017 for Esomeprazole and COA (B. No. M-1601117, Mfg. date 10-2016) for Naproxen respectively of both the drug substances from respective manufacturers is submitted. COAs from drug product manufacturer with same batch numbers are also 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	Firm has submitted stability studies of both the drug substances from drug substance manufacturers at zone Iva condition.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Esomeprazole Magnesium: Firm has submitted copy of certificate No. 60625/TS/2021 dated 27-10-2016 in the name of M/s Metrochem API Private Limited Unit-I, issued by DCA, Telangana valid till 26-10-2017. Naproxen: Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of mutual agreement between M/s kaizan pharma and m/s Platinum pharma wherein they agreed to provide raw material (active & in-actives) to each other only for research and development purpose upon request. Naproxen: Firm has submitted copy of commercial invoice No. 5117500752 dated 30-11-2016 mentioning 1000kg of Naproxen, B. No. M-1601117 from M/s Divi's laboratories limited India to M/s Platinum pharma. Esomeprazole Magnesium:

		Firm has submitted copy of commercial invoice No. AE017 dated 30-04-2016 mentioning 10kgs of Esomeprazole Magnesium, B. No. ESM/1604139.
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 submitted that they follow the qualitative composition of innovator product.
10.	Complete batch manufacturing record of three stability batches.	Complete record for following three batches is submitted; TF-07, TF-08 & TF-09.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against Vimivo tablets500/20 of Astrazenica. However, results are not in tabulated form nor any F2 values are submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 5117500752 dated 30-11-2016 mentioning 1000kg of Naproxen, B. No. M-1601117 from M/s Divi's laboratories limited India to M/s Platinum pharma. Esomeprazole Magnesium: Firm has submitted copy of commercial invoice No. AE017 dated 30-04-2016 mentioning 10kgs of Esomeprazole Magnesium, B. No. ESM/1604139. However, neither of the invoice is attested by DRAP. Firm has also submitted copy of airway bills and form 3 and form 7.
2.	Record of comparative dissolution data (where applicable) in tabulated form with values of F2 shall be submitted.	Firm has submitted CDP studies against the innovator product i.e. Vimovo Tablets manufactured by M/s AstraZeneca.
3.	valid DML/GMP certificate of API manufacturer issued by concerned	Firm has submitted copy of GMP certificate valid till 26-10-2023.

	regulatory authority of country of origin shall be submitted.	

Decision: Approved. Registration letter will be issued after submission of valid copy of GMP certificate of the drug substance manufacturer (Metrochem API Pvt. Ltd., Unit-I) issued by relevant/concerned regulatory authority.

105.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Ranalaz 375mg Tablet.
	Composition	Each Film Coated Tablet Contains: Ranolazine ……375mg
	Diary No. Date of R& I & fee	Dy. No. 16868: 07-03-2019. PKR 20,000/-: 05-03-2019.
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form-5.
	Finished product Specifications	BP specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA Approved (as prolonged release tablet)
	Me-too status	Could not be confirmed.
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Remarks of the Evaluator	• Revise your formulation as per the reference product along with submission of full fee of registration. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 329th meeting of Registration Board.	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.

STABILITY STUDY DATA

Drug	Ranalaz 375mg Tablet.
Manufacturer of API	M/s Trichem Life Sciences Limited, Plot No. 106(B) & 107, Humnabad Industrial Area, Gadwanthi Village, Humnabad Taluka, Dist. Karnataka, India.
API Lot No.	RNZL/20180929. RNZL/20180718.

Description of Pack (Container closure system)	Alu-PVC (Opaque).		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 tablets.	1000 tablets.	1000 tablets.
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	08-02-2022	08-02-2022
No. of Batches	03		
Date of Submission	Dy. No. 39629 dated 30-12-2022.		

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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: i. The HPLC software is 21CFR Compliant. ii. 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 (Batch No. RNZL/20180718 and RNZL/20180929, Mfg. date 07-2018 & 09/2018 respectively) of the drug substance (Ranolazine) from M/s Trichem Lifesciences limited, India.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP/18-19/31 dated 25-02-2019 mentioning 06 kg of Ranolazine attested by Assistant Director I&E, DRAP, Karachi dated 22-03-2021. Firm has also submitted attested copy of form 6.
7.	Protocols followed for conduction of stability study	Not submitted.

8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Revision of label claim as per reference product with submission of full fee shall be submitted.	Firm has submitted that there was a typo error in the submitted label claim and their formulation is prolonged release with following label claim; Each prolonged release tablet contains: Ranolazine …….. 375mg.
2.	BP specifications are claimed for the applied formulation. Pharmacopoeial monograph shall be submitted.	Firm has submitted that they are following innovator specifications.
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted.	Submitted.
4.	valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Not submitted.
5.	Method used for analysis of API from API Manufacturer shall be submitted.	Submitted.
6.	Stability study data of drug substance at zone Iva shall be submitted.	Firm has submitted both real time and accelerated stability data of three batches of the drug substance as per zone Iva. RNZ/20110101, RNZ/20120401 & RNZ/20130301.
7.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
8.	Method used for analysis of FPP shall be submitted.	Firm has submitted analytical method for the finished product. However, dissolution is for some other formulation.

9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Firm is using same excipients as per reference product.
10.	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted.
11.	Record of comparative dissolution data (where applicable) shall be submitted.	Firm has submitted CDP studies against Ranexa 375mg PR tablets, manufactured by Menarinic Indria laboratories and values of F2 are in acceptable ranges.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. shall be submitted.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Submitted.

Decision: Approved with innovator specifications and following label claim;
Each prolonged release tablet contains:
Ranolazine …….. 375mg.

- **Registration letter will be issued after Submission of differential fee for new molecule as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Firm will also submit valid copy of GMP certificate of the drug substance manufacturer from relevant authority and dissolution method before registration letter issuance.**

106.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Ranalaz 500mg Tablet.
	Composition	Each Film Coated Tablet Contains: Ranolazine ……500mg
	Diary No. Date of R& I & fee	Dy. No. 16870: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form-5.
	Finished product Specifications	BP specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA Approved (as prolonged release tablet)
	Me-too status	Razine ER 500mg Tablet by CCL.
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.

	Remarks of the Evaluator	• Revise your formulation as per the reference product along with submission of full fee of registration.
	Decision of 329th meeting of Registration Board.	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.

STABILITY STUDY DATA			
Drug	Ranalaz 500mg Tablet.		
Manufacturer of API	M/s Trichem Life Sciences Limited, Plot No. 106(B) & 107, Humnabad Industrial Area, Gadwanthi Village, Humnabad Taluka, Dist. Karnataka, India.		
API Lot No.	RNZL/20180929. RNZL/20180718.		
Description of Pack (Container closure system)	Alu-PVC (Opaque).		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1000 tablets.	1000 tablets.	1000 tablets.
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	14-02-2022	17-02-2022	17-02-2022
No. of Batches	03		
Date of Submission	Dy. No. 39630 dated 30-12-2022.		

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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: iii. The HPLC software is 21CFR Compliant. iv. 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 (Batch No. RNZL/20180718 and RNZL/20180929, Mfg. date 07-2018 & 09/2018 respectively) of the drug substance (Ranolazine) from M/s Trichem Lifesciences limited, India.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP/18-19/31 dated 25-02-2019 mentioning 06 kg of Ranolazine attested by Assistant Director I&E, DRAP, Karachi dated 22-03-2021. Firm has also submitted attested copy of form 6.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Revision of label claim as per reference product with submission of full fee shall be submitted.	Firm has submitted that there was a typo error in the submitted label claim and their formulation is prolonged release with following label claim; Each prolonged release tablet contains: Ranolazine …….. 500mg.
2.	BP specifications are claimed for the applied formulation. Pharmacopoeial monograph shall be submitted.	Firm has submitted that they are following innovator specifications.
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted.	Submitted.

4.	valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Not submitted.
5.	Method used for analysis of API from API Manufacturer shall be submitted.	Submitted.
6.	Stability study data of drug substance at zone Iva shall be submitted.	Firm has submitted both real time and accelerated stability data of three batches of the drug substance as per zone Iva. RNZ/20110101, RNZ/20120401 & RNZ/20130301.
7.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
8.	Method used for analysis of FPP shall be submitted.	Firm has submitted analytical method for the finished product. However, dissolution is for some other formulation.
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Firm is using same excipients as per reference product.
10.	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted.
11.	Record of comparative dissolution data (where applicable) shall be submitted.	Firm has submitted CDP studies against Ranexa 500mg PR tablets, manufactured by Menarinic Indria laboratories and values of F2 are in acceptable ranges.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. shall be submitted.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Submitted.

Decision: Approved with innovator specifications and following label claim;
Each prolonged release tablet contains:
Ranolazine …….. 500mg.

- **Registration letter will be issued after Submission of full fee of generic product for pre-registration variation in label claim as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Firm will also submit valid copy of GMP certificate of the drug substance manufacturer from relevant authority and dissolution method before registration letter issuance.**

107.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Ranalaz 750mg Tablet.

	Composition	Each Film Coated Tablet Contains: Ranolazine ……750mg
	Diary No. Date of R& I & fee	Dy. No. 16869: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form-5.
	Finished product Specifications	BP specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA Approved (as prolonged release tablet)
	Me-too status	Could not be confirmed.
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Remarks of the Evaluator	• Revise your formulation as per the reference product along with submission of full fee of registration. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 329th meeting of Registration Board.	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.

STABILITY STUDY DATA

Drug	Ranalaz 750mg Tablet.		
Manufacturer of API	M/s Trichem Life Sciences Limited, Plot No. 106(B) & 107, Humnabad Industrial Area, Gadwanthi Village, Humnabad Taluka, Dist. Karnataka, India.		
API Lot No.	RNZL/20180929. RNZL/20180718.		
Description of Pack (Container closure system)	Alu-PVC (Opaque).		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TF-01	TF-02	TF-03

Batch Size	1000 tablets.	1000 tablets.	1000 tablets.
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	25-02-2022	25-02-2022
No. of Batches	03		
Date of Submission	Dy. No. 39631 dated 30-12-2022.		

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	Last product specific inspection of firm was conducted for "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms following points: v. The HPLC software is 21CFR Compliant. vi. 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 (Batch No. RNZL/20180718 and RNZL/20180929, Mfg. date 07-2018 & 09/2018 respectively) of the drug substance (Ranolazine) from M/s Trichem Lifesciences limited, India.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. EXP/18-19/31 dated 25-02-2019 mentioning 06 kg of Ranolazine attested by Assistant Director I&E, DRAP, Karachi dated 22-03-2021. Firm has also submitted attested copy of form 6.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like	Submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Revision of label claim as per reference product with submission of full fee shall be submitted.	Firm has submitted that there was a typo error in the submitted label claim and their formulation is prolonged release with following label claim; Each prolonged release tablet contains: Ranolazine …….. 750mg.
2.	BP specifications are claimed for the applied formulation. Pharmacopoeial monograph shall be submitted.	Firm has submitted that they are following innovator specifications.
3.	Certificate of Analysis of API from Finished Product manufacturer shall be submitted.	Submitted.
4.	valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Not submitted.
5.	Method used for analysis of API from API Manufacturer shall be submitted.	Submitted.
6.	Stability study data of drug substance at zone Iva shall be submitted.	Firm has submitted both real time and accelerated stability data of three batches of the drug substance as per zone Iva. RNZ/20110101, RNZ/20120401 & RNZ/20130301.
7.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
8.	Method used for analysis of FPP shall be submitted.	Firm has submitted analytical method for the finished product. However, dissolution is for some other formulation.
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Firm is using same excipients as per reference product.
10.	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted.
11.	Record of comparative dissolution data (where applicable) shall be submitted.	Firm has submitted CDP studies against Ranexa 750mg PR tablets, manufactured by Menarinic Indria laboratories and values of F2 are in acceptable ranges.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA,	Submitted.

	summary data sheets etc. shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Submitted.

Decision: Approved with innovator specifications and following label claim;
Each prolonged release tablet contains:
Ranolazine …….. 375mg.

- **Registration letter will be issued after Submission of full fee for new molecule as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Firm will also submit valid copy of GMP certificate of the drug substance manufacturer from relevant authority and dissolution method before registration letter issuance.**

108.	Name and address of manufacturer/ Applicant	**M/s. High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23 Korangi Industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Swiflo 4mg Capsule.
	Composition	Each capsule contains: Silodosin ……..…. 4mg
	Diary No. Date of R & I & fee	Dy. No. 20062; 04-06-2018; Rs.**50,000** (01-06-2018).
	Pharmacological Group	Alpha-1 adrenergic receptor antagonist
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	30's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	RAPAFLO (Silodosin) 4mg Capsule for oral use (USFDA Approved)
	Me-too status	Could not be confirmed.
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	• This molecule requires submission of **stability** studies data on at least three batches at real and accelerated conditions. • The applied formulation is non- pharmacopoeial. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision of 291st meeting of Registration Board.	Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Drug	Swiflo (Silodosin) 4mg Capsule.

Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province China.		
API Lot No.	13000-190803		
Description of Pack (Container closure system)	Alu-Alu blister 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.	4SWPD01/21	4SWPD02/21	4SWPD03/21
Batch Size	11111 Capsules	11111 Capsules	11111 Capsules
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	02-09-2021	02-09-2021	02-09-2021
No. of Batches	03		
Date of Submission	Dy. No. 11114 dated 09-05-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Lasodex 60mg Capsule in its 313th Meeting on the basis of inspection conducted by the following panel dated 23rd Sep, 2021. i Prof Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board). ii Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi. iii Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available.
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 drug substance manufacturer with B. No. 13000-190803, Mfg. date 22-08-2019. COA from the drug product manufacturer is also submitted.
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	The firm has submitted copy of Accelerated stability studies (40°C ± 2°C & 75±5% RH) for 06 Month & Long-Term stability studies on Zone IV-B (30°C ± 2°C & 75±5% RH) for 24 Months of 03 Batch No. 13000-170802, 13000-170803 & 13000-170804
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML & GMP Certificate of manufacturer "M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., DML: Valid up to 16-06-2025 (issued by Zhejiang province Food and Drug Administration Bureau) GMP: issued by CFDA dated 15-03-2018 valid till 14-03-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Commercial Invoice No. TYI191056 dated 11-12-2019 mentioning 1kg quantity of silodosin batch number 13000-190803, manufacturing date August 22, 2019. Invoice is also attested by AD (I&E) DRAP, Karachi dated 20-12-2019.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols followed for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted Finished Product Specifications and Testing Method of Complete record of finished product.
9.	Drug-excipients compatibility studies (where applicable)	The firm has submitted Drug-excipients compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches i.e. 4SWPD01/21, 4SWPD02/21 & 4SWPD03/21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against comparator product Sildoso 4mg Capsule, B. No. RZ3. Comparative dissolution studies have been performed in following mediums: 1. 0.1N HCl pH 1.2 2. Acetate buffer pH 4.5 3. Phosphate buffer pH 6.8 Values of F2 are in acceptable range.
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.	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 submitted by the firm
1.	Both the COAs have different specifications for water content tests. Clarification shall be submitted.	Firm has submitted corrected COA from the drug product manufacturer.
2.	COA of the drug product manufacturer has different batch number mentioned than that of the API manufacturer. Justify?	Corrected COA with same batch number as that of the drug substance manufacturer is submitted by the drug product manufacturer.
3.	Specifications mentioned by the drug substance manufacturer on COA are JP while drug product manufacturer has mentioned MS. Clarification shall be submitted.	Revised Specification as per JP is submitted.
4.	Details of the manufacturer of the comparator product against which CDP is performed shall be submitted.	Sildoso 4mg capsules manufactured by CCL pharma.
5.	Batches are manufactured in July while stability studies are initiated in September. Justification in the delay shall be submitted.	Firm has submitted that delay during the period was due to checking of following aspects; Pharmaceutical equivalence for both strengths. CDP studies for both the strengths. They further submitted that they will comply the initiation of stability studies within 30 days in future.

Decision: Approved.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

109.	Name and address of manufacturer/ Applicant	**M/s. High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23 Korangi Industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Swiflo 8mg Capsule.
	Composition	Each capsule contains: Silodosin ……..…. 8mg
	Diary No. Date of R & I & fee	Dy. No. 20070; 04-06-2018; Rs. **20,000** (01-06-2018).
	Pharmacological Group	Alpha-1 adrenergic receptor antagonist
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	30's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	RAPAFLO (Silodosin) 4mg Capsule for oral use (USFDA Approved)
	Me-too status	Could not be confirmed.

	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	• This molecule requires submission of stability studies Minutes of 291st of Meeting of Registration Board, DRAP (2-4th September, 2019) 717 data on at least three batches at real and accelerated conditions. • The applied formulation is non- pharmacopoeial. • Differential fees need to be submitted as the applied molecule requires stability. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision of 291st meeting of Registration Board.	Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.

STABILITY STUDY DATA

Drug	Swiflo (Silodosin) 8mg Capsule.		
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province China.		
API Lot No.	13000-190803		
Description of Pack (Container closure system)	Alu-Alu blister 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.	8SWPD01/21	8SWPD02/21	8SWPD03/21
Batch Size	9090 Capsules	9090 Capsules	9090 Capsules
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	02-09-2021	02-09-2021	02-09-2021
No. of Batches	03		
Date of Submission	Dy. No. 11115 dated 09-05-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Lasodex 60mg Capsule in its 313th Meeting on the basis of inspection conducted by the following panel dated 23rd Sep, 2021.

		i Prof Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board). ii Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi. iii Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available.
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 drug substance manufacturer with B. No. 13000-190803, Mfg. date 22-08-2019. COA from the drug product manufacturer is also submitted.
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	The firm has submitted copy of Accelerated stability studies (40°C ± 2°C & 75±5% RH) for 06 Month & Long-Term stability studies on Zone IV-B (30°C ± 2°C & 75±5% RH) for 24 Months of 03 Batch No. 13000-170802, 13000-170803 & 13000-170804
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML & GMP Certificate of manufacturer "M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., DML: Valid up to 16-06-2025 (issued by Zhejiang province Food and Drug Administration Bureau) GMP: issued by CFDA dated 15-03-2018 valid till 14-03-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Commercial Invoice No. TYI191056 dated 11-12-2019 mentioning 1kg quantity of silodosin batch number 13000-190803, manufacturing date August 22, 2019. Invoice is also attested by AD (I&E) DRAP, Karachi dated 20-12-2019.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols followed for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted Finished Product Specifications and Testing Method of Complete record of finished product.

9.	Drug-excipients compatibility studies (where applicable)	The firm has submitted Drug-excipients compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches i.e. 8SWPD01/21, 8SWPD02/21& 8SWPD03/21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against comparator product Sildoso 8mg Capsule, B. No. SA4. Comparative dissolution studies have been performed in following mediums: 4. 0.1N HCl pH 1.2 5. Acetate buffer pH 4.5 6. Phosphate buffer pH 6.8 Values of F2 are in acceptable range.
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.	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 submitted by the firm
1.	Both the COAs have different specifications for water content tests. Clarification shall be submitted.	Firm has submitted corrected COA from the drug product manufacturer.
2.	COA of the drug product manufacturer has different batch number mentioned than that of the API manufacturer. Justify?	Corrected COA with same batch number as that of the drug substance manufacturer is submitted by the drug product manufacturer.
3.	Specifications mentioned by the drug substance manufacturer on COA are JP while drug product manufacturer has mentioned MS. Clarification shall be submitted.	Revised Specification as per JP is submitted.
4.	Details of the manufacturer of the comparator product against which CDP is performed shall be submitted.	Sildoso 8mg capsules manufactured by CCL pharma.
5.	Batches are manufactured in July while stability studies are initiated in September. Justification in the delay shall be submitted.	Firm has submitted that delay during the period was due to checking of following aspects; Pharmaceutical equivalence for both strengths. CDP studies for both the strengths. They further submitted that they will comply the initiation of stability studies within 30 days in future.

Decision: Approved. **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**		
110.	Name and address of manufacturer/ Applicant	High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VINOVO 375mg + 20mg Tablet
	Composition	Each modified Release tablet contains; Naproxen……. 375mg (Enteric coated core) Esomeprazole as magnesium trihydrate…...20mg (Immediate release coat)
	Diary No. Date of R & I & fee	Dy. No ----- dated 15-08-2017; Rs. 50,000/- dated 15-08-2017. Duplicate dossier is also submitted for information by the firm.
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimovo 375/20mg Tablet by Bayer Australia (Approved in TGA-Australia)
	Me-too status	Glomov 375/20mg Tablet by Global Pharmaceuticals
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	VINOVO (Naproxen 375mg + Esomeprazole as magnesium trihydrate 20mg) Tablet		
Manufacturer of API	**NAPROXEN**: M/s Divi's Laboratories Limited, Unit-2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh - 531 162, India. **ESOMEPRAZOLE**: M/s Everest Organics Limited, Aroor Village, Sadasivpet Mandal, Sangareddy Dist., Telangana. 502 291, India.		
API Lot No.	**Naproxen**: 2-M-B-3021118 **Esomeprazole Magnesium Trihydrate**: ESM/E-019/19		
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 / 75% ± 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.	3NEPD01/2021	3NEPD02/2021	3NEPD03/2021
Batch Size	2857 Tablets	2857 Tablets	2857 Tablets

Manufacturing Date	Dec 2021	Dec 2021	Dec 2021
Date of Initiation	01-07-2022	01-07-2022	01-07-2022
No. of Batches	03		
Date of Submission	Dy. No. dated 13-02-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th Meeting on the basis of inspection conducted by the following panel dated 12th July, 2018; i. Dr. Rafeeq Alam Khan, Meritorious Professor and Chairman, Department of Pharmacology, University of Karachi. (Member Registration Board). ii. Syed Muzaffar Ali Jafri, Director DTL Sindh, Karachi (Member Registration Board). iii. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi. iv The HPLC is 21CFR Compliant. v Audit trail on the testing were available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Naproxen:** Firm has submitted copy of COA with B. No. 2-M-B-3021118, Mfg. date 11-2018 from M/s Divi's Laboratories Limited, Unit-2. COA from the finished product manufacturer with same batch number. **Esomeprazole:** Firm has submitted copy of COA with B. No. ESM/E-019/19, Mfg. date 01-2019 from M/s Everest Organics Limited. COA from the finished product manufacturer with same batch number.
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 both the drug substances/API from both API Manufacturer and Finished Product manufacturer.
4.	Stability study data of API from API manufacturer	**Naproxen**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability studies data on zone IV-A for 60 months. Batch No. M5M042, M5M043 & M5M044. **Esomeprazole**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability data on zone IV-B for 12 months. Batch No. ESM/116/18, ESM/117/18 & ESM/118/18.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Naproxen**: Copy of GMP Certificate No. No. HMFO7-14051/927/2021-TECH-DCA issued by Drug Control administration Andhra Pradesh dated 26-06-2021 is submitted. Certificate is valid till 25-06-2024.

		Copy of license retention certificate till 17-01-2028 issued by DCA Andhra Pradesh is also submitted by the firm. **Esomeprazole**: Copy of GMP Certificate No. No. No: 95495/TS/ 2022A issued by Drug Control Administration Telangana dated 15/08/2022 is submitted. Certificate is valid till 14-08-2023. Copy of Drug Manufacturing License retention certificate valid till 31/12/2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Naproxen**: Firm has submitted copy of commercial invoice No. 5318500900 dated 31-01-2019 specifying 10Kg of Naproxen Sodium. Firm has also submitted copy of Form 6 mentioning the same quantity of naproxen attested by Assistant Director, DRAP, Karachi dated 08-02-2019. **Esomeprazole**: Firm has submitted copy of commercial invoice No. EXP/150/18-19 dated 21-01-2019 specifying 2.5Kg of Esomeprazole Magnesium Trihydrate. Firm has also submitted copy of Form 6 mentioning the same quantity of Esomeprazole magnesium Trihydrate attested by Assistant Director, DRAP, Karachi dated 28-01-2019.
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 submitted drug excipient compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three trial batches i.e. Trial Batch No.: 3NEPD01/21, 3NEPD02/21 & 3NEPD03/21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Glomov 375/20mg Tablet, B. No. 21G112 manufactured by M/s Global pharma. The details are as follows: Comparative dissolution studies have been performed in following mediums: 1. 0.1N HCl pH 1.2 2. Acetate buffer pH 4.5 3. Phosphate buffer pH 6.8 (Naproxen enteric coated core) 4. Phosphate buffer pH 7.4 (Esomeprazole immediate release coat)
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.	Submitted

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

Remarks of Evaluator:

S. No.	Observations	Reply by the firm
1.	Justification shall be submitted for using 90-minutes dissolution time for esomeprazole while the label claim has mentioned it as immediate release core and also the innovator product has mentioned 45 minutes.	Results are within the limit as per innovator product at 45-minute time point in phosphate buffer. Firm will revise their dissolution time limit for Esomeprazole at buffer stage from 90 minute to 45 minutes.
2.	Justification shall be submitted for delay in the testing of the product.	They submitted that they will comply the initiation of stability studies within 30 days in future.

Decision: Approved.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

111.	Name and address of manufacturer/ Applicant	High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VINOVO 500mg + 20mg Tablet
	Composition	Each modified Release tablet contains; Naproxen……. 500mg (Enteric coated core) Esomeprazole as magnesium trihydrate…...20mg (Immediate release coat)
	Diary No. Date of R & I & fee	Dy. No. 11889 dated 15-08-2017; Rs. 50,000/- dated 15-08-2017.
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimovo 500/20mg Tablet by Bayer Australia (Approved in TGA-Australia)
	Me-too status	Glomov 500/20mg Tablet by Global Pharmaceuticals
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	VINOVO (Naproxen 500mg + Esomeprazole as magnesium trihydrate 20mg) Tablet
Manufacturer of API	**NAPROXEN**: M/s Divi's Laboratories Limited, Unit-2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh - 531 162, India.

	ESOMEPRAZOLE: M/s Everest Organics Limited, Aroor Village, Sadasivpet Mandal, Sangareddy Dist., Telangana. 502 291, India.		
API Lot No.	**Naproxen**: 2-M-B-3021118 **Esomeprazole Magnesium Trihydrate**: ESM/E-019/19		
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 / 75% ± 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.	5NEPD01/21	5NEPD02/21	5NEPD03/21
Batch Size	2857 Tablets	2857 Tablets	2857 Tablets
Manufacturing Date	Dec 2021	Dec 2021	Dec 2021
Date of Initiation	04-07-2022	14-07-2022	14-07-2022
No. of Batches	03		
Date of Submission	Dy. No. dated 13-02-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th Meeting on the basis of inspection conducted by the following panel dated 12th July, 2018; i. Dr. Rafeeq Alam Khan, Meritorious Professor and Chairman, Department of Pharmacology, University of Karachi. (Member Registration Board). ii. Syed Muzaffar Ali Jafri, Director DTL Sindh, Karachi (Member Registration Board). iii. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi. vi The HPLC is 21CFR Compliant. vii Audit trail on the testing were available
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Naproxen:** Firm has submitted copy of COA with B. No. 2-M-B-3021118, Mfg. date 11-2018 from M/s Divi's Laboratories Limited, Unit-2. COA from the finished product manufacturer with same batch number. Esomeprazole: Firm has submitted copy of COA with B. No. ESM/E-019/19, Mfg. date 01-2019 from M/s Everest Organics Limited. COA from the finished product manufacturer with same batch number.
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 both the drug substances/API from both API Manufacturer and Finished Product manufacturer.

4.	Stability study data of API from API manufacturer	**Naproxen**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability studies data on zone IV-A for 60 months. Batch No. M5M042, M5M043 & M5M044. **Esomeprazole**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability data on zone IV-B for 12 months. Batch No. ESM/116/18, ESM/117/18 & ESM/118/18.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Naproxen**: Copy of GMP Certificate No. No.HMFO7-14051/927/2021-TECH-DCA issued by Drug Control administration Andhra Pradesh dated 26-06-2021 is submitted. Certificate is valid till 25-06-2024. Copy of license retention certificate till 17-01-2028 issued by DCA Andhra Pradesh is also submitted by the firm. **Esomeprazole**: Copy of GMP Certificate No. No. No: 95495/TS/ 2022A issued by Drug Control Administration Telangana dated 15/08/2022is submitted. Certificate is valid till 14-08-2023. Copy of Drug Manufacturing License retention certificate valid till 31/12/2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Naproxen**: Firm has submitted copy of commercial invoice No. 5318500900 dated 31-01-2019 specifying 10Kg of Naproxen Sodium. Firm has also submitted copy of Form 6 mentioning the same quantity of naproxen attested by Assistant Director, DRAP, Karachi dated 08-02-2019. **Esomeprazole**: Firm has submitted copy of commercial invoice No. EXP/150/18-19 dated 21-01-2019 specifying 2.5Kg of Esomeprazole Magnesium Trihydrate. Firm has also submitted copy of Form 6 mentioning the same quantity of Esomeprazole magnesium Trihydrate attested by Assistant Director, DRAP, Karachi dated 28-01-2019.
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 submitted drug excipient compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three trial batches i.e. Trial Batch No.: 5NEPD01/21, 5NEPD02/21 & 5NEPD03/21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against Vimovo 500/20mg Tablet, B. No. 01527S, Mfg. date 02/2021 manufactured by M/s Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley *Park* East, Uxbridge, Middlesex UB1 1 1BD, UK. The details are as follows:

		Comparative dissolution studies have been performed in following mediums: 5. 0.1N HCl pH 1.2 6. Acetate buffer pH 4.5 7. Phosphate buffer pH 6.8 (Naproxen enteric coated core) 8. Phosphate buffer pH 7.4 (Esomeprazole immediate release coat)
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.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S. No.	Observations	Reply by the firm
1.	Justification shall be submitted for using 90-minutes dissolution time for esomeprazole while the label claim has mentioned it as immediate release core and also the innovator product has mentioned 45 minutes.	Results are within the limit as per innovator product at 45-minute time point in phosphate buffer. Firm will revise their dissolution time limit for Esomeprazole at buffer stage from 90 minute to 45 minutes.
2.	Justification shall be submitted for delay in the testing of the product.	They submitted that they will comply the initiation of stability studies within 30 days in future.

Decision: Approved.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

112.	Name and address of manufacturer / Applicant	**M/s McOlson Research Laboratories (Pvt.) Ltd., 26-Km, Lahore - Sharikpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Darimac 7.5mg tablets.
	Composition	Each Extended Release Film Tablet Contains: Darifenacin hydrobromide eq. to Darifenacin …7.5mg
	Diary No. Date of R& I & fee	Form-5D Dy. No 38713 dated 26-11-2018. Rs. 50,000/- dated 22-11-2018 (From PEC main list) (Duplicate receiving submitted.)
	Pharmacological Group	Drugs for urinary frequency and incontinence. ATC Code: G04BD10.
	Type of Form	Form 5D.
	Finished product Specifications	In house specification.

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	MHRA approved.
	Me-too status	N/A.
	GMP status	Could not be confirmed.
	Remarks of the Evaluator.	•

STABILITY STUDY DATA

Drug	Darimac 7.5mg tablets.		
Manufacturer of API	M/s Jilin Huikang Pharmaceutical Co. Ltd., Junction of Zhengda Street and Ping'an Road, Jilin Economic and Technological Development Zone, Jilin Province, China.		
API Lot No.	API lot No. 200701.		
Description of Pack (Container closure system)	Light yellow colour, rounded, biconvex film coated tablets plain on both sides blistered in Alu-Alu plain foil packed in unit carton with packing 1 x 10's.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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.	DLT-PB-01.	DLT-PB-02.	DLT-PB-03.
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	17-12.2020	17-12.2020	17-12.2020
No. of Batches	03		
Date of Submission	Dy. No. 12199 dated 19-05-2022.		

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	Detox 90mg tablet was approved in 312 meeting of the Registration Board Firm has referred last onsite panel inspection for Detox 90mg tablet that was approved in 312 meeting of the Registration Board with inspection dated 31-12-2020 & 11-01-2021 by following panel: 1. Mr. Muhammad Sohail, Director DTL, Lahore. 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Uzma Barkat, Assistant Director DRAP, Lahore.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Firm has submitted Copy of COA (B. No. 200701, Mfg. date 12-07-2020) of the drug substance from both drug substance and drug product manufacturer.
Firm has also submitted COA of the working standard.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Submitted.</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 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.
Batches:(080101, 080102 & 080103).</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 No. JL20180052 dated 24-09-2018 in the name of M/s Jilin Huikang Pharmaceutical Co. Ltd., Junction of Zhengda Street and Ping’an Road, Jilin Economic and Technological Development Zone, Jilin Province, China.
Certificate is valid till 23-09-2023.</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 letter No. 16701/2018/DRAP-AD-VII (I&E) 24-12-2028 mentioning 0.105kg of Darifenacin HBr signed by AD-I&E, DRAP, Lahore.
They also submitted copy of commercial invoice attested by AD-I&E, DRAP, Lahore dated 28-08-2020.</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>Submitted.</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>DLT-PB-01</td><td>1000 Tablets</td><td>26-11.2020</td></tr>
<tr><td>DLT-PB-02</td><td>1000 Tablets</td><td>26-11.2020</td></tr>
<tr><td>DLT-PB-03</td><td>1000 Tablets</td><td>26-11.2020</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. Darimac 7.5mg Tablet against Emselex 7.5mg tablets, B. No. 21B003 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>
</table>

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.	Valid copy of GMP certificate of the applicant and section approval letter shall be submitted.	Copy of GMP certificate issued on the basis of inspection conducted on 04-06-2022 mentioning tablet general section is submitted by the firm. Firm has also submitted letter No. F. 1-17/2007-lic (pt.) dated 17-01-2011 mentioning tablet section.
2.	Valid copy of GMP certificate of the drug substance shall be submitted.	Firm has submitted copy of GMP certificate issued by Jilin Drug Administration dated 24-06-2020 valid till 23-06-2026.
3.	Analytical method submitted by the drug substance manufacturer has mentioned USP while that submitted by the drug product manufacturer has mentioned in house. Clarification shall be submitted.	The drug substance manufacturer referenced USP General Chapters to show compliance with pharmacopoeial standards, while analysis was performed using validated in-house methods. This reference confirms that the tests align with USP principles, ensuring global quality standards. The drug product manufacturer tested raw material according to the drug substance manufacturer's specifications using validated methods, ensuring consistency and reliability. Both approaches ensure product quality, safety, and efficacy. Supporting validation data is already submitted which is available in dossier to confirm adherence to regulatory requirements
4.	Analytical method for assay test submitted by the drug product manufacturer for drug substance is completely changed from that of the drug substance manufacturer. Clarification shall be submitted.	The drug substance manufacturer employed a titrimetric method, which is a simple and well-established technique for raw material testing. However, the drug product manufacturer developed and validated an in-house HPLC method to ensure higher precision, specificity, and suitability for Darifenacin Hydrobromide. HPLC is more sensitive and capable of detecting impurities and degradation products that titrimetry cannot identify. The in-house HPLC method was validated according to ICH Q2(R1) guidelines, ensuring reliability, accuracy, and robustness for testing the finished product. This method provides better control over product quality, ensuring compliance with regulatory standards for safety and efficacy
5.	GMP certificate is for M/s Jilin Huikang Pharmaceutical Co. Ltd., while COAs and	Firm has submitted that M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd. and M/s Jilin Huikang

	stability data sheets of the drug substances are from M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd. Clarification shall be submitted.	Pharmaceutical Co. Ltd., belong to a group of Company. Meanwhile M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd., is responsible for international marketing and sales of products of M/s Jilin Huikang Pharmaceutical Co. Ltd.,

Decision: Approved with innovator specifications.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

113.	Name and address of manufacturer / Applicant	**M/s McOlson Research Laboratories (Pvt.) Ltd., 26-Km, Lahore - Sharikpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Darimac 15mg tablets.
	Composition	Each Extended Release Film Tablet Contains: Darifenacin hydrobromide eq. to Darifenacin …15mg
	Diary No. Date of R& I & fee	Form-5D Dy. No 38714 dated 26-11-2018. Rs. 50,000/- dated 22-11-2018 (From PEC main list) (Duplicate receiving submitted.)
	Pharmacological Group	Drugs for urinary frequency and incontinence. ATC Code: G04BD10.
	Type of Form	Form 5D.
	Finished product Specifications	In house specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	MHRA approved.
	Me-too status	N/A.
	GMP status	Could not be confirmed.
	Remarks of the Evaluator.	

STABILITY STUDY DATA

Drug	Darimac 15mg tablets.		
Manufacturer of API	M/s Jilin Huikang Pharmaceutical Co. Ltd., Junction of Zhengda Street and Ping'an Road, Jilin Economic and Technological Development Zone, Jilin Province, China.		
API Lot No.	API lot No. 200701.		
Description of Pack (Container closure system)	Light yellow colour, rounded, biconvex film coated tablets plain on both sides blistered in Alu-Alu plain foil packed in unit carton with packing 1 x 10's.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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.	DMT-PB-01.	DMT-PB-02.	DMT-PB-03.
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets

Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	17-12.2020	17-12.2020	17-12.2020
No. of Batches	03		
Date of Submission	Dy. No. 12200 dated 19-05-2022.		

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	Detox 90mg tablet was approved in 312 meeting of the Registration Board Firm has referred last onsite panel inspection for Detox 90mg tablet that was approved in 312 meeting of the Registration Board with inspection dated 31-12-2020 & 11-01-2021 by following panel: 1. Mr. Muhammad Sohail, Director DTL, Lahore. 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Uzma Barkat, Assistant Director DRAP, Lahore.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (B. No. 200701, Mfg. date 12-07-2020) of the drug substance from both drug substance and drug product manufacturer. Firm has also submitted COA of the working standard.
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	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 6 months. Batches:(080101, 080102 & 080103).
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. JL20180052 dated 24-09-2018 in the name of M/s Jilin Huikang Pharmaceutical Co. Ltd., Junction of Zhengda Street and Ping'an Road, Jilin Economic and Technological Development Zone, Jilin Province, China. Certificate is valid till 23-09-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter No. 16701/2018/DRAP-AD-VII (I&E) 24-12-2028 mentioning 0.105kg of Darifenacin HBr signed by AD-I&E, DRAP, Lahore. They also submitted copy of commercial invoice attested by AD-I&E, DRAP, Lahore dated 28-08-2020.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.

<table>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Submitted.</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>DMT-PB-01</td><td>1000 Tablets</td><td>26-11.2020</td></tr>
<tr><td>DMT-PB-02</td><td>1000 Tablets</td><td>26-11.2020</td></tr>
<tr><td>DMT-PB-03</td><td>1000 Tablets</td><td>26-11.2020</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. Darimac 15mg Tablet against Emselex 15mg tablets, B. No. 21C004 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>
</table>

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Valid copy of GMP certificate of the applicant and section approval letter shall be submitted.	Copy of GMP certificate issued on the basis of inspection conducted on 04-06-2022 mentioning tablet general section is submitted by the firm. Firm has also submitted letter No. F. 1-17/2007-lic (pt.) dated 17-01-2011 mentioning tablet section.
2.	Valid copy of GMP certificate of the drug substance shall be submitted.	Firm has submitted copy of GMP certificate issued by Jilin Drug Administration dated 24-06-2020 valid till 23-06-2026.
3.	Analytical method submitted by the drug substance manufacturer has mentioned USP while that submitted by the drug product manufacturer has mentioned in house. Clarification shall be submitted.	The drug substance manufacturer referenced USP General Chapters to show compliance with pharmacopoeial standards, while analysis was performed using validated in-house methods. This reference confirms that the tests align with USP principles, ensuring global quality standards. The drug product manufacturer tested raw material according to the drug substance manufacturer's specifications using validated methods, ensuring consistency and reliability. Both approaches ensure product quality, safety, and efficacy. Supporting validation data is already submitted which is available in dossier to confirm adherence to regulatory requirements

4.	Analytical method for assay test submitted by the drug product manufacturer for drug substance is completely changed from that of the drug substance manufacturer. Clarification shall be submitted.	The drug substance manufacturer employed a titrimetric method, which is a simple and well-established technique for raw material testing. However, the drug product manufacturer developed and validated an in-house HPLC method to ensure higher precision, specificity, and suitability for Darifenacin Hydrobromide. HPLC is more sensitive and capable of detecting impurities and degradation products that titrimetry cannot identify. The in-house HPLC method was validated according to ICH Q2(R1) guidelines, ensuring reliability, accuracy, and robustness for testing the finished product. This method provides better control over product quality, ensuring compliance with regulatory standards for safety and efficacy
5.	GMP certificate is for M/s M/s Jilin Huikang Pharmaceutical Co. Ltd., while COAs and stability data sheets of the drug substances are from M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd. Clarification shall be submitted.	Firm has submitted that M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd. and M/s Jilin Huikang Pharmaceutical Co. Ltd., belong to a group of Company. Meanwhile M/s Beijing Lianben Phar-Chemicals Tech. Co., Ltd., is responsible for international marketing and sales of products of M/s Jilin Huikang Pharmaceutical Co. Ltd.,

Decision: Approved with innovator specifications.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

114.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Esoprox 375/20mg Tablet
	Composition	Each Modified Release Tablet contains: Naproxen ……375mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Diary No. Date of R& I & fee	Form-5D Dy. No 41300 dated 07-12-2018. Rs. 50,000/- dated 07-12-2018. (From PEC list.)
	Pharmacological Group	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Type of Form	Form-5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	TGA Approved.
	Me-too status	N/A.

	GMP status	Not available.	
STABILITY STUDY DATA			
Drug	Esoprox 375/20mg Tablet.		
Manufacturer of API	Esomeprazole Magnesium: M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India. Naproxen: M/s Divi's Laboratories Limited, Unit-II, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India.		
API Lot No.	Naproxen: 2-M-B-2660819. Esomeprazole; ESM/2012119.		
Description of Pack (Container closure system)	Yellow coloured oval biconvex shaped film coated tablets.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	NEA_t-T2-21	NEA_t-T3-21	NEA_t-T4-21
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	30-08-2021	30-08-2021	30-08-2021
No. of Batches	03		
Date of Submission	Dy. No. 20945 dated 15-08-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. ESM/2012119, Mfg. date 02-2021) for Esomeprazole and COA (B. No. 2-M-B-2660819, Mfg. date 08-2019) for Naproxen respectively) of both the drug substances from respective manufacturers is submitted. COAs from drug product manufacturer with same batch number is also 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	Firm has submitted stability studies of both the drug substances from drug substance manufacturers at zone Iva condition.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Esomeprazole Magnesium: Firm has submitted copy of certificate No. 4084/A3/2019 dated 20-05-2020 in the name of M/s Metrochem API Private Limited Unit-I, issued by DCA, Telangana valid till 19-05-2023. Naproxen: Firm has submitted copy of certificate No. HMF07-14051/927/2021-TECH-DCA dated 26-06-2021 in the name of M/s Divi's Laboratories Unit II issued by DCA, Andhra Pradesh, India valid till 25-06-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Esomeprazole: Firm has submitted copy of commercial invoice No. AE/20/0615 dated 22-0302021 mentioning 25 kg of Esomeprazole Magnesium Batch No. ESM/2012119, Mfg. date 02-2021 attested by Assistant Director, DRAP, Lahore dated 29-03-2021. Naproxen: Firm has submitted copy of commercial invoice No. BPIPL/INV/050/02/1920 dated 04-02-2020 mentioning 5kg of Naproxen, B. No. 2-M-B-2660819, Mfg. date 08-2019 attested by Assistant Director, DRAP, Lahore dated 19-02-2020.
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 submitted that they follow the qualitative composition of innovator product.
10.	Complete batch manufacturing record of three stability batches.	Complete record for following three batches is submitted; NEA_t-T2-21, NEA_t-T3-21 & NEA_t-T4-21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against Glomov 37 5mgl20mg Tablet, B. No. 21J160 manufactured by M/s Global pharmaceuticals. Values of F2 are in acceptable ranges.
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.	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-04-2022.
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A.
3.	Valid DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Esomeprazole Magnesium: Firm has submitted copy of GMP certificate No. 128045/TS/2024 dated 02-01-2024 issued by DCA, Telangana in the name of M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India valid till 31-12-2024. Naproxen: Firm has submitted copy certificate adted 26-06-2024 issued by DCA Andhra Pradesh in the name of M/s Divi's Laboratories Limited, Unit-II, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India valid for three years.

Decision: Approved.

115.	Name and address of manufacturer / Applicant	**M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.**
	Brand Name +Dosage Form + Strength	Esoprox 500/20mg Tablet.
	Composition	Each Modified Release Tablet contains: Naproxen ……500mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Diary No. Date of R& I & fee	Form-5D Dy. No 41301 dated 07-12-2018. Rs. 50,000/- dated 07-12-2018. (From PEC list.)
	Pharmacological Group	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Type of Form	Form-5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	TGA Approved.
	Me-too status	N/A.
	GMP status	Not available.

STABILITY STUDY DATA

Drug	Esoprox 500/20mg Tablet.		
Manufacturer of API	Esomeprazole Magnesium: M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India. Naproxen: M/s Divi's Laboratories Limited, Unit-II, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India.		
API Lot No.	Naproxen: 2-M-B-2660819. Esomeprazole; ESM/2012119.		
Description of Pack (Container closure system)	Yellow coloured oval biconvex shaped film coated tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	NEB_t-T1-21	NEB_t-T2-21	NEB_t-T3-21
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	30-08-2021	30-08-2021	30-08-2021
No. of Batches	03		
Date of Submission	Dy. No. 25344 dated 07-09-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. ESM/2012119, Mfg. date 02-2021) for Esomeprazole and COA (B. No. 2-M-B-2660819, Mfg. date 08-2019) for Naproxen respectively) of both the drug substances from respective manufacturers is submitted. COAs from drug product manufacturer with same batch number is also 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	Firm has submitted stability studies of both the drug substances from drug substance manufacturers at zone Iva condition.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Esomeprazole Magnesium: Firm has submitted copy of certificate No. 4084/A3/2019 dated 20-05-2020 in the name of M/s Metrochem API Private Limited Unit-I, issued by DCA, Telangana valid till 19-05-2023. Naproxen: Firm has submitted copy of certificate No. HMF07-14051/927/2021-TECH-DCA dated 26-06-2021 in the name of M/s Divi's Laboratories Unit II issued by DCA, Andhra Pradesh, India valid till 25-06-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Esomeprazole: Firm has submitted copy of commercial invoice No. AE/20/0615 dated 22-0302021 mentioning 25 kg of Esomeprazole Magnesium Batch No. ESM/2012119, Mfg. date 02-2021 attested by Assistant Director, DRAP, Lahore dated 29-03-2021. Naproxen: Firm has submitted copy of commercial invoice No. BPIPL/INV/050/02/1920 dated 04-02-2020 mentioning 5kg of Naproxen, B. No. 2-M-B-2660819, Mfg. date 08-2019 attested by Assistant Director, DRAP, Lahore dated 19-02-2020.
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 submitted that they follow the qualitative composition of innovator product.
10.	Complete batch manufacturing record of three stability batches.	Complete record for following three batches is submitted; NEB_t-T1-21, NEB_t-T2-21 & NEB_t-T3-21.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against Glomov 500/20mg Tablet, B. No. 21K149 manufactured by M/s Global pharmaceuticals. Values of F2 are in acceptable ranges.
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.	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 14-04-2022.
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A.
3.	Valid DML/GMP certificate of both API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Esomeprazole Magnesium: Firm has submitted copy of GMP certificate No. 128045/TS/2024 dated 02-01-2024 issued by DCA, Telangana in the name of M/s Metrochem API Private Limited Unit-I, Plot No. 62/C/6, Pipeline Road, Phase-I, I.D.A Jeedimethla, Quthbullapur (M), Medchal- Malkajjgri (Dist), Telangana State, India valid till 31-12-2024. Naproxen: Firm has submitted copy certificate adted 26-06-2024 issued by DCA Andhra Pradesh in the name of M/s Divi's Laboratories Limited, Unit-II, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India valid for three years.

Decision: Approved.

116.	Name and address of manufacturer / Applicant	**M/s Neutro Pharma (Pvt) Ltd., 9.5 km, Sheikhupura Road, Lahore.**
	Brand Name +Dosage Form + Strength	Dipose gel 5%.
	Composition	Each gram of Gel contains: Dapsone ……..……. 50mg.
	Diary No. Date of R& I & fee	Form-5D Dy. No 13431 dated 07-03-2019. Rs.50000/- dated 07-03-2019. (Information extracted from PEC main list.)
	Pharmacological Group	Anti-Acne Preparations.
	Type of Form	Form 5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulator Authorities	ACZONE® (dapsone) Gel, 5%, for topical use USFDA approved.
	Me-too status	N/A.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dipose gel 5%.
Manufacturer of API	M/s Dipharma Francis S.r.I., Stab. CaronnoPertusellaVa Origgio 23 Italy.
API Lot No.	1910427.
Description of Pack (Container closure system)	White to off white gritty translucent material with visible drug substance particles.

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.	DPAg-T2-21	DPAg-T3-21	DPAg-T4-21
Batch Size	300 Tubes.	300 Tubes.	300 Tubes.
Manufacturing Date	17-12-2021	22-12-2021	22-12-2021
Date of Initiation	24-12.2021	24-12.2021	24-12.2021
No. of Batches	03		
Date of Submission	Dy. No. dated 18-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not Submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. 1910427, Mfg. date 06/09/2019) of the drug substance (Dapsone USP) from M/s Dipharma Francis S.r.I. Italy. Firm has also submitted copy of COA from drug product manufacturer 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 Finished Product Manufacturer is provided only.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 22033000371 dated 03-08-2020 mentioning 1kg of Dapsone, B. No. 1920427 attested by Assistant Director, DRAP Lahore vide No. 12769/2020-DRAP dated 09-09-2020.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted. However, only assay test is given while no other specification and tests are given in the analysis method.
9.	Drug-excipients compatibility studies (where applicable)	No response against this point submitted.

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>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>DPAgT2-21</td><td>300 Tubes.</td><td>17-12.2021</td></tr><tr><td>DPAgT3-21</td><td>300 Tubes.</td><td>22-12.2021</td></tr><tr><td>DPAgT2-21</td><td>300 Tubes.</td><td>22-12.2021</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>N/A.
Firm has submitted pharmaceutical equivalence studies against Dasone Gel 5%, manufactured by M/s Crystolite pharma.</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:<table><tr><th>Sr. No.</th><th>Observations</th><th>Reply submitted by the firm</th></tr><tr><td>1.</td><td>Method used for analysis of API from API Manufacturer shall be submitted.</td><td>Submitted.</td></tr><tr><td>2.</td><td>Evidence of section approval letter from licensing Division shall be submitted.</td><td>Firm has submitted DML wherein General Skin Ointment section is mentioned.
GMP certificate has mentioned Cream/Ointment section.</td></tr><tr><td>3.</td><td>Both real time and accelerated stability data of the drug substance from the drug substance manufacturer as per Zone Iva shall be submitted.</td><td>Submitted.</td></tr><tr><td>4.</td><td>Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.</td><td>Firm has submitted copy of GMP certificate No. IT/API/53/H/2023 dated 20-02-2023 valid for three years.</td></tr><tr><td>5.</td><td>Specifications and analysis method for the all the test of gel formulation shall be submitted.</td><td>Submitted.</td></tr><tr><td>6.</td><td>Drug-excipients compatibility studies (where applicable) shall be submitted.</td><td>Firm has submitted that they use same ingredients as that of the innovator product. So compatibility studies not applicable.</td></tr><tr><td>7.</td><td>Details of the primary packaging material shall be submitted with pack sizes.</td><td>Plastic tube with PP cap.</td></tr><tr><td>8.</td><td>Stability data has not included all the tests for Gel formulation. Clarification shall be submitted.</td><td>Firm has submitted revised COAs and stability summary sheets wherein they have added required tests for gel formulations.</td></tr></table></td></tr>
<tr><td colspan="3">Decision: Approved.</td></tr>
</table>

117.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan (Pvt.) Ltd., F/423, SITE, Karachi.**
	Brand Name +Dosage Form + Strength	Emgly Met Tablet 500mg + 12.5mg.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 12.5mg Metformin HCl …… 500mg
	Diary No. Date of R& I & fee	From-5D Dy. No. 7511 dated 05-07-2017. PKR 50,000/- dated 03-07-2017 (From PEC list). (Duplicate receiving also attached.)
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Synjardy Tablets, USFDA Approved.
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	Could not be confirmed.
	Remarks of the Evaluator.	•

STABILITY STUDY DATA

Drug	Emgly Met Tablet 500mg + 12.5mg.		
Manufacturer of API	**Empagliflozin:** M/s Chifeng Arker Pharmaceutical Technology Co. Ltd., No 8 Mysuri Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin Hydrochloride: M/s Smruthi Organics Limited, Unit II, Plot No A-27, M.I.D.C., Chincholi, taluka Mohol, District Solapur, India.		
API Lot No.	Empagliflozin: D86-200401. Metformin HCL: MET-1074/20.		
Description of Pack (Container closure system)	Primary packed in Alu-Alu blister which is further 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.	EXP-T-1075	PLT-T-141	PLT-T-141
Batch Size	1000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	01-2021	02-2021	02-2021
Date of Initiation	02.2021	03-2021	03-2021
No. of Batches	03		
Date of Submission	Dy. No. Dated 22-02-2023.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA with Batch No. D86-200401, Mfg. date 16-04-20 for Empagliflozin from both the drug substance and drug product manufacturer. Firm has submitted copy of COA with Batch No. MET-1074/20, Mfg. date 07-2020 for Metformin HCl from both the drug substance and drug 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 both the drug substances/API from both API Manufacturer and Finished Product manufacturer.
4.	Stability study data of API from API manufacturer	**Empagliflozin**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability studies data on zone IV-A for 24 months. Batch No. D86-151201, D86-151202 & D86-151203. **Metformin HCl**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability data on zone IV-A for 60 months. Batch No. DMFH-026/10, DMFH-027/10 & DMFH-028/10.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: firm has submitted copy of Drug production license No. 20160053 issued by Inner Mongolia Drug Administration valid till 28-12-2025. Metformin HCl: Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/86368/2019/11/ 3011 dated 14-11-2019 issued by FDA Maharashtra State India. Valid till 13-11-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of commercial invoice No. PSPW-200429-2 dated 29-04-2020 mentioning 350gm of Empagliflozin and the invoice is also attested by Assistant Director, DRAP, Karachi dated 19-05-2020. Metformin HCl: Firm has also submitted copy of commercial invoice mentioning four different batches of Metformin HCl including the Batch No. MET-1074/20 and the invoice is also attested by Assistant Director, DRAP, Karachi dated 26-08-2020.
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 excipients as that of the innovator product.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: EXP-T-1075, PLT-T-141 & PLT-T-142.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Observations	Reply submitted by firm
1.	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	Valid copy of GMP certificate for Metformin HCl shall be submitted.	
3.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
4.	Record of comparative dissolution data (where applicable) in three different mediums with reference or comparator product shall be submitted.	

Decision: Approved.
Registration letter will be issued after submission CDP results for the applied formulation and valid copy of GMP certificate for drug substance manufacturer (Metformin HCl).

118.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan (Pvt.) Ltd., F/423, SITE, Karachi.**
	Brand Name +Dosage Form + Strength	Emgly Met Tablet 1000mg + 12.5mg.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 12.5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	From-5D Dy. No. 7511 dated 05-07-2017. PKR 50,000/- dated 03-07-2017 (From PEC list). (Duplicate receiving also attached.)
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D.
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	Could not be confirmed.
	Remarks of the Evaluator.	•

STABILITY STUDY DATA

Drug	Emgly Met Tablet 1000mg + 12.5mg.		
Manufacturer of API	**Empagliflozin:** M/s Chifeng Arker Pharmaceutical Technology Co. Ltd., No 8 Mysuri Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin Hydrochloride: M/s Smruthi Organics Limited, Unit II, Plot No A-27, M.I.D.C., Chincholi, taluka Mohol, District Solapur, India.		
API Lot No.	Empagliflozin: D86-200401. Metformin HCL: MET-1074/20.		
Description of Pack (Container closure system)	Primary packed in Alu-Alu blister which is further 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.	EXP-T-1076	PLT-T-143	PLT-T-144
Batch Size	1000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	01-2021	02-2021	02-2021
Date of Initiation	02.2021	03-2021	03-2021
No. of Batches	03		
Date of Submission	Dy. No. Dated 22-02-2023.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA with Batch No. D86-200401, Mfg. date 16-04-20 for Empagliflozin from both the drug substance and drug product manufacturer. Firm has submitted copy of COA with Batch No. MET-1074/20, Mfg. date 07-2020 for Metformin HCl from both the drug substance and drug 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 both the drug substances/API from both

		API Manufacturer and Finished Product manufacturer.
4.	Stability study data of API from API manufacturer	**Empagliflozin**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability studies data on zone IV-A for 24 months. Batch No. D86-151201, D86-151202 & D86-151203. **Metformin HCl**: Firm has submitted stability study data of 3 batches for accelerated storage conditions for 6 months & Long-Term stability data on zone IV-A for 60 months. Batch No. DMFH-026/10, DMFH-027/10 & DMFH-028/10.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: firm has submitted copy of Drug production license No. 20160053 issued by Inner Mongolia Drug Administration valid till 28-12-2025. Metformin HCl: Copy of GMP certificate No. NEW-WHO-GMP/CERT/PD/86368/2019/11/ 3011 dated 14-11-2019 issued by FDA Maharashtra State India. Valid till 13-11-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of commercial invoice No. PSPW-200429-2 dated 29-04-2020 mentioning 350gm of Empagliflozin and the invoice is also attested by Assistant Director, DRAP, Karachi dated 19-05-2020. Metformin HCl: Firm has also submitted copy of commercial invoice mentioning four different batches of Metformin HCl including the Batch No. MET-1074/20 and the invoice is also attested by Assistant Director, DRAP, Karachi dated 26-08-2020.
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 excipients as that of the innovator product.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: EXP-T-1076, PLT-T-143 & PLT-T-144.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Observations	Reply submitted by firm
1.	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	Valid copy of GMP certificate for Metformin HCl shall be submitted.	
3.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
4.	Record of comparative dissolution data (where applicable) in three different mediums with reference or comparator product shall be submitted.	

Decision: Approved.
Registration letter will be issued after submission CDP results for the applied formulation and valid copy of GMP certificate for drug substance manufacturer (Metformin HCl).

119.	Name and address of manufacturer / Applicant	**M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.**
	Brand Name +Dosage Form + Strength	Empxin M 5mg/500mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 5mg Metformin HCl …… 500mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 12174 dated 06-03-2019. Rs.20, 000/- dated 06-03-2019. (As per information in the PEC main list)
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Not found.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	Synjardy Tablets, USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	Could not be confirmed.

STABILITY STUDY DATA

Drug	Empxin M 5mg/500mg Tablet.
Manufacturer of API	No details of both the drug substance manufacturer is given by the applicant.
API Lot No.	Not given.
Description of Pack (Container closure system)	No details submitted by the firm.
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	05-06.2020	10-06.2020	20-06.2020
No. of Batches	03		
Date of Submission	Dy. No. 39320 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted. *However, no dissolution test is given in the Analysis of the finished product. Furthermore, firm has used UV method of analysis for the determination of assay test of both the active substances.*
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Details of the manufacturer of both the drug substances shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
4.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
8.	• In the submitted assay method, standard preparation for metformin is not submitted. Clarification shall be submitted. • Specifications for the dissolution test shall be submitted. • Method used for analysis of dissolution test of the finished Product shall be submitted. • Justification shall be used for using UV method in the assay test instead of using HPLC method which is more reliable.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Record of comparative dissolution data shall be submitted.	
11.	• API lot number used during the trial batches shall be submitted. • Data of 03 batches will be supported by attested respective documents like COA shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board, after thorough deliberation and considering the fact that the firm has applied UV spectrophotometric method for Assay test of Drug product although the HPLC method is available for the drug substance analysis hence Board, decided to reject the instant case.

120.	Name and address of manufacturer / Applicant	**M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.**
	Brand Name +Dosage Form + Strength	Empxin M 12.5mg/1000mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin …….... 12.5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 12175 dated 06-03-2019. Rs.20, 000/- dated 06-03-2019. (As per information in the PEC main list)

	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Not found.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Elzanor Tablet 12.5/1000mg, M/s Tabros Pharma, Reg. No. 101359
	GMP status	Could not be confirmed.

STABILITY STUDY DATA

Drug	Empxin M 12.5mg/1000mg Tablet.		
Manufacturer of API	No details of both the drug substance manufacturer is given by the applicant.		
API Lot No.	Not given.		
Description of Pack (Container closure system)	No details submitted by the firm.		
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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	10-07.2020	25-07.2020	02-08.2020
No. of Batches	03		
Date of Submission	Dy. No. 39320 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted. *However, no dissolution test is given in the Analysis of the finished product. Furthermore, firm has used UV method of analysis for the determination of assay test of both the active substances.*
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Details of the manufacturer of both the drug substances shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
4.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
8.	• In the submitted assay method, standard preparation for metformin is not submitted. Clarification shall be submitted. • Specifications for the dissolution test shall be submitted. • Method used for analysis of dissolution test of the finished Product shall be submitted.	

	• Justification shall be used for using UV method in the assay test instead of using HPLC method which is more reliable.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Record of comparative dissolution data shall be submitted.	
11.	• API lot number used during the trial batches shall be submitted. • Data of 03 batches will be supported by attested respective documents like COA shall be submitted. • Justification shall be submitted for over writing the UV data as the print has mentioned different strength while it is changed by pen.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board, after thorough deliberation and considering the fact that the firm has applied UV spectrophotometric method for Assay test of Drug product although the HPLC method is available for the drug substance analysis hence Board, decided to reject the instant case.

121.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Gliem-M 5/500mg Tablet.
	Composition	Each tablet contains: Empagliflozin ……..……. 5mg. Metformin HCl ……. 500mg.
	Diary No. Date of R& I & fee	Form-5 Dy. No 38604 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on20-12-2024 with receiving of 29-12-2022 & 23-11-2018.
	Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.
	Me-too status	Diampa-M 5mg/500mg Tablets, Getz Pharma.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Gliem-M 5/500mg Tablet.
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. **Metformin HCl** (MEF/11030557): Aarti Drugs Limited, India.
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)

Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-007	TGM-008	TGM-009
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39312 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.

10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted..	
12.	Record of comparative dissolution data shall be submitted.	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	

16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

122.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Gliem-M 5/1000mg Tablet.
	Composition	Each tablet contains: Empagliflozin ……..……. 5mg. Metformin HCl ……. 1000mg.
	Diary No. Date of R& I & fee	Form-5 Dy. No. 38603 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on 20-12-2024 with receiving of 29-12-2022 & 23-11-2018.
	Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.
	Type of Form	Form 5.
	Finished product Specifications	Navegal's Specifications.
	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.
	Me-too status	Diampa-M 5mg/1000mg Tablets, Getz Pharma.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Gliem-M 5/1000mg Tablet.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. **Metformin HCl**: Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-010	TGM-011	TGM-012
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		

Date of Submission	Dy. No. 39313 dated 29-12-2022.	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted..	
12.	Record of comparative dissolution data shall be submitted.	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

123.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Gliem-M 12.5/500mg Tablet.
	Composition	Each tablet contains: Empagliflozin ……..……. 12.5mg. Metformin HCl ……. 500mg.
	Diary No. Date of R& I & fee	Form-5 Dy. No 38605 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on20-12-2024 with receiving of 29-12-2022 & 23-11-2018.
	Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.

	Type of Form	Form 5.
	Finished product Specifications	Navegal's Specifications.
	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.
	Me-too status	Empozin-M Tablets 12.5 mg+500mg Tablets, M/s Macter International.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Gliem-M 12.5/500mg Tablet.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. **Metformin HCl**: Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-001	TGM-002	TGM-003
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39314 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	

5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted..	
12.	Record of comparative dissolution data shall be submitted.	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

124.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Gliem-M 12.5/1000mg Tablet.
	Composition	Each tablet contains: Empagliflozin ……..……. 12.5mg. Metformin HCl ……. 1000mg.
	Diary No. Date of R& I & fee	Form-5 Dy. No 38597 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on20-12-2024 with receiving of 29-12-2022 & 23-11-2018.
	Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.
	Type of Form	Form 5.
	Finished product Specifications	Navegal's Specifications.
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.
	Me-too status	Empozin-M Tablets 12.5 mg+1000mg Tablets, M/s Macter International.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Gliem-M 12.5/1000mg Tablet.

Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. **Metformin HCl**: Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-004	TGM-005	TGM-006
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39315 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.

8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted..	
12.	Record of comparative dissolution data shall be submitted.	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	

14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

125.	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	Aczo gel 5%.
	Composition	Each gram of Gel contains: Dapsone ……..……. 50mg.
	Diary No. Date of R& I & fee	Form-5D Dy. No 73 dated 18-05-2015 Rs. 50,000/- dated 18-05-2015. (From PEC stability applications list and duplicate copy submitted.)
	Pharmacological Group	Anti-Acne Preparations
	Type of Form	5D.
	Finished product Specifications	Tabros Specification.
	Pack size & Demanded Price	10gm, 30gm & 60gm tubes and as per DPC.
	Approval status of product in Reference Regulator Authorities	USFDA approved.
	Me-too status	N/A.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Aczo gel 5%.		
Manufacturer of API	M/s Nuray Chemicals (Pvt.) Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur District Tamil Nadu, India.		
API Lot No.	DPSRD210002.		
Description of Pack (Container closure system)	Gritty translucent white homogenized gel, packed in plastic collapsible tubes.		
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/ACZ	TR001-2/ACZ	TR001-3/ACZ
Batch Size	80 Tubes.	80 Tubes.	80 Tubes.
Manufacturing Date	07-03.2022	08-03.2022	09-03.2022
Date of Initiation	02-04.2022	02-04.2022	02-04.2022

No. of Batches	03
Date of Submission	Dy. No. 31986 dated 07-11-2022.

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 submitted that previously same dosage form is not inspected. However, they referred last onsite panel inspection for tablet dosage form 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. DPSRD210002, Mfg. date 09-2021) of the drug substance (Dapsone USP) from M/s Nuray Chemicals (Pvt.) Ltd., India. Firm has also submitted copy of COA from drug product manufacturer 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 60 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: (DPSM130002, DPSM130003 & DPSM130004).
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. 13626/D1/4/20201 dated 17-02-2022 in the name of M/s Nuray Chemicals Private Limited issued by Department of Food Safety and Drug Control Administration Government of Tamilnadu. Certificate is valid till31-12-2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 mentioning Dapsone USP 1.2kg along with reference standard and impurities standards attested by Assistant Director, DRAP Karachi dated 15-12-2021. Copy of commercial invoice with same batch number mentioned on COA is also submitted attested by Assistant Director, DRAP Karachi.
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/ACZ / 80 Tubes. / 07-03.2022 TR001-2/ACZ / 80 Tubes. / 08-03.2022 TR001-13ACZ / 80 Tubes. / 09-03.2022
11.	Record of comparative dissolution data (where applicable)	N/A.
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:

Observation	Reply submitted.
Analytical method parameter of the assay test submitted by the drug substance manufacturer are different from that of USP such as Wavelength, Injection volume & sample and standard concentration etc. clarification shall be submitted.	Firm has submitted that the Assay Analytical Method performed by the drug substance manufacturer using High-Performance Liquid Chromatography (HPLC) differs from the United States Pharmacopoeia (USP) method. While the drug manufacturer tests for all impurities using HPLC, the USP method typically employs Thin Layer Chromatography (TLC) for related substance analysis. Consequently, the drug manufacturer's use of HPLC provides a more comprehensive and quantitative assessment of all impurities, with the assay method conducted in a similar timeframe as the impurity testing method. In contrast, Tabros Pharma follows to the USP method for drug testing, utilizing HPLC for the Assay method, which aligns with the standard USP procedure.

Decision: Approved with innovator specifications.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

126.	Name and address of manufacturer / Applicant	**M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/500mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin …….... 12.5mg

		Metformin HCl …… 500mg
	Diary No. Date of R& I & fee	Dy. No. 13746: 07-03-2019. PKR 20,000/-: 07-03-2019.
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator3.	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • 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.
	Decision of 323rd meeting of Registration Board.	Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Glifmet 12.5/500mg Tablet.		
Manufacturer of API	No details of the drug substance manufacturer is given by the applicant.		
API Lot No.	Empagliflozin: D86210401 & EGF20210501S. Metformin HCL: MEF/12051638. *API lot numbers are extracted from the stability data sheets of the drug product.*		
Description of Pack (Container closure system)	2 x 7's tablets in Alu-Alu blister packed in card board 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.	T053-A	T053-B	T053-C
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2022	06-2022	06-2022

Date of Initiation	07-06.2022	07-06.2022	07-06.2022
No. of Batches	03		
Date of Submission	Dy. No. 8129 dated 07-08-2024. Firm has submitted regarding re submission of stability studies again for evaluation of file Glifmet 12.5/500mg tablets. They also submitted a document dated 29-05-2023 in DRAP R&I wherein they submitted shortcoming for 07 product including Glifmet 12.5/500 tablets and also submitted that stability will be submitted very soon.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: T-053-A, T-053-B & T-053-B.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
3.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Record of comparative dissolution data shall be submitted.	
11.	Data of 03 batches will be supported by attested respective documents like COA shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Justification shall be submitted for using 45 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

127.	Name and address of manufacturer / Applicant	**M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/850mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 12.5mg Metformin HCl …… 850mg
	Diary No. Date of R& I & fee	Dy. No. 13747: 07-03-2019. PKR 20,000/-: 07-03-2019.
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator3.	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

		• 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
	Decision of 323rd meeting of Registration Board.	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.

STABILITY STUDY DATA			
Drug	Glifmet 12.5/850mg Tablet.		
Manufacturer of API	No details of the drug substance manufacturer is given by the applicant.		
API Lot No.	Empagliflozin: D86210401. Metformin HCL: MEF/12051638. *API lot numbers are extracted from the stability data sheets of the drug product.*		
Description of Pack (Container closure system)	Yellow to dark yellow blue oblong, biconvex film coated tablets bisected on one side, 2 x 7's tablets in Alu-Alu blister packed in card board 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.	T054-A	T054-B	T054-
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	07-06.2022	07-06.2022	07-06.2022
No. of Batches	03		
Date of Submission	Dy. No. 8130 dated 07-08-2024. Firm has submitted regarding re submission of stability studies again for evaluation of file Glifmet 12.5/850mg tablets. They also submitted a document dated 29-05-2023 in DRAP R&I wherein they submitted shortcoming for 07 product including Glifmet 12.5/850 tablets and also submitted that stability will be submitted very soon.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**

1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
3.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches will be supported by attested respective documents like COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
14.	Justification shall be submitted for using 45 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

128.	Name and address of manufacturer / Applicant	**M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Brand Name +Dosage Form + Strength	Glifmet 5/1000mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	Dy. No. 13745: 07-03-2019. PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Not available.
	GMP status	Not available.
	Remarks of the Evaluator3.	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

		• 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
	Decision of 323rd meeting of Registration Board.	Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.
	Remarks of the Evaluator.	

STABILITY STUDY DATA			
Drug			
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition			
Time Period			
Frequency			
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	
4.	Stability study data of API from API manufacturer	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	

6.	Documents for the procurement of API with approval from DRAP (in case of import).	
7.	Protocols followed for conduction of stability study	
8.	Method used for analysis of FPP	
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be 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.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Receiving of the stability data in DRAP shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
4.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

12.	Data of 03 batches will be supported by attested respective documents like COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
14.	Justification shall be submitted for using 45 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

129.	Name and address of manufacturer / Applicant	**M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/1000mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 12.5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	Dy. No. 13748: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic.
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	USFDA Approved.
	Me-too status	Diajard-M Tablet by Highnoon.
	GMP status	Not available.
	Remarks of the Evaluator3.	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • 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
	Decision of 323rd meeting of Registration Board.	Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Glifmet 12.5/1000mg Tablet.
Manufacturer of API	No details of the drug substance manufacturer is given by the applicant.
API Lot No.	Empagliflozin: D86210401 & EGF20210501S. Metformin HCL: MEF/12051638. *API lot numbers are extracted from the stability data sheets of the drug product.*
Description of Pack (Container closure system)	Alu-Alu blister of 14's packed in printed unit carton, further packed in a master shipper.

Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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.	T052-A	T052-B	T052-C
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	09-05-2022	09-05-2022	09-05-2022
No. of Batches	03		
Date of Submission	Data of this product was submitted in soft form. Firm has asked to submit receiving of stability data submission in DRAP.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like	Not submitted.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Receiving of the stability data in DRAP shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer and drug product manufacturer shall be submitted.	
4.	Method used for analysis of both the drug substances/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	
9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches will be supported by attested respective documents like COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
14.	Justification shall be submitted for using 45 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

130.	Name and address of manufacturer / Applicant	**M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Xempo 5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	Dy. No. 14101: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Synjardy Tablets, USFDA Approved.
	Me-too status	Diajard-M Tablet by Highnoon
	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.	• Stability data already submitted on 08-06-2022. • Xenglu-Met Tablets by Getz
	Decision of 323rd meeting of Registration board.	Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Em-Met Tablet 5/1000mg Tablet.		
Manufacturer of API	**Empagliflozin:** Huainan Shunlong Pharmaceutical Co, Ltd., No. 9 Yongxing Road, Economic and Technological Development Zone, Huainan City, Anhui Province China. **Metformin Hydrochloride:** M/s Aarti Drugs Limited, Plot No.211-213 Road No.2, G.I.D.C Sarigam, Tal. Umbergaon, Dist.: Valsad, Gujarat, India.		
API Lot No.	Empagliflozin: 20190907. Metformin HCL: MEF-19112927.		
Description of Pack (Container closure system)	2 x 7's.		
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.	T-038	T-039	T-040
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	12.07-2021	14.07-2021	15.07-2021
No. of Batches	03		
Date of Submission	Dy. No. 13920, Dated 08-06-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA with Batch No. 20190907, Mfg. date 09-2019 for Empagliflozin from both the drug substance and drug product manufacturer. Firm has submitted copy of COA with Batch No. MEF-19112927, Mfg. date 11-2019 for Metformin HCl from both the drug substance and drug product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	**Empagliflozin**: Not submitted. **Metformin HCl**: Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: Not submitted. Metformin HCl: Copy of GMP certificate No. AH20180451 dated 08-04-2018 issued by CFDA is submitted. Valid till 07-04-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of commercial invoice No. JF20191019 dated 14-11-2019 mentioning 410gm of Empagliflozin and the invoice is also attested by Assistant Director, DRAP, Islamabad dated 03-01-2020. Metformin HCl: Firm has also submitted copy of commercial invoice No. EXP/2095/19-20 mentioning 500kg of Metformin HCl with B. No. MEF-19112927 and the invoice is also attested by Assistant Director, DRAP, Islamabad dated 06-01-2020.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies of their applied formulation against Synjardy tablets, B. No. 004417.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observations	Reply submitted by firm
1.	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	Valid copy of GMP certificate for Metformin HCl shall be submitted. Valid copy of GMP certificate for Empagliflozin shall be submitted.	
3.	Method used for analysis of both the API and from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
5.	Description of Pack (Container closure system) shall be submitted.	
6.	Justification shall be submitted for using 30-minute time for dissolution test with respect to the innovator product. Pictorial evidence of the innovator product with visible details of batch number, name of manufacturer shall be submitted.	
7.	Real time stability data is performed in October while the batches are manufactured in July. Justification shall be submitted in this delay.	
8.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
9.	Complete batch manufacturing record of three stability batches shall be submitted.	
10.	Data of 03 batches will be 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 shall be submitted.	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

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

131.	Name and address of manufacturer / Applicant	**M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Xempo-Wen 12.5/1000 mg Tablet.
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……..... 12.5mg Metformin HCl …… 1000mg
	Diary No. Date of R& I & fee	Dy. No. 14102: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5.
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulator Authorities	Synjardy Tablets, USFDA Approved.
	Me-too status	Diajard-M Tablet by Highnoon
	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.	• Stability data already submitted on 08-06-2022. • Xenglu-Met Tablets by Getz
	Decision of 323rd meeting of Registration board.	Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Em-Met Tablet 12.5/1000mg Tablet.		
Manufacturer of API	**Empagliflozin:** Huainan Shunlong Pharmaceutical Co, Ltd., No. 9 Yongxing Road, Economic and Technological Development Zone, Huainan City, Anhui Province China. **Metformin Hydrochloride:** M/s Aarti Drugs Limited, Plot No.211-213 Road No.2, G.I.D.C Sarigam, Tal. Umbergaon, Dist.: Valsad, Gujarat, India.		
API Lot No.	Empagliflozin: 20190907. Metformin HCL: MEF-19112927.		
Description of Pack (Container closure system)	2 x 7's.		
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.	T-033	T-034	T-040
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	06-2021	07-2021	07-2021
Date of Initiation	15.06-2021	16.06-2021	15.06-2021
No. of Batches	03		
Date of Submission	Dy. No. 20535, Dated 20-07-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA with Batch No. 20190907, Mfg. date 09-2019 for Empagliflozin

		from both the drug substance and drug product manufacturer. Firm has submitted copy of COA with Batch No. MEF-19112927, Mfg. date 11-2019 for Metformin HCl from both the drug substance and drug product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	**Empagliflozin**: Not submitted. **Metformin HCl**: Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: Not submitted. Metformin HCl: Copy of GMP certificate No. AH20180451 dated 08-04-2018 issued by CFDA is submitted. Valid till 07-04-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of commercial invoice No. JF20191019 dated 14-11-2019 mentioning 410gm of Empagliflozin and the invoice is also attested by Assistant Director, DRAP, Islamabad dated 03-01-2020. Metformin HCl: Firm has also submitted copy of commercial invoice No. EXP/2095/19-20 mentioning 500kg of Metformin HCl with B. No. MEF-19112927 and the invoice is also attested by Assistant Director, DRAP, Islamabad dated 06-01-2020.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies of their applied formulation against Synjardy tablets, B. No. 103016.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted
Remarks of Evaluator:		

Sr. No.	Observations	Reply submitted by firm
1.	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	Valid copy of GMP certificate for Metformin HCl shall be submitted. Valid copy of GMP certificate for Empagliflozin shall be submitted.	
3.	Method used for analysis of both the API and from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
5.	Description of Pack (Container closure system) shall be submitted.	
6.	Justification shall be submitted for using 30-minute time for dissolution test with respect to the innovator product. Pictorial evidence of the innovator product with visible details of batch number, name of manufacturer shall be submitted.	
7.	Real time stability data is performed in October while the batches are manufactured in July. Justification shall be submitted in this delay.	
8.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
9.	Complete batch manufacturing record of three stability batches shall be submitted.	
10.	Data of 03 batches will be 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 shall be submitted.	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

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

132.	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	Davir tablet 60mg.
	Composition	Each film coated tablet contains: Daclatasvir as Dihydrochloride…… ….60mg
	Diary No. Date of R& I & fee	From-5D Dy. No. 348 dated 15-03-2017 Rs. 50,000/- dated 15-03-2017. From PEC main list.
	Pharmacological Group	J05A Direct Acting Antivirals.
	Type of Form	Form-5D.
	Finished product Specifications	Not confirmed.
	Pack size & Demanded Price	Not confirmed.

	Approval status of product in Reference Regulator Authorities	Daclatasvir (Dihydrochloride) Tablet, Film-coated 60mg, Hetero Labs Ltd, WHO Product ID HP012. USFDA and Health Canada Discontinued.
	Me-too status	Clavir Tablet by Hilton Pharma
	GMP status	Not confirmed..
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Davir tablet 60mg.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China		
API Lot No.	RD-DCL-201807161.		
Description of Pack (Container closure system)	Almost white coloured film coated, Oval Tablet, having scored line on one side. Packed in Alu-Alu 7's blister and introduced in a card board box.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TDR-001	TDR-002	TDR-002
Batch Size	1100 Tablets.	1100 Tablets.	1100 Tablets.
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	17-07-2020.	17-07-2020.	17-07-2020.
No. of Batches	03		
Date of Submission	Dy. No.8856 dated 18-03-2021.		

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	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. RD-DCL-201807161, Mfg. date 16-07-2018) of the drug substance (Daclatasvir Dihydrochloride) from M/s Nantong Chanyoo, China. Firm has also submitted COA from the drug product manufacturer with same batch Number and manufacturing date etc.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analysis method of the drug substance from both the drug substance manufacturer and finished product manufacturer are submitted.

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 12 months and at accelerated conditions; 40˚C ± 2˚C / 75% ± 5% RH. Batch No. (201602001, 201602002 & 201602003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration is submitted by the firm.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. CY118242 dated 10-10-2018 mentioning 250gms of Daclatasvir Hydrochloride. Firm has also submitted copy of Form 3 and form 7. *However, no clearance certificate is provided by the firm for import with approval from DRAP.*
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Same excipients.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of 03 Batches: TDR-001, TDR-002 & TDR-003
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies of the applied formulation against Daklana Tablet in three mediums. In acidic medium both the reference and test product have shown more than 85% release within 15 minutes. While in both the buffer media, F2 values are in acceptable ranges.
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.	Documents for procurement of API.	Firm has submitted copy of commercial invoice No. CY118242 dated 10-10-2018 mentioning 250gm of Daclatasvir Dihydrochloride attested

		by Assistant Director, DRAP Lahore dated 08-01-2019.
2.	Details of the reference product i.e. manufacturer, batch number and country shall be submitted.	Brand Name Daklana 60mg Tablet, B. No. 1Y129 Mfg. 09-2019 EXP: 09-2021 Manufactured by : Ferozsons laboratories Limited Pakistan Reg # 085240.

Decision: Approved with innovator specifications.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

133.	Name and address of manufacturer/ Applicant	**High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Letrum-M 2.5/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Linagliptin ……..…2.5mg Metformin HCl ……..…500mg
	Diary No. Date of R & I & fee	Form-5D Dy. No 1222 dated 07-07-2014. Rs. 50,000/- dated 07-07-2014. (From PEC list)
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	Type of Form	Form 5D.
	Finished product Specification	Not available.
	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	N/A.
	GMP status	Not available.
	Remarks of the Evaluator	Application of M/s High Q pharma with same composition is already been considered in 343rd meeting of the Registration Board.
	Decision: Registration Board decided to reject the instant application as the applied formulation of the firm in same strength has already been considered in 343rd meeting of the Registration Board.	
134.	Name and address of manufacturer/ Applicant	**High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Letrum-M 2.5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Linagliptin ……2.5mg Metformin HCl ……850mg
	Diary No. Date of R & I & fee	Form-5D Dy. No 1223 dated 07-07-2014. Rs. 50,000/- dated 07-07-2014. (From PEC list)
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	Type of Form	Form 5D.
	Finished product Specification	Not available.

	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	N/A.
	GMP status	Not available.
	Remarks of the Evaluator	Application of M/s High Q pharma with same composition is already been considered in 343rd meeting of the Registration Board.
	Decision: Registration Board decided to reject the instant application as the applied formulation of the firm in same strength has already been considered on Form 5F in 343rd meeting of the Registration Board.	
135.	Name and address of manufacturer/ Applicant	**High-Q Pharmaceuticals, Plot 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Letrum-M 2.5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Linagliptin ……..…2.5mg Metformin HCl ……..…1000mg
	Diary No. Date of R & I & fee	Form-5D Dy. No 1224 dated 07-07-2014. Rs. 50,000/- dated 07-07-2014. (From PEC list)
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	Type of Form	Form 5D.
	Finished product Specification	Not available.
	Pack size & Demanded Price	Not available.
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	N/A.
	GMP status	Not available.
	Remarks of the Evaluator	Application of M/s High Q pharma with same composition is already been considered in 343rd meeting of the Registration Board.
	Decision: Registration Board decided to reject the instant application as the applied formulation of the firm in same strength has already been considered on Form 5F in 343rd meeting of the Registration Board.	
136.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin-M 5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy. No. 15770: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5

	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator	

Decision of 323rd RB: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug			
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition			
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			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	dated 24.04.2023 (From PEC list)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.
7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.

10.	Record of comparative dissolution data is required.
11.	Stability Summary sheets are also required. (As per format recommended by RB)
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.

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

137.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin-M 12.5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy. No. 15771: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator	

Decision of 323rd RB: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug			
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition			
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			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	dated 24.04.2023 (From PEC list)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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)	Not submitted
Remarks of Evaluator:		

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.
7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.
10.	Record of comparative dissolution data is required.
11.	Stability Summary sheets are also required. (As per format recommended by RB)
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.

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

138.	Name and address of manufacturer / Applicant	M/s Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Zempa M 5/500mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…5mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy. No. 15993: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • 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. • Revise your label claim as per the reference product to film coated tablet along with submission of requisite fee.

Decision of 323rd RB: Deferred for following submissions:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with 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.
- Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

STABILITY STUDY DATA

Drug			
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition			
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			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	dated 24.04.2023 (From PEC list)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.
7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.
10.	Record of comparative dissolution data is required.

11.	Stability Summary sheets are also required. (As per format recommended by RB)
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.
13.	Evidence of Revision of label along with requisite fee in compliance to decision of 323rd RB is also not submitted.

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

139.	Name and address of manufacturer / Applicant	M/s Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Zempa M 12.5/1000mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…12.5mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy. No. 15994: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • 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. • Revise your label claim as per the reference product to film coated tablet along with submission of requisite fee.

Decision of 323rd RB: Deferred for following submissions:

- Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Stability study data as per the guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	
Manufacturer of API	
API Lot No.	

Description of Pack (Container closure system)			
Stability Storage Condition			
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			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	dated 24.04.2023 (From PEC list)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted

10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.
7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.
10.	Record of comparative dissolution data is required.
11.	Stability Summary sheets are also required. (As per format recommended by RB)
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.
13.	Evidence of Revision of label along with requisite fee in compliance to decision of 323rd RB is also not submitted.

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

140.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Diamant-M 12.5/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg

		Metformin…500mg
	Diary No. Date of R& I & fee	Form-5D Dy. No 35128 dated 23-10-2018 Rs.50,000/- dated 22-10-2018.
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Diamant-M 12.5/500 mg Tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition			
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	001	002	003
Batch Size	3.75kg	3.75kg	3.75kg
Manufacturing Date	01.2018	01.2018	01.2018
Date of Initiation	23.02.2018	22.04.2018	22.04.2018
No. of Batches	03		
Date of Submission	dated		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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)	Not submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
2.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
3.	Protocols followed for conduction of stability study and details of tests are required
4.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)

5.	Complete batch manufacturing record of three stability batches is required.
6.	Method used for analysis of FPP is required.
7.	Reports of stability studies of API from manufacturer of both API are required.
8.	Analysis reports for excipients used is required.
9.	Drug-excipients compatibility studies is required.
10.	Record of comparative dissolution data is required.
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.

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

141.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Esonap 500/20 mg Tablet
	Composition	Each Modified Release Tablet Contains: Naproxen Sodium…500mg Esomeprazole Magnesium Trihydrate…20mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 14287 dated 17-04-2018 Rs.20,000/- dated 04-04-2018
	Pharmacological Group	Propionic acid derivatives ATC Code: M01AE52
	Type of Form	Form 5
	Finished product Specifications	As per innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved Dr. Reddys
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Esonap 500/20 mg Tablet		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition			
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
Date of Submission	Dy. No/ 8728 dated 05.04.2022

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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	Not submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator:

Sr. No.	Observation
1.	The innovator product contains Naproxen free acid, not its sodium salt.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Stability summary sheets are required
4.	Method used for analysis of API along with COA. / COA of both drug substances by both drug product manufacturer and drug substance manufacturers are required.
5.	Approval of API by regulatory authority of country of origin (DML) or GMP certificate of API manufacturer issued by regulatory authority of country of origin are required.
6.	Protocols followed for conduction of stability study and details of tests are required
7.	Documents confirming import of API etc. (AD Attested invoices or clearance certificates)
8.	Complete batch manufacturing record of three stability batches is required.
9.	Method used for analysis of FPP is required.
10.	Reports of stability studies of API from manufacturer of both API are required.
11.	Analysis reports for excipients used is required.
12.	Drug-excipients compatibility studies is required.
13.	Record of comparative dissolution data is required.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required.

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

Agenda of Ms. Maham Misbah

Case no. 01 Registration applications of drugs for which stability study data is submitted

a. New cases/ Verification of stability study data/ Exemption from onsite verification of stability data

142.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals. Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Meltog 25mg Tablet
	Composition	Each film coated tablet contains: Agomelatine…25mg
	Diary No. Date of R& I & fee	Dy.No. 460 dated 07-02-2017, Rs.50,000/- Deposit Slip No. 0545188 (Copy).
	Pharmacological Group	Antidepressant
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	As per DPC/SRO

	Approval status of product in Reference Regulatory Authorities	TGA Approved
	Me-too status	Agoviz 25mg film coated Tablet by PharmEvo (Reg.No. 086887).
	GMP status	Copy of certificate of GMP generated against inspection conducted on 17/05/2023 is submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Mehta API Pvt Ltd, India.		
API Lot No.	Agomelatine: LT-DAGN/013/17-18		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	RD/PR21-046/T2/S1	RD/PR21-046/T2/S2	RD/PR21-046/T2/S3
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 5998 Dated 04-03-2022		

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 Vesoft 400mg/100mg Tablets which was conducted on 12th July, 2018 and was presented in 284th meeting of Registration Board held on 31st July-01st August, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available • The firm possesses stability chambers with adequate monitoring and control.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of CoA of Batch No. LT-DAGN/013/17-18 from M/s Mehta API Pvt Ltd, India is submitted. Copy of CoA of Batch No. LT-DAGN/013/17-18 from M/s High Q Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted

4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (30°C ± 2°C & 70±5%RH) & long term, 48 Months (40°C ± 2°C &70±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. NEW-WHO-GMP/CERT/KD/117960/2022/11/42037 for M/s Mehta API Pvt Ltd. Gut No. 546, 571, 519 &520, Village Kumbhavali, Taluka Palghar, Maharashtra, India, issued by Food and Drug Administration Maharashtra, India, valid till 08-09-2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. 1819/APM00010 dated 12-04-2018 cleared by ADC (Karachi) dated 06-12-2018 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product against the reference product Agoviz 25mg Tablet of M/s PharmEvo (Pvt.) Ltd in 3 dissolution media. The value for similarity factor is in the acceptable range.
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[xxiii]:		
Decision: Approved.		

143.	**Name and address of manufacturer / Applicant**	**M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Linamet 2.5/1000mg tablet
	Composition	Each tablet contains: Linagliptin….2.5mg Metformin….1000mg
	Type of Form/ Diary No. Date of R& I & fee	Form 5D/ 3-5-12

<table>
<tr><td rowspan="4">144.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Getz Pharma Pvt Ltd.
29-30/27, Korangi Industrial Area, Karachi.</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>Linamet 2.5/850mg tablet</td></tr>
<tr><td>Composition</td><td>Each tablet contains:
Linagliptin….2.5mg
Metformin….1000mg</td></tr>
<tr><td>Type of Form/
Diary No. Date of R& I & fee</td><td>Form 5D/ 3-5-12</td></tr>
<tr><td rowspan="5">145.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Getz Pharma Pvt Ltd.
29-30/27, Korangi Industrial Area, Karachi.</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>Linamet 2.5/500mg tablet</td></tr>
<tr><td>Composition</td><td>Each tablet contains:
Linagliptin….2.5mg
Metformin….500mg</td></tr>
<tr><td>Type of Form/
Diary No. Date of R& I & fee</td><td>Form 5D/ 3-5-12</td></tr>
<tr><td colspan="2">Remarks of Evaluator:
Applicant has submitted Letter No.RA-CL/358/1224 dated 19-12-2024 that Linamet range has been applied on CTD format (Form5F) with the following Tracking IDs:
<table>
<tr><td>Sr. No.</td><td>Product name</td><td>eApp Tracking IDs</td></tr>
<tr><td>1.</td><td>Linamet 2.5/1000mg tablet</td><td>73P-A5Y-2N98</td></tr>
<tr><td>2.</td><td>Linamet 2.5/850mg tablet</td><td>ZQ7-LVA-32TJ</td></tr>
<tr><td>3.</td><td>Linamet 2.5/500mg tablet</td><td>ZHX-JT3-ART6</td></tr>
</table>
Applicant has requested to withdraw the applications submitted on Form 5D and further requested that their applications on CTD be considered for review.</td></tr>
<tr><td colspan="2">Decision: Registration Board acceded to the request of the applicant for withdrawal of their Linamet range (Linamet 2.5/1000mg tablet, Linamet 2.5/850mg tablet and Linamet 2.5/500mg tablet) and declared them as disposed off while the registration applications of same formulations applied on Form 5F shall be considered on their turn.</td></tr>
<tr><td rowspan="8">146.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Novamed Pharmaceuticals(Pvt.)Ltd ., 28km Ferozepur Road Lahore</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>Auron tablet 25mg</td></tr>
<tr><td>Composition</td><td>Each extended release tablet contains:
Mirabegron……..25 mg</td></tr>
<tr><td>Diary No. Date of R& I & fee</td><td>From-5D Dy. No.35 dated 03-11-2016 Rs. 50,000/- No. 0510605</td></tr>
<tr><td>Pharmacological Group</td><td>Urological</td></tr>
<tr><td>Type of Form</td><td>Form 5</td></tr>
<tr><td>Finished product Specifications</td><td>In house specifications</td></tr>
<tr><td>Pack size & Demanded Price</td><td>As per DPC/SRO</td></tr>
<tr><td>Approval status of product in Reference Regulatory Authorities</td><td>MYRBETRIQ 25 mg (mirabegron extended-release film-coated tablet), USFDA approved.</td></tr>
</table>

	Me-too status	Mirabet Tablet 25mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	Last GMP inspection was conducted on 07-04-2023 and GMP Compliance status was satisfactory.

STABILITY STUDY DATA			
Manufacturer of API	M/s Viwit Pharmaceutical Co., Limited Address: 88, Weizhi Road, Tengzhou Biopharma Park, Shandong, China		
API Lot No.	337001-201601001R1		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RD/PR20-009/T1/S1	RD/PR20-009/T1/S1	RD/PR20-009/T1/S1
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	21-01-2021	21-01-2021	21-01-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. Dated 23-04-2022 & Dy No. 14258 Dated 31-12-2024		

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 "Sofonil 400mg (Sofosbuvir) Tablets, which was conducted on 06th March, 2017 and was presented in 268th meeting of Registration board held on 20-21st March, 2017. Registration Board decided to approve registration of Sofonil Tablets (Sofosbuvir 400mg) by M/s. NovaMed Pharmaceutical (Pvt.) Ltd., Lahore. Following observation regarding HPLC system was recorded in report: • The HPLC software is 21CFR compliant as per record available with the firm • Audit trail on the testing reports were shown to the panel during inspection.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted for Batch No. 337001-201601001R1

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of APIs from both API Manufacturer 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 API. 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 for three 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 DML certificate of API manufacturer from Tengzhou Food and Drug Administration, PRC. Validity of license: 25-10-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2020060506 dated 17/06/2020, for import of 500g of Mirabegron (Batch No. 337001-201601001R1) in name of M/s Novamed Pharmaceuticals(Pvt.) Ltd.,28km Ferozepur Road Lahore. Clearance certificate is issued by AD (I&E) DRAP, Lahore dated 01-07-2020.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against Myrebetriq XR Tablet 25mg in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8).
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[xxiii]: The applicant was advised to submit consolidated and complete stability studies data as per guidelines approved in 293rd meeting of Registration Board. The response of the applicant was received vide Letter No. NMP/DRA/STB02/M01 dated 30-12-2024 (Dy No. 14258 dated 31-12-2024). Details of response are mentioned above.		
Decision: Approved.		
147.	**Name and address of manufacturer / Applicant**	**M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore**

	Brand Name +Dosage Form + Strength	Matine 25mg tablet
	Composition	Each film coated tablet contains: Agomelatine….25mg
	Type of Form/ Diary No. Date of R& I & fee	Form 5D/ Date of R&I: 07-03-2019
	Remarks of Evaluator	Applicant has submitted Letter No. Nil dated 19-12-2024 on the Subject: Request for Consideration of New Application on Form 5F and withdrawal of previous submission on Form 5D, wherein it stated that the applied product has been submitted on From 5F (CTD) with Tracking ID 97S-U2U-QVMW. Applicant has requested to proceed with the newly submitted application on Form 5F and has formally withdrawn the previous submission on Form 5D.
	Decision: Registration Board acceded to the request of the applicant for withdrawal of their application and declared it as disposed off while the registration applications of same formulation applied on Form 5F shall be considered on its turn.	
148.	**Name and address of manufacturer / Applicant**	**M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore**
	Brand Name +Dosage Form + Strength	Picrol Cream 1% w/w
	Composition	Pimecrolimus 1% w/w/
	Type of Form/ Diary No. Date of R& I & fee	Form 5D/ Date of R&I: 07-03-2019
	Remarks of Evaluator	Applicant has submitted Letter No. Nil dated 19-12-2024 on the Subject: Request for Consideration of New Application on Form 5F and withdrawal of previous submission on Form 5D, wherein it stated that the applied product has been submitted on From 5F (CTD) with Tracking DH3-6N6-NDPB. Applicant has requested to proceed with the newly submitted application on Form 5F and has formally withdrawn the previous submission on Form 5D.
	Decision: Registration Board acceded to the request of the applicant for withdrawal of their application and declared it as disposed off while the registration applications of same formulation applied on Form 5F shall be considered on its turn.	
149.	**Name and address of manufacturer / Applicant**	**M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore**
	Brand Name +Dosage Form + Strength	Motais ointment 0.1%
	Composition	Each gram contains: Mometasone furoate…..1 mg
	Diary No. Date of R& I & fee	Form-5D Dy. No. 13430 dated 07-03-2019 Rs. 50,000/- No. 0844963 **(Duplicate)**
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5D

	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	15g, 30g, 50g/SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved.
	Me-too status	Mometaval 0.1% Ointment, Reg# 108375, Valor Pharmaceuticals, Islamabad.
	GMP status	GMP inspection certificate No. 103/2022-DRAP (AD-992029227387) dated 30-06-2022 issued on the basis of evaluation conducted on 14-04-2022 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Aurisco Pharmaceutical Co., Limited Address: Badu Industrial Park zone, Tiantai County, Zhejiang Province, PRC.		
API Lot No.	A3-191101		
Description of Pack (Container closure system)	15g tube Aluminium tube		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	MFA_c T1-21	MFA_c T2-21	MFA_c T3-21
Batch Size	500 tubes	500 tubes	500 tubes
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	26-12-2021	26-12-2021	26-12-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 28377 Dated 06-10-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# A3-191101) of API API from both API Manufacturer and Finished Product Manufacturer is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 36 Months (30°C ± 2°C &65±5%RH) stability study reports of 03 batches.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML for M/s Aurisco Pharmaceutical Co., Limited, Badu Industrial Park zone, Tiantai County, Zhejiang Province, PRC issued by Zhegiang Food and Drug Administration, PRC, valid till 06-09-2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. 20T-051 dated 17-02-2020 cleared by DRAP field office, Lahore dated 28-02-2020 is submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not Applicable
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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[xxiii]:
Applicant shall submit the following

Sr. No.	Shortcomings	Response of applicant
i.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Submitted

Decision: Approved.

150.	**Name and address of manufacturer / Applicant**	**M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore**
	Brand Name +Dosage Form + Strength	Neuhal Cream 0.05%
	Composition	Each gm Contains: Halobetasol Propionate…0.5mg
	Diary No. Date of R& I & fee	Form-5D Dy. No. 13427 dated 07-03-2019 Rs. 50,000/- No. 0844960 **(Duplicate)**
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5D

	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	1's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved.
	Me-too status	Halsol Cream 0.05%, Reg# 087315, Crytolite Pharmaceuticals, Islamabad.
	GMP status	GMP inspection certificate No. 103/2022-DRAP (AD-992029227387) dated 30-06-2022 issued on the basis of evaluation conducted on 14-04-2022 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Swati Spentose Pvt. Ltd plot no. A-1/2102 & 2103, phase 3 G.I.D.C VAPI Gujarat state, India		
API Lot No.	HLP/919001		
Description of Pack (Container closure system)	Aluminium tube		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	HBA_o T1-21	HBA_o T2-21	HBA_o T3-21
Batch Size	150 tubes	150 tubes	150 tubes
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	29-12-2021	29-12-2021	29-12-2021
No. of Batches	03		
Date of Submission of stability data	Dy No.33125 Dated 18-11-2022		

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	Product Specific Inspection of the firm was conducted for Dexzol (Dexlansoprazole) 30mg & 60mg Capsule, for which the inspection was conducted on 10-11-2020. The report was presented in 297th meeting of Registration Board. Authenticity of stability data submitted by the firm for registration of Dexzol has been verified.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# HLP/919001) of API from both API Manufacturer and Finished Product Manufacturer is submitted.

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of accelerated, 06 Months (25°C ± 2°C & 60±5%RH) & long term, 36 Months (5°C ± 3°C) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. 20082165 issued by Food and Drug Administration, Gujarat ,India valid till 17-08-2023 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. SVII/I/032/19-20 dated 18-03-2020 cleared by DRAP field office, Lahore dated 02-04-2020 is submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not Applicable
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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[xxiii]:
Applicant shall submit the following

Sr. No.	Shortcomings
i.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
ii.	Long term Stability study data of API from API manufacturer is submitted for 36 months whereas assigned shelf life as per CoA is 5 years. Real time stability studies data of API from API manufacturer shall be submitted for complete assigned shelf life.
iii.	BMRs and stability data is submitted for ointment instead of cream. Clarify the dosage form and submit associated data, accordingly. Drug excipient compatibility studies (if applicable) shall also be submitted.

Decision: Deferred for submission of following:

- **Clarification regarding the dosage form, whether it is cream or ointment and submission of BMRs, stability studies results and all associated data, accordingly,**

- **Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin,**
- **Long term Stability study data of API from API manufacturer for 60 months at Zone Iva conditions,**
- **Drug excipient compatibility studies (if applicable).**

151.	**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	Luridon Tablet 60mg
	Composition	Each film coated tablet contains: Lurasidone HCl…60mg
	Diary No. Date of R& I & fee	Dy.No. 4033 dated 20-04-2017 (Duplicate), Rs.50,000/- Deposit Slip No. 0524795 (Duplicate).
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5D
	Finished product Specifications	Innovator specifications
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rasidon 60mg film coated Tablet by Hilton (Reg.No. 93086) Rasidon 20mg film coated Tablet by Hilton (Reg.No. 93085) Rasidon 40mg film coated Tablet by Hilton (Reg.No. 89370) Rasidon 80mg film coated Tablet by Hilton (Reg.No. 89371)
	GMP status	Copy of certificate of GMP generated against inspection conducted on 09-01-2024 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceutical Co. Ltd.		
API Lot No.	0200-202009001		
Description of Pack (Container closure system)	Alu Alu 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 Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21PD-3879-01-T	21PD-3880-02-T	21PD-3881-03-T
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets

Manufacturing Date	August-21	August-21	August-21
Date of Initiation	02- 09-2021	02- 09-2021	02- 09-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 20287 Dated 18-07-2022		

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	Submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 6 Months** (40°C ± 2°C &70±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.	Not submitted from regulatory authority of country of origin
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. ZY20102701G/W dated 27-10-2020 cleared by ADC (Karachi) dated 02-12-2020 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same. Applicant has submitted undertaking stating the same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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

152.	**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	Luridon Tablet 80mg
	Composition	Each film coated tablet contains: Lurasidone HCl…80mg
	Diary No. Date of R& I & fee	Dated 20-04-2017 (Duplicate) Rs. 50,000/- DS No. 0524796 (Duplicate)
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5D
	Finished product Specifications	Innovator specifications
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rasidon 60mg film coated Tablet by Hilton (Reg.No. 93086) Rasidon 20mg film coated Tablet by Hilton (Reg.No. 93085) Rasidon 40mg film coated Tablet by Hilton (Reg.No. 89370) Rasidon 80mg film coated Tablet by Hilton (Reg.No. 89371)
	GMP status	Copy of certificate of GMP generated against inspection conducted on 09-01-2024 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceutical Co. Ltd.		
API Lot No.	0200-202009001		
Description of Pack (Container closure system)	Alu Alu 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 Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21PD-3864-22-T	21PD-3865-23-T	21PD-3866-24-T
Batch Size	2500 tabs	2500 tabs	2500 tabs
Manufacturing Date	08-21	08-21	08-21
Date of Initiation	02-09-2021	02-09-2021	02-09-2021

No. of Batches	03
Date of Submission of stability data	Dy No. 20288 Dated 18-07-2022

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	Submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 6 Months** (40°C ± 2°C &70±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.	Not submitted from regulatory authority of country of origin
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. ZY20102701G/W dated 27-10-2020 cleared by ADC (Karachi) dated 02-12-2020 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same. Applicant has submitted undertaking stating the same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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

153.	**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	Luridon Tablet 20mg
	Composition	Each film coated tablet contains: Lurasidone HCl…20mg
	Diary No. Date of R& I & fee	Dated 20-04-2017 (Duplicate), Rs. 50,000/- DS No. 0524793 (Duplicate)
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5D
	Finished product Specifications	Innovator specifications
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rasidon 60mg film coated Tablet by Hilton (Reg.No. 93086) Rasidon 20mg film coated Tablet by Hilton (Reg.No. 93085) Rasidon 40mg film coated Tablet by Hilton (Reg.No. 89370) Rasidon 80mg film coated Tablet by Hilton (Reg.No. 89371)
	GMP status	Copy of certificate of GMP generated against inspection conducted on 09-01-2024 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceutical Co. Ltd.		
API Lot No.	0200-202009001		
Description of Pack (Container closure system)	Alu Alu 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 Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21PD-3885-02-T	21PD-3886-03-T	21PD-3887-04-T
Batch Size	2500 tabs	2500 tabs	2500 tabs
Manufacturing Date	08-21	08-21	08-21
Date of Initiation	02-09-2021	02-09-2021	02-09-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 20285 Dated 18-07-2022		

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	Submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 6 Months** (40°C ± 2°C &70±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.	Not submitted from regulatory authority of country of origin
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. ZY20102701G/W dated 27-10-2020 cleared by ADC (Karachi) dated 02-12-2020 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same. Applicant has submitted undertaking stating the same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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
154.	**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	Luridon Tablet 40mg
	Composition	Each film coated tablet contains: Lurasidone HCl…40mg
	Diary No. Date of R& I & fee	Dated 20-04-2017 (Duplicate), Rs. 50,000/- DS No. 0524794 (Duplicate)
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5D
	Finished product Specifications	Innovator specifications
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rasidon 60mg film coated Tablet by Hilton (Reg.No. 93086) Rasidon 20mg film coated Tablet by Hilton (Reg.No. 93085) Rasidon 40mg film coated Tablet by Hilton (Reg.No. 89370) Rasidon 80mg film coated Tablet by Hilton (Reg.No. 89371)
	GMP status	Copy of certificate of GMP generated against inspection conducted on 09-01-2024 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceutical Co. Ltd.		
API Lot No.	0200-202009001		
Description of Pack (Container closure system)	Alu Alu 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 Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21PD-3882-02-T	21PD-3883-03-T	21PD-3884-04-T
Batch Size	2500 tabs	2500 tabs	2500 tabs
Manufacturing Date	08-21	08-21	08-21
Date of Initiation	02-09-2021	02-09-2021	02-09-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. 20286 Dated 18-07-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status

•	Reference of previous approval of applications with stability study data of the firm	Submitted
•	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
•	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
•	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 6 Months** (40°C ± 2°C &70±5%RH) stability study reports of 03 batches.
•	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted from regulatory authority of country of origin
•	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. ZY20102701G/W dated 27-10-2020 cleared by ADC (Karachi) dated 02-12-2020 are submitted.
•	Protocols followed for conduction of stability study	Submitted
•	Method used for analysis of FPP	Submitted
•	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same. Applicant has submitted undertaking stating the same.
•	Complete batch manufacturing record of three stability batches.	Submitted
•	Record of comparative dissolution data (where applicable)	Not submitted.
•	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
•	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
•	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[xxiii]:

Sr. No.	Shortcomings	Response of applicant
i.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by	DML certificate of API manufacturer valid till 06-12-2025 issued by concerned

	concerned regulatory authority of country of origin shall be submitted.	regulatory authority of country of origin is submitted.
ii.	Real time Stability study data of API from API manufacturer shall be submitted for complete assigned shelf life of the API i.e 2years.	Submitted for 36 months.
iii.	Record of Comparative dissolution data shall be submitted.	The CDP data of Luridon 20mg Tablet, Luridon 40mg Tablet and Luridon 80mg Tablet is submitted against Latuda Tablets (PMDA, Japan Approved) of respective strengths. For CDP of Luridon 60mg Tablet, the applicant's response is as follows: "We would like to inform your kind authority that our products Lurasidone HCl 20mg Tablet, Lurasidone HCI 40mg Tablet, Lurasidone HCl 60mg Tablet and Lurasidone HCl 80mg Tablet are dose proportional in accordance with EMA Guidelines on the Investigation of Bioequivalence which states that: • The pharmaceutical products are manufactured by the same manufacturing process. • The qualitative composition of the different strengths is the same. • The composition of the strengths are quantitatively proportional, i.e. the ratio between the amounts of each excipient to the amount of active substance(s) is the same for all strengths. In view of the above, we have benchmarked Latuda 20mg Tablet as reference product for Lurasidone HCl 60mg Tablet." *The guidelines cited by the applicant refer to biowaivers. The guidelines are not applicable to in-vitro comparative dissolution testing.*

Decision: Registration Board approved the applications of Luridon Tablet 60mg , Luridon Tablet 80mg , Luridon Tablet 20mg & Luridon Tablet 40mg. Registration letter of Luridon Tablet 60mg shall be issued after submission of satisfactory record of comparative dissolution profile report and associated data of Luridon 60mg tablet with the reference product.

155.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name +Dosage Form + Strength	Solif-T MR 0.4+6mg
	Composition	Each bilayered modified release film-coated tablet Contains:

		Solifenacin succinate eq. to Solifenacin…6mg Tamsulosin Hydrochloride eq. to Tamsulosin…0.4mg
	Diary No. Date of R& I & fee	Dy.No. 4862 dated 06-06-2017 (Duplicate), Rs.20,000/- Deposit Slip No.0798047 (Duplicate).
	Pharmacological Group	Alpha-Adrenoceptor antagonist
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's ,28's 30's/ As per PRC
	Approval status of product in Reference Regulatory Authorities	Vesomni Tablet by M/s Astellas Pharma Ltd., EMA Approved. Mingerlan 6 mg/0.4 mg, modified-release tablets (Approved in Germany)
	Me-too status	Tamsolin -S by M/s Getz Pharma (Reg.No. 89374)
	GMP status	Copy of certificate of GMP dated 13-06-2023 is submitted.

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: RD0171-012 Solifenacin Succinate: RD0172-008		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21SB(B)-284-01	21SB(B)-285-02	21SB(B)-286-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	20-12-2021	20-12-2021	20-12-2021
No. of Batches	03		
Date of Submission of stability data	Dy No.33614 Dated 22-11-2022		

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 Wymly Tablet 25mg Tablets which was conducted on 09th April, 2018 and was presented in 281st meeting of Registration Board held on 11th April-13th April, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available • The firm possesses stability chambers with adequate monitoring and control.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Solifenacin succinate granules: RD0172-008 Tamsulosin granules: RD0171-012
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 60 Months** (40°C ± 2°C &70±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.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product against the reference product Vesommi Tablet 10mg Tablet
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[xxiii]:		

Sr. No.	Shortcomings
1.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
2.	Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.
3.	Label claim shall be changed according to reference product, as follows along with submission of full fee of registration: Each modified-release tablet contains: Solifenacin succinate 6mg, corresponding to 4.5 mg solifenacin Tamsulosin hydrochloride 0.4 mg corresponding to 0.37 mg tamsulosin.
4.	Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosin granules as "modified release" and does not include test of dissolution hence it is not evident that the Tamsulosin granules are modified release or otherwise. Justification shall be submitted in this regard.
5.	Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.
6.	Details shall be submitted clearly stating the measures adopted during the manufacturing process to: • modify the drug release of Tamsulosin in the finished product, • obtain bilayer tablet.

Decision: Deferred for submission of following:

- **Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin,**
- **Documents confirming import of drug substance used for formulation of stability batches duly attested by DRAP,**
- **Clarification regarding immediate release & modified release layer of the dosage form in the label claim,**
- **Clarification regarding Tamsulosin granules, whether they are modified release granules or otherwise,**
- **Measures adopted during the manufacturing process to modify the drug release of Tamsulosin in the finished product and to obtain bilayer tablet,**
- **Change in label claim according to reference product, as follows along with submission of full fee of registration:**
  "Each modified-release tablet contains:
  Solifenacin succinate 6mg, corresponding to 4.5 mg Solifenacin
  Tamsulosin hydrochloride 0.4 mg corresponding to 0.37 mg Tamsulosin".

156.	**Name and address of manufacturer / Applicant**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Sunny D Tablet 30,000 IU
	Composition	Each Film Coated Tablet Contains: Cholecalciferol…30,000 IU
	Diary No. Date of R& I & fee	Dy.No. 32069 dated 26-09-2018, Rs.50,000/- dated 26-09-2018
	Pharmacological Group	Vitamin
	Type of Form	Form 5D

	Finished product Specifications	Not submitted
	Pack size & Demanded Price	As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	Not submitted
	Me-too status	Not submitted
	GMP status	Not submitted

STABILITY STUDIES DATA

Manufacturer of API	Not submitted		
API Lot No.	Not submitted		
Description of Pack (Container closure system)	Not submitted		
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 (month) Real Time: 0,3,6 (month)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	28-01-2022	28-01-2022	28-01-2022
No. of Batches	03		
Date of Submission of stability data	Dy No.31972 Dated 04-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Not submitted

4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7.	Protocols followed for conduction of stability study	Not submitted
8.	Method used for analysis of FPP	Not submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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[xxiii]: Applicant shall submit consolidated and complete stability studies data as per decision of 293rd meeting of RB		
Decision: Deferred for submission of consolidated and complete stability studies data as per decision of 293rd meeting of RB.		

b. Deferred cases/ Verification of stability study data/ Exemption from onsite verification of stability data

157.	Name and address of manufacturer/ Applicant	**M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Vortox Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide 12.7 Eq. to Vortioxetine…10mg
	Diary No. Date of R & I & fee	Dy. No 12537 dated 05-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications

	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Brintellix 10mg tablet by M/s Lundebeck
	GMP status	GMP inspection dated 04-07-2018 concluding good GMP compliance.
158.	Name and address of manufacturer/ Applicant	**M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.**
	Brand Name + Dosage Form + Strength	Vortox Tablet 20mg
	Composition	"Each Film Coated Tablet Contains: Vortioxetine hydrobromide 25.42 Eq. to Vortioxetine…20mg"
	Diary No. Date of R & I & fee	Dy. No 12538 dated 05-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Brintellix 10mg tablet by M/s Lundebeck
	GMP status	GMP inspection dated 04-07-2018 concluding good GMP compliance.
	Decision of 290th meeting of RB:	Registration Board reviewed the previous decision and deferred the cases of Vortox 10mg tablet and Vortox 20mg tablet for submission of stability studies as directed by Registration Board in its 278th meeting.
	Remarks of Evaluator:	iii. Complete Stability study data is required as per the guidelines approved in 293rd meeting of Registration Board. iv. Valid GMP certificate of applicant shall be submitted.
	Decision: Deferred for submission of the following: • **Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board,** • **Valid GMP certificate of applicant.**	

159.	**Name and address of manufacture / Applicant**	**M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan**
	Brand Name + Dosage Form and Strength	Luras 40mg Tablet
	Composition	Each Tablet Contains: Lurasidone as HCl……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7282 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti-psychotic
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LATUDA (20mg, 40mg, 60mg, 80mg, 120mg) film coated tablets USFDA Approved
	Me-too-status	Luda 40mg tablets of Genome pharmaceuticals (Reg#095154)
	GMP Status	The firm was inspected on 04-07-2018 and conclusion of inspection was: Based on above observations their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm revised the formulation from uncoated to film coated tablets and submitted revised master formulation. The firm also revised the label claim without considering the salt factor along with submission of Rs. 5000/- on deposit slip No# 2032872 dated 01.02.2021. the revised label claim is as under: Each Film Coated Tablet Contains: Lurasidone HCl……..…40mg • Submit stability studies data as per the guidelines approved in 293rd meeting of Registration Board.
160.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Luras 80mg Tablet
	Composition	Each Tablet Contains: Lurasidone as HCl…….80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7283 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti-psychotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LATUDA (20mg, 40mg, 60mg, 80mg, 120mg) film coated tablets USFDA Approved
	Me-too-status	Luda 80mg tablets of Genome pharmaceuticals (Reg#095155)
	GMP Status	The firm was inspected on 04-07-2018 and conclusion of inspection was: Based on above observations their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm revised the formulation from uncoated to film coated tablets and submitted revised master formulation. The firm also revised the label claim without considering the salt factor along with submission of Rs. 5000/- on deposit slip No# 2032873 dated 01.02.2021. the revised label claim is as under: Each Film Coated Tablet Contains: Lurasidone HCl……..…80mg • Submit stability studies data as per the guidelines approved in 293rd meeting of Registration Board.
	Decision of 307th meeting of RB:	**Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**
	Remarks of Evaluator:	i. Complete Stability study data is required as per the guidelines approved in 293rd meeting of Registration Board. ii. Valid GMP certificate of applicant shall be submitted.
	Decision: Deferred for submission of the following: • **Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board,** • **Valid GMP certificate of applicant.**	

161.	Name and address of manufacturer/ Applicant	**M/s NABIQASIM INDUSTRIES (PVT) LTD.** 17 / 24, Korangi Industrial Area,

		Karachi – Pakistan.
	Brand Name + Dosage Form + Strength	Depxet tablet 5mg
	Composition	Each film coated tablet contains: Vortioxetine Hydrobromide… 5mg
	Diary No. Date of R & I & fee	Dy. No 17712 dated 14-5-2018 ; Rs. 20,000/- dated 14-5-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 5mg (FDA Approved)
	Me-too status	Brintellix tablet
	GMP status	GMP certificate issued on 22-05-2023 on the basis of inspection conducted on 22-05-2023.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm is required
	Decision of 290th meeting of RB:	Deferred for submission of application along with stability studies & requisite Form

STABILITY STUDY DATA

Drug	Depxet tablet 5mg		
Manufacturer of API	Lianyungang Jari Pharmaceutical		
API Lot No.	3804-201803001		
Description of Pack (Container closure system)	Alu-PVC blister 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)		
Batch No.	323DS01	323DS02	323DS03
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	25-01-2020	25-01-2020	25-01-2020
No. of Batches	03		
Date of Submission	30-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for SOVIR-C Tablet (Sofosbuvir 400mg) ,

<table>
<tr><td></td><td></td><td>for which the inspection was conducted on 27-10-2020 and the report was presented in 297th meeting of Registration Board. The report confirms following points:
iii. The HPLC software is 21CFR compliant.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.</td><td>Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of Accelerated stability studies (40°C ± 2°C & 75±5% RH) for 06 Months & Long-Term on Zone IV-B (30°C ± 2°C & 75±5% RH) for 36 months of 03 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>The Firm has submitted copy of DML & GMP Certificate of manufacturer “Lianyungang Jari Pharmaceuticals “
GMP: Valid up to 29-11-2024</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted Copy of Commercial Invoice (invoice no.ZY18031602G1W) attested by AD (I&E) DRAP dated 14-05-2018 has been submitted for 700g of Vortioxetine hydrobromide.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols followed for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A (As per Innovator’s Formulation)</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record for all batches.</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 “Vorneu tablet”.

The details are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of Hilton Pharma</th></tr>
<tr><td>Brand name</td><td>Vorneu tablet 5mg</td><td>Depxet tablet 5mg</td></tr>
<tr><td>Batch No.</td><td>138718</td><td>323DS011</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. 0.1N HCl pH 1.2
2. Acetate buffer pH 4.5
3. Phosphate buffer pH 6.8</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.	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.	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
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 (real time and accelerated)
Remarks of Evaluator:		
Decision: Approved. Firm shall submit requisite differential fee prior to issuance of Registration letter.		

162.	Name and address of manufacturer/ Applicant	**M/s NABIQASIM INDUSTRIES (PVT) LTD.** 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Brand Name + Dosage Form + Strength	Depxet tablet 10mg
	Composition	Each film coated tablet contains: Vortioxetine Hydrobromide… 10mg
	Diary No. Date of R & I & fee	Dy. No - dated ; Rs. 20,000/- dated 14-5-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 5mg (FDA Approved)
	Me-too status	Brintellix tablet
	GMP status	GMP certificate issued on 22-05-2023 on the basis of inspection conducted on 22-05-2023.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is required
	Decision of 290th meeting of RB:	Deferred for submission of application along with stability studies & requisite Form

STABILITY STUDY DATA

Drug	Depxet tablet 10mg
Manufacturer of API	Lianyungang Jari Pharmaceutical
API Lot No.	3804-201803001
Description of Pack (Container closure system)	Alu-PVC blister 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: 12 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)

Batch No.	324DS01	324DS02	324DS03
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	25-01-2020	25-01-2020	25-01-2020
No. of Batches	03		
Date of Submission	30-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for SOVIR-C Tablet (Sofosbuvir 400mg) , for which the inspection was conducted on 27-10-2020 and the report was presented in 297th meeting of Registration Board. The report confirms following points: iv. The HPLC software is 21CFR compliant.
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	The firm has submitted copy of **Accelerated stability studies** (40°C ± 2°C & 75±5% RH) for **06 Months** & **Long-Term on Zone IV-B** (30°C ± 2°C & 75±5% RH) for **36 months** of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The Firm has submitted copy of DML & GMP Certificate of manufacturer "Lianyungang Jari Pharmaceuticals " **GMP: Valid up to 29-11-2024**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Commercial Invoice (invoice no.ZY18031602G1W) attested by AD (I&E) DRAP dated 14-05-2018 has been submitted for 700g of Vortioxetine hydrobromide.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols followed for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.
9.	Drug-excipients compatibility studies (where applicable)	N/A (As per Innovator's Formulation)
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted Comparative dissolution study of their product against "Vorneu tablet".

		The details are as follows: <table><tr><th>Feature</th><th>Reference product</th><th>Product of Hilton Pharma</th></tr><tr><td>Brand name</td><td>Vorneu tablet 10mg</td><td>Depxet tablet 10mg</td></tr><tr><td>Batch No.</td><td>138682</td><td>324DS01</td></tr></table> Comparative dissolution studies have been performed in following mediums: 4. 0.1N HCl pH 1.2 5. Acetate buffer pH 4.5 6. Phosphate buffer pH 6.8
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.	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
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 (real time and accelerated)
Remarks of Evaluator:		
Decision: Approved.		

163.	Name and address of manufacturer/ Applicant	**M/s NABIQASIM INDUSTRIES (PVT) LTD.** 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Brand Name + Dosage Form + Strength	Depxet tablet 15mg
	Composition	Each film coated tablet contains: Vortioxetine Hydrobromide… 15mg
	Diary No. Date of R & I & fee	Dy. No - dated ; Rs. 20,000/- dated 14-5-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 15mg (FDA Approved)
	Me-too status	Brintellix tablet
	GMP status	GMP certificate issued on 22-05-2023 on the basis of inspection conducted on 22-05-2023.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is required
412.	Decision of 290th meeting of RB:	Deferred for submission of application along with stability studies & requisite Form
STABILITY STUDY DATA		
Drug	Depxet tablet 15mg	

Manufacturer of API	Lianyungang Jari Pharmaceutical		
API Lot No.	3804-201803001		
Description of Pack (Container closure system)	Alu-PVC blister 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)		
Batch No.	325DS01	325DS02	325DS03
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	25-01-2020	25-01-2020	25-01-2020
No. of Batches	03		
Date of Submission	30-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for SOVIR-C Tablet (Sofosbuvir 400mg) , for which the inspection was conducted on 27-10-2020 and the report was presented in 297th meeting of Registration Board. The report confirms following points: v. The HPLC software is 21CFR compliant.
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	The firm has submitted copy of **Accelerated stability studies** (40°C ± 2°C & 75±5% RH) for **06 Months** & **Long-Term on Zone IV-B** (30°C ± 2°C & 75±5% RH) for **36 months** of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The Firm has submitted copy of DML & GMP Certificate of manufacturer "Lianyungang Jari Pharmaceuticals " **GMP: Valid up to 29-11-2024**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Commercial Invoice (invoice no.ZY18031602G1W) attested by AD (I&E) DRAP dated 14-05-2018 has been submitted for 700g of Vortioxetine hydrobromide.

<table>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols followed for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A (As per Innovator’s Formulation)</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record for all batches.</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 “Vorneu tablet”.

The details are as follows:<table><tr><th>Feature</th><th>Reference product</th><th>Product of Hilton Pharma</th></tr><tr><td>Brand name</td><td>Vorneu tablet 15mg</td><td>Depxet tablet 15mg</td></tr><tr><td>Batch No.</td><td>139239</td><td>325DS01</td></tr></table>
Comparative dissolution studies have been performed in following mediums:
7. 0.1N HCl pH 1.2
8. Acetate buffer pH 4.5
9. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing</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>Firm has submitted Record of Digital data logger for temperature and 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. Firm shall submit requisite differential fee prior to issuance of Registration letter.</td></tr>
</table>

164.	Name and address of manufacturer/ Applicant	**M/s NABIQASIM INDUSTRIES (PVT) LTD.** 17 / 24, Korangi Industrial Area, Karachi – Pakistan
	Brand Name + Dosage Form + Strength	Depxet tablet 20mg
	Composition	Each film coated tablet contains: Vortioxetine Hydrobromide… 20mg
	Diary No. Date of R & I & fee	Dy. No - dated ; Rs. 20,000/- dated 14-5-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 20mg (FDA Approved)
	Me-too status	Brintellix tablet
	GMP status	GMP certificate issued on 22-05-2023 on the basis of inspection conducted on 22-05-2023.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is required
413.	Decision of 290th meeting of RB:	Deferred for submission of application along with stability studies & requisite Form

STABILITY STUDY DATA

Drug	Depxet tablet 20mg		
Manufacturer of API	Lianyungang Jari Pharmaceutical		
API Lot No.	3804-201803001		
Description of Pack (Container closure system)	Alu-PVC blister 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)		
Batch No.	326DS01	326DS02	326DS03
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	25-01-2020	25-01-2020	25-01-2020
No. of Batches	03		
Date of Submission	30-12-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Last Product Specific Inspection of the firm was conducted for SOVIR-C Tablet (Sofosbuvir 400mg) for which the inspection was conducted on 27-10-2020 and the report was presented in 297th meeting of Registration Board. The report confirms following points: vi. The HPLC software is 21CFR compliant.
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.

<table>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of Accelerated stability studies (40°C ± 2°C & 75±5% RH) for 06 Months & Long-Term on Zone IV-B (30°C ± 2°C & 75±5% RH) for 36 months of 03 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>The Firm has submitted copy of DML & GMP Certificate of manufacturer “Lianyungang Jari Pharmaceuticals “
GMP: Valid up to 29-11-2024</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted Copy of Commercial Invoice (invoice no.ZY18031602G1W) attested by AD (I&E) DRAP dated 14-05-2018 has been submitted for 700g of Vortioxetine hydrobromide.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols followed for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>N/A (As per Innovator’s Formulation)</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record for all batches.</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 “Vorneu tablet”.

The details are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of Hilton Pharma</th></tr>
<tr><td>Brand name</td><td>Vorneu tablet 20mg</td><td>Depxet tablet 20mg</td></tr>
<tr><td>Batch No.</td><td>138698</td><td>326DS01</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
10. 0.1N HCl pH 1.2
11. Acetate buffer pH 4.5
12. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing</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>Firm has submitted Record of Digital data logger for temperature and 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.</td></tr>
</table>

<table>
<tr><td>165.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Dynatis Pakistan (Pvt) Ltd. Plot No.710 Sundar Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>BEGREM Tablet 50 mg</td></tr>
<tr><td></td><td>Composition</td><td>Each film coated tablet contains:
Mirabegron……..50 mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy.No. 12381 dated 06-03-2019, Rs.20,000/- Deposit Slip No. (Copy).
Differential fee: Rs.22,500/- Deposit Slip No.3123696531.</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Urological</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished product Specifications</td><td>In house specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>30’s, As per DPC/SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities</td><td>MYRBETRIQ 50 mg (mirabegron extended-release film-coated tablet), USFDA approved.</td></tr>
<tr><td></td><td>Me-too status</td><td>Mirabet Tablet 50mg, Reg# 090503, CCL Pharmaceuticals, Lahore.</td></tr>
<tr><td></td><td>GMP status</td><td>Inspection for DML renewal was conducted on 28-03-2024.</td></tr>
<tr><td></td><td>Remark of the Evaluator XVI</td><td><table><tr><td>Firm has mentioned Methylene chloride in their master formulation and manufacturing method, letter was issued to firm for submission of revised formulation.</td><td rowspan="3">Firm has submitted revised form -5 mentioning:
“Each extended release tablet contains:
Mirabegron……...50 mg along with revised master formulation and manufacturing method along with fee challan No. 005459348 of 7500/=dated 23-02-2022.
Firm has provided stability data which will be processed as per que.</td></tr><tr><td>The available RRA product is Extended release tablet dosage form whereas per submitted form-5, this is regular release tablet.</td></tr><tr><td>Stability study data required as per the guidelines approved in 293rd meeting of Registration Board</td></tr></table></td></tr>
<tr><td></td><td>Decision of 316th meeting of RB:</td><td>Deferred for following;
• Evaluation of Stability data on its turn.
• Firm shall submit differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from immediate release tablet to extended release tablet), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API	M/s Anhui Haikang Pharmaceutical Co., Ltd, China.		
API Lot No.	Mirabegron: 20051001		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	TDN004	TDN003	----------
Batch Size	5000 Tablets	5000 Tablets	----------
Manufacturing Date	10-2020	10-2020	----------
Date of Initiation	28-10-2020	28-10-2020	----------
No. of Batches	03		
Date of Submission of stability data	Dy No. 20925 Dated 25-07-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of CoA of Batch No. 20051001 from M/s Anhui Haikang Pharmaceutical Co., Ltd, China is submitted. Copy of CoA of Batch No. 20051001 from M/s Dynatis Pakistan (Pvt) Ltd is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 24 Months** (40°C ± 2°C &70±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. 20190399 for M/s Anhui Haikang Pharmaceutical Co., Ltd, China issued by Anhui Provincial Drug Administration, PRC, valid till 31-12-2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form 6 and Commercial Invoice No. WD202003005 dated 28-07-2020 cleared by DRAP field office, Lahore dated 13-08-2020 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted

9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product Mybega 50mg Extended release Tablet of M/s Getz Pharma Ltd in 3 dissolution media. The value for similarity factor is in the acceptable range.
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

166.	**Name and address of manufacturer / Applicant**	**M/s Dynatis Pakistan (Pvt) Ltd. Plot No.710 Sundar Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	BEGREM Tablet 25 mg
	Composition	Each film coated tablet contains: Mirabegron……..25 mg
	Diary No. Date of R& I & fee	Dy.No. 12380 dated 06-03-2019, Rs.20,000/- Deposit Slip No. (Copy). Differential fee: Rs.22,500/- Deposit Slip No.79834949.
	Pharmacological Group	Urological
	Type of Form	Form 5
	Finished product Specifications	In house specifications
	Pack size & Demanded Price	30's, As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 25 mg (mirabegron extended-release tablet), USFDA approved.
	Me-too status	Mirabet Tablet 50mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	Last GMP inspection is conducted on 26-03-2021 and GMP certificate has been issued to firm on 01-07-2021.
	Remark of the Evaluator XVI	Firm has mentioned Methylene chloride in their master formulation and manufacturing method, letter was issued Firm has submitted revised form -5 mentioning: "Each extended release tablet contains:

		to firm for submission of revised formulation.	Mirabegron……...50 mg along with revised master formulation and manufacturing method along with fee challan No. 005459348 of 7500/=dated 23-02-2022. Firm has provided stability data which will be processed as per que.
		The available RRA product is Extended release tablet dosage form whereas per submitted form-5, this is regular release tablet.	
		Stability study data required as per the guidelines approved in 293RD meeting of Registration Board	
	Decision of 316th meeting of RB:	Deferred for following; • Evaluation of Stability data on its turn. • Firm shall submit differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from immediate release tablet to extended release tablet), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.	

STABILITY STUDY DATA

Manufacturer of API	M/s Anhui Haikang Pharmaceutical Co., Ltd, China.		
API Lot No.	Mirabegron: 20051001		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	TDM006	TDM007	----------
Batch Size	5000 Tablets	5000 Tablets	----------
Manufacturing Date	10-2020	10-2020	----------
Date of Initiation	28-10-2020	28-10-2020	----------
No. of Batches	03		
Date of Submission of stability data	Dy No. 20924 Dated 25-07-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of CoA of Batch No. 20051001 from M/s Anhui Haikang Pharmaceutical Co., Ltd, China is submitted. Copy of CoA of Batch No. 20051001 from M/s Dynatis Pakistan (Pvt) Ltd is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 24 Months** (40°C ± 2°C &70±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. 20190399 for M/s Anhui Haikang Pharmaceutical Co., Ltd, China issued by Anhui Provincial Drug Administration, PRC, valid till 31-12-2025 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form 6 and Commercial Invoice No. WD202003005 dated 28-07-2020 cleared by DRAP field office, Lahore dated 13-08-2020 are submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product Mybega 50mg Extended release Tablet of M/s Getz Pharma Ltd in 3 dissolution media. The value for similarity factor is in the acceptable range.
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[xxiii]:

- Applicant has submitted differential fee. Details are added in the relevant column.
- Title of the applicant was changed from M/s Dynatis Pakistan Pvt Ltd to M/s CCL Pharmaceuticals (Pvt) Ltd vide Letter No. F.1-22/2013-Lic (Vol-I) dated 29-April-2024.

Sr. No.	**Shortcomings**	**Response of applicant**

i.	The recommended sampling time intervals for Mirabegron Extended release tablet are 1, 3, 5, 7, 8.5, 10 and 12 hours according to USFDA Dissolution database whereas applicant has given sampling intervals of 3, 5, 8.5 and 12 hours. Justification shall be submitted.	Time points for testing were chosen based on a thorough literature review of the USFDA Clinical Pharmacology and Biopharmaceutics review (Application No. 202611Orig1s000), a copy of which is submitted. Furthermore, in compliance with USP <1092>, three time points (3 hours, 5 1 hours, and 8.5 hours) were selected to encompass the early, intermediate, and final stages of dissolution, with an additional time point at 12 hours to ensure comprehensive coverage.
Decision: Approved. Applicant shall submit requisite fee for change of title of firm for each strength, prior to issuance of Registration letter.		

Agenda of Ms. Najia Saleem

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

a. Original dossiers/duplicate dossiers with verified receipt in DRAP

168.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Akima 250mg/2ml Injection
	Composition	Each 2ml ampule contains: Amikacin as Sulphate…250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12928 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	aminoglycosides
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml x 1's;As per SRO
	RRA status	Amikacin solution for Injection Manufacturer Hospira UK Limited **MHRA approved**
	Me-too status	Grasil of M/s Sami Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved.	
169.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	Akima 100mg/2ml Injection
	Composition	Each 2ml ampule contains: Amikacin as Sulphate…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12920 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	aminoglycosides
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml x 1's;As per SRO
	RRA status	AMIKACIN 500mg/2ml Injection **MHRA approved**
	Me-too status	Grasil of M/s Sami Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved.	
170.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gemifloxate 320mg Tablet
	Composition	Each film coated tablet contains: Gemifloxacin as Mesylate…320mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12855 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Fluoroquinolone
	Finished product Specifications	EG specs
	Pack size & Demanded Price	7's;As per SRO
	RRA status	Factive USFDA with status **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Me-too status	Crohit 320mg tablet of M/s Horizon Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
171.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Memaneg 10mg Tablet
	Composition	Each film coated tablet contains: Memantine HCl…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12869 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	NMDA antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	56's;As per SRO

	RRA status	HPRA Ireland approved
	Me-too status	Synaptol 10mg tablet of M/s Medisure Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved.	
172.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Quitpain 50mg/ml Injection
	Composition	Each 1ml ampoule contains: Tramadol as HCl…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12905 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Opiate analogue
	Finished product Specifications	EG specs
	Pack size & Demanded Price	5's; As per SRO
	RRA status	MHRA approved
	Me-too status	Ramol of M/s Macter Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications and change of brand name. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
173.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Droqvine 40/320mg capsule
	Composition	Each capsule contains Dihydroartemisinin…40mg Piperaquine Phosphate…320mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 12923 dated 06-03-2019 Rs.50,000/- dated 05-03-2019
	Pharmacological Group	Anti-malarial
	Finished product Specifications	EG specs
	Pack size & Demanded Price	8's; As per SRO
	RRA status	**Could not be confirmed as capsule dosage form**
	Me-too status	Temquin Capsule of M/s Searle IV Solutions (Pvt) Ltd. (078603)
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

174.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Tolmex 200mcg Tablet
	Composition	Each tablet contains: Misoprostol…200mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12912 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAID
	Finished product Specifications	EG specs
	Pack size & Demanded Price	10's; As per SRO
	RRA status	Cytotec tablet 200mcg of GD Searle USFDA
	Me-too status	Prosotec tablet 200mcg of M/s Atco Labs
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	API not used as HPMC dispersion form
	Decision: Approved with Intl. Pharmacopoeia specifications and with following label claim in line with reference product: **Each Tablet Contains:** **Misoprostol Dispersion eq. to Misoprostol……200 mcg** **Moreover, firm shall submit the following before issuance of registration letter:** • **Revised form 5 along with master formula and method of manufacturing** • **Fee Rs. 37,000/- for pre-approval change/correction of formulation and FPP specifications.**	
175.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Empatin Tablet 10mg/5mg
	Composition	Each film coated tablet contains: Empagliflozin…10mg Linagliptin…5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12909 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Anti-diabetic drug
	Finished product Specifications	EG specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	Glyxambi
	Me-too status	Glem-Lin Tablet 10mg/5mg of M/s Nabiqasim Industries Karachi. 114371
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	**Shortcomings:** • **Stability studies data** not submitted.
	Decision: Registration Board rejected the instant application since the firm has not submitted stability study data of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
176.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	Navilol 2.5mg Tablet
	Composition	Each tablet contains: Nebivolol as HCl…2.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12854 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Selective beta-1 antagonist
	Finished product Specifications	EG specs
	Pack size & Demanded Price	10's; As per SRO
	RRA status	MHRA approved
	Me-too status	Byscard of M/s Searle Pharmaceuticals
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
177.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Atroez Tablet 10/40mg
	Composition	Each film coated tablet contains: Ezetimibe…10mg Atorvastatin…40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12927 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Cholesterol lowering drug/ HMG-CoA reductase
	Finished product Specifications	EG specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	Liptruzet (USA)
	Me-too status	Simazit 10/40mg Tablet of M/s Wenovo Pharmaceuticals, Rawalpindi (118961)
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
178.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Topimeg 50mg Tablet
	Composition	Each film coated tablet contains: Topiramate…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12867 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Sulphamate anti-epileptic
	Finished product Specifications	EG specs

	Pack size & Demanded Price	10's, 20's, 60's; As per SRO
	RRA status	Topamax USA
	Me-too status	Amtec of M/s Sharooq
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
179.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Axepime 2g Injection
	Composition	Each vial contains: Cefepime (as HCl with L-Arginine)…2gram
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12862 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Cephalosporin antibiotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1 vial; As per SRO
	RRA status	Maxipime
	Me-too status	Cefi 2gm, Evercef
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	Cephalosporin dry powder Injection
	Decision: Approved.	
180.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Oricoxin 60mg Tablet
	Composition	Each film coated tablet contains: Etoricoxib…60mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12861 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Cyclooxygenase inhibitor
	Finished product Specifications	EG specs
	Pack size & Demanded Price	10's; As per SRO
	RRA status	Arcoxia UK
	Me-too status	Arcox
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
181.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	Meloximil 10/40mg Tablet
	Composition	Each tablet contains: Olmesartan Medoxomil…40mg Amlodipine (as besylate)…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12918 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Angiotensin II antagonist/ calcium antagonist
	Finished product Specifications	EG specs
	Pack size & Demanded Price	20's; As per SRO
	RRA status	Azor tablets USFDA
	Me-too status	Olesta-AM 10mg+40mg Tablet of M/s The Searle Company Limited (076190)
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
182.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Evosul 25mg Tablet
	Composition	Each film coated tablet contains: Levosulpiride…25mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12916 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Antipsychotic/ gastroprokinetic
	Finished product Specifications	EG specs
	Pack size & Demanded Price	2x10's; As per SRO
	RRA status	Levobren Italy
	Me-too status	C-pride
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
183.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Letrocid 2.5mg Tablet
	Composition	Each film coated tablet contains: Letrozole…2.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12864 dated 06-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Non-steroidal aromatase inhibitor
	Finished product Specifications	USP specs

	Pack size & Demanded Price	10's, 30's; As per SRO
	RRA status	Femara MHRA
	Me-too status	Losiral of M/s CCL Pharmaceuticals (Pvt.) Ltd. 053873
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
184.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Densetron 4mg/2ml Injection
	Composition	Each 2ml ampule contains: Ondansetron as HCl Dihydrate…4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12921 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	5HT3 antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml x 5's; As per SRO
	RRA status	Zofran
	Me-too status	Ondisan
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
185.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Skabval 97/103mg Tablet
	Composition	Each tablet contains: Sacubitril…97mg Valsartan…103mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy.No 12914 dated 06-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Neprilysin inhibitor and angiotensin II blocker
	Finished product Specifications	EG specs
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	RRA status	Entresto
	Me-too status	Verisar Tablet 97/103mg of M/s Nabiqasim Industries Pvt. Ltd., Karachi. 114607
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	**Stability data not submitted**

	Decision: Registration Board rejected the instant application since the firm has not submitted stability study data of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
186.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Omepra Plus capsule
	Composition	Each capsule contains: Omeprazole ….20mg Sodium Bicarbonate ….1100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Duplicate dossier Dy. No 8266 dated 07-08-2012 Rs. 5000/-dated 19-12-2019 (Original) Rs. 7000/-dated 06-09-2012 (photocopy) **verified vide Dy. No. 8759 dated 06-09-2012** Rs.8000/- dated 03-09-2012 (photocopy) **verified vide Dy. No. 8640 dated 03-09-2012**
	Pharmacological Group	PPI, Antacid
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	Zegrid USFDA approved
	Me-too status	Omigood 20/1100mg Capsule of M/s Goodman Laboratories, Rawat. (115606)
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challans of fee Rs. 7000/- and Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
187.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Pamid Injection
	Composition	Each ml contains: Pamidronate Disodium …. 3mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 8631 dated 03-09-2012 **(Original dossier)** Rs.8000/- (Original) Rs.12000/- (Original) Dy No.32046 -R&I dated 29-01-2020
	Pharmacological Group	Diphosphonate
	Finished product Specifications	EG specs
	Pack size & Demanded Price	10ml Vial, As per SRO
	RRA status	USFDA
	Me-too status	Dronopam Injection 30mg of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd., Karachi (103020)
	GMP status	Follow up inspection for CAPA verification dated 25-08-2022, the panel recommended resumption of production in compliance with GMP production.
	Remarks of the Evaluator	

	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval variation in FPP specifications before issuance of registration letter.	
188.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Indutrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Crotosone Cream
	Composition	Each gram contains: Crotamiton ….10%w/w Hydrocortisone ….0.25%w/w
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16862 dated 06-07-2023 **(Duplicate dossier) verified vide Dy. No 341 dated 20-02-2013 from R&I** Rs. 20000/- dated 19-02-2013 (**duplicate challan**)
	Pharmacological Group	Antipruritic/antiseptic/ corticosteroid
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	15gm tube or As per SRO; As per SRO
	RRA status	Eurax HC cream UK
	Me-too status	Eurax HC cream, Crotomite HC
	GMP status	Panel inspection for GMP compliance dated 26-08-2024
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
189.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Indutrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	F Sid ointment
	Composition	Each gram contains: Fusidic acid (as sodium fusidate)….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16846 dated 06-07-2023 **(Duplicate dossier) verified vide Dy. No 349 dated 20-02-2013 from R&I** Rs. 20000/- dated 19-02-2013 (**duplicate challan**)
	Pharmacological Group	Antibacterial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5gm and 15gm; As per SRO
	RRA status	Fucidin ointment Australia
	Me-too status	Fucidin ointment (Reg. No. 15538)
	GMP status	Panel inspection for GMP compliance dated 26-08-2024
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
190.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Indutrial Estate Riawind Road, Lahore.

	Brand Name +Dosage Form + Strength	F sid-B cream
	Composition	Each gram contains: Fusidic acid ….20mg Betamethasone as valerate….1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16863 dated 06-07-2023 **(Duplicate dossier) verified vide Dy. No 339 dated 20-02-2013 from R&I** Rs. 20000/- dated 19-02-2013 (**duplicate challan**)
	Pharmacological Group	Antibacterial/corticosteroid
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5gm and 15gm; As per SRO
	RRA status	Fucibet cream UK
	Me-too status	Fucicort cream (Reg. No. 015540)
	GMP status	Panel inspection for GMP compliance dated 26-08-2024
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
191.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Indutrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Technobet-RD ointment
	Composition	Each gram contains: Betamethasone valrate (B.P) equivalent to betamethasone 0.025%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16845 dated 06-07-2023 **(Duplicate dossier) verified vide Dy. No 348 dated 20-02-2013 from R&I** Rs. 20000/- dated 19-02-2013 (**duplicate challan**)
	Pharmacological Group	Corticosteroid
	Finished product Specifications	BP specs
	Pack size & Demanded Price	100gm; As per SRO
	RRA status	Betnovate RD ointment UK
	Me-too status	Betnovate RD ointment GSK
	GMP status	Panel inspection for GMP compliance dated 26-08-2024
	Remarks of the Evaluator	
	Decision: Approved. Registration letter shall be issued after fee verification as per procedure adopted by Registration Board in its 285th meeting.	
192.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Serlinz 600mg Tablet
	Composition	Each film coated tablet contains: Linezolid……..600mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10582 dated 27-04-2022 **(Duplicate dossier) verified vide Dy. No 10343 dated 08-11-2010 from R&I**

		Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Oxazolidinone, Antibiotics.
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	Zyvox UK
	Me-too status	Linzogen 600mg Tablet Reg. No. 117406
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Tablet (G) section** confirmed vide panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML.
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
193.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Serlinz 400mg Tablet
	Composition	Each film coated tablet contains: Linezolid……..400mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10581 dated 27-04-2022 **(Duplicate dossier) verified vide Dy. No 10344 dated 08-11-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Oxazolidinone, Antibiotics.
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	Zyvox UK
	Me-too status	Linzoheim 400mg Tablet Reg. No. 118854
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Tablet (G) section** confirmed vide panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML.
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
194.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Serlinz 200mg/100ml Infusion
	Composition	Each 100ml Infusion contains: Linezolid……..200mg
	Type of Form, Diary No. Date of R&	Form-5 Dy. No 10580 dated 27-04-2022

	I & fee	**(Duplicate dossier) verified vide Dy. No 10342 dated 08-11-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Oxazolidinone, Antibiotics.
	Finished product Specifications	Neutro specs
	Pack size & Demanded Price	As per SRO
	RRA status	Zyvox 200mg/100ml USFDA
	Me-too status	Adylinz Infusion 200mg/100ml (IV) of M/s Saydon Pharmaceutical Industries (Pvt) Ltd, Peshawar. 115878
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Liquid injectable ampoule/vial (G) section** confirmed vide panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML.
	Decision: Approved with as per innovator's specifications. Registration Board further decided that letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
195.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Grani Injection
	Composition	Each 1ml contains: Granisetron as HCl…..1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10860 dated 29-04-2022 **(Duplicate dossier) verified vide Dy. No 8155 dated 31-12-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	5-HT3 Receptor antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	5's x 1ml, As per SRO
	RRA status	MHRA approved
	Me-too status	Granon Solution for Injection of M/s Biocare Pharmaceutica, Lahore. (114214)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Liquid injectable ampoule/vial (G) section** confirmed vide panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML.
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of registration letter.	
196.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.

	Brand Name +Dosage Form + Strength	Fluzol infusion
	Composition	Each ml contains: Fluconazole…2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10859 dated 29-04-2022 **(Duplicate dossier) verified vide Dy. No 839 dated 31-12-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Antifungal
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA approved
	Me-too status	Fluwan Infusion 100mg/50ml (115653) of M/s Swan Pharmaceutical Pvt Ltd, Islamabad
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Already registered for the applicant FC-Zole Infusion 200mg /100ml Reg. No. 118975 in 100ml pack size.**
	Decision: Registration Board rejected instant application as firm already holds registration of FC-Zole Infusion 200mg /100ml (Fluconazole) vide Reg. No. 118975.	
197.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Cholrid-10mg Tablets
	Composition	Each tablet contains: Simvastatin…..10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9909 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8202 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Anti-hyperlipidemic agent
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	Zocor tablets USFDA approved
	Me-too status	Simvax 10mg f/c Tablet Evolution Pharmaceuticals (Pvt.) Ltd. (111793)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	Film coated tablet in RRA
	Decision: Approved with following label claim: **Each film coated tablet contains:** **Simvastatin…..10mg** **Registration Board further decided that registration letter shall be issued after the following:** • **Verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board.**	

	• **Submission of fee Rs. 37,000/- for pre-approval correction/revision of formulation in line with reference product.**	
198.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Cholrid-20mg Tablets
	Composition	Each film coated tablet contains: Simvastatin…..20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9910 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8186 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Anti-hyperlipidemic agent
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	Zocor tablets USFDA approved
	Me-too status	Simvax 20mg f/c Tablet Evolution Pharmaceuticals (Pvt.) Ltd. (111794)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
199.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Cholrid-80mg Tablets
	Composition	Each film coated tablet contains: Simvastatin…..80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9911 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8184 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Anti-hyperlipidemic agent
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	Zocor tablets USFDA approved
	Me-too status	Modlip 80mg Tablets of M/s Wilshire Laboratories (Private) Limited (049985)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	

200.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Virocid 200mg Tablets
	Composition	Each film coated tablet contains: Ribavirin…..200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16578 dated 27-04-2022 **(Duplicate dossier) verified vide Dy. No 8199 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Antiviral
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA approved
	Me-too status	Inv-Reno 200mg Tablet of Invictus Pharmaceuticals. (109726)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
201.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Virocid 400mg Tablets
	Composition	Each film coated tablet contains: Ribavirin…..400mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 16577 dated 27-04-2022 **(Duplicate dossier) verified vide Dy. No 8177 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Antiviral
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA approved
	Me-too status	Inv-Reno 400mg Tablet of Invictus Pharmaceuticals. (109727)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
202.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.

	Brand Name +Dosage Form + Strength	Dilotin 20mg Capsule
	Composition	Each Delayed release capsule contains: Duloxetine HCl……20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9908 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8196 dated 31-08-2010 from R&I.** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	SSNRI
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA approved
	Me-too status	Eziness Capsule 20mg of Don Valley (071149)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	**Source of pellets not mentioned along with fee for standardization of label claim**
	Decision: Deferred for submission of the following: • **revision of label claim in line with reference product along with prescribed fee for revision of formulation** • **source of pellets along with fee and supporting documents** • **verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board**	
203.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Nuzar 50mg Tablet
	Composition	Each film coated tablet contains: Losartan Potassium….50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9913 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8191 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Angiotensin-II Receptor Antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA approved
	Me-too status	Parlak Tablet 50mg of Ambrosia Pharmaceuticals Rawat Islamabad (069969)
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	

204.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Nuzar 100mg Tablet
	Composition	Each film coated tablet contains: Losartan Potassium….100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9914 dated 19-04-2022 **(Duplicate dossier) verified vide Dy. No 8180 dated 31-08-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Angiotensin-II Receptor Antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA approved
	Me-too status	Loran Tablets 100mg (068798) Wise Pharmaceuticals, Rawat Islamabad, Islamabad
	GMP status	panel inspection dated 13-04-2022 and 14-04-2022 for renewal of DML
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan of Rs. 8000/- will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
205.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Alendre C Tablet
	Composition	Each tablet contains: Alendronate Sodium…70mg Cholecalciferol…70mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6157 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Bisphosphonate / Vitamin
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	USFDA approved
	Me-too status	BonPart Plus Tablet of M/s Barrett Hodgson Pakistan (Pvt) Ltd., Karachi (061444)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following:	

	• **verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	
206.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Alendre Tablet
	Composition	Each tablet contains: Alendronate Sodium…70mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6161 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Bisphosphonate
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	USFDA approved
	Me-too status	Obiferol Tablet of M/s Obsons pharmaceuticals (113245)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **Submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.** • **Latest GMP inspection report conducted within period of three years.**	
207.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dexi Tablets
	Composition	Each tablet contains: Dexibuprofen…400mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6162 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	NSAID

	Finished product Specifications	Wise specs
	Pack size & Demanded Price	1x10's, As per SRO
	RRA status	MHRA approved
	Me-too status	Dex-Profen 400mg Tablet of M/s Trigon Pharmaceuticals (Private) Ltd. (110877)
	GMP status	
	Remarks of the Evaluator	**Film coated tablets in MHRA**
	Decision: Approved with as per innovator's specifications and following label claim: **Each film coated tablet contains:** **Dexibuprofen…400mg** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	
208.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rezal S Capsule
	Composition	Each capsule contains: Omeprazole…40mg Sodium bicarbonate…1100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6165 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	PPI, Antacid
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	Zegrid USFDA approved
	Me-too status	TEpH Insta 40 Capsules of M/s SAMI Pharmaceuticals Pvt. Ltd. (070562)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with as per innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 9000/- for pre-approval variation in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	

209.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rezal S Capsule
	Composition	Each capsule contains: Omeprazole…20mg Sodium bicarbonate…1100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6166 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	PPI, Antacid
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	Zegrid USFDA approved
	Me-too status	TEpH Insta 20 Capsules of M/s SAMI Pharmaceuticals Pvt. Ltd. (070561)
	GMP status	
	Remarks of the Evaluator	The submission has been verified by R&I section for both Rezal-S capsule & Itope tablet with same diary number and date of submission.
	Decision: Approved with as per innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **Verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **Submission of fee Rs. 9000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **Latest GMP inspection report conducted within period of three years.**	
210.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Itope Tablet
	Composition	Each tablet contains: Itopride HCl…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6166 dated 05-07-2012 from R&I** Rs.8000/- (photo copy)

		Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Gastrointestinal agent
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	MHRA (**as film coated tablets**)
	Me-too status	Itop 50mg Tablet of Ms Nexus Pharma (Pvt) Ltd (070489)
	GMP status	
	Remarks of the Evaluator	The submission has been verified by R&I section for both Rezal-S capsule & Itope tablet with same diary number and date of submission.
	Decision: Approved with as per innovator's specifications and following label claim: **Each film coated tablet contains:** **Itopride HCl…50mg** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **Verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **Submission of fee Rs. 9000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **Latest GMP inspection report conducted within period of three years.**	
211.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Amlo Tablet
	Composition	Each tablet contains: Amlodipine Besylate…10mg Valsartan…160mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6167 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Antihypertensive
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	USFDA approved
	Me-too status	Valdosar Tablet 10mg+160mg of M/s Pinnacle Biotech (Pvt.) Ltd., Karachi. 114647
	GMP status	
	Remarks of the Evaluator	**RRA approved label claim is as;** **Each film coated tablet contains:** **Amlodipine as Besylate…10mg**

		Valsartan……160mg
	Decision: Approved with as per innovator's specifications and following label claim: **Each film coated tablet contains:** **Amlodipine as Besylate…10mg** **Valsartan……160mg** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 37000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	
212.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Amlo Tablet
	Composition	Each tablet contains: Amlodipine Besylate…5mg Valsartan…80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6165-A dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Antihypertensive
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	USFDA
	Me-too status	Valdosar Tablet 5mg+80mg of M/s Pinnacle Biotech (Pvt.) Ltd., Karachi. 114647
	GMP status	
	Remarks of the Evaluator	**RRA approved label claim is as;** **Each film coated tablet contains:** **Amlodipine as Besylate…5mg** **Valsartan……80mg**
	Decision: Approved with as per innovator's specifications and following label claim: **Each film coated tablet contains:** **Amlodipine as Besylate…5mg** **Valsartan……80mg** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 37000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.**	

	• **latest GMP inspection report conducted within period of three years.**	
213.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Glimp Tablet
	Composition	Each tablet contains: Glimiperide…1mg Metformin…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6164 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Antidiabetic
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Limi tablet 1/500 of M/s Dyson
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • RRA status could not be confirmed
	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.	
214.	Name and address of manufacturer / Applicant	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Glimp Tablet
	Composition	Each tablet contains: Glimiperide…2mg Metformin…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 6164 dated 05-07-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- (photo copy) **verified vide Dy No.32461 -R&I dated 31-01-2020.**
	Pharmacological Group	Antidiabetic
	Finished product Specifications	Wise specs
	Pack size & Demanded Price	2x10's, As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Limi tablet 2/500 of M/s Dyson

	GMP status	
	Remarks of the Evaluator	**Shortcomings:** RRA status could not be confirmed
	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.	
215.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-288,I-9, industrial |Area, Islamabad
	Brand Name +Dosage Form + Strength	Neso 500/20mg tablet
	Composition	Each delayed release tablet contains: Naproxen (acid resistant granules)….500mg Esomeprazole as magnesium….20mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 1756 dated 20-01-2011 (**Verified from R&I)** Rs.15000/- (Photocopy) Rs.5000/- (Original) Dy. No. 25151 dated 25-09-2020
	Pharmacological Group	Beta Blocker
	Finished product Specifications	Wilson's specs
	Pack size & Demanded Price	
	RRA status	USFDA
	Me-too status	Eznepo of M/s Wnsfeild
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Stability data not submitted • As per manufacturing method firm has manufactured bi-layer tablet while RRA approved formulation is Core Coated.
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
216.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-288,I-9, industrial |Area, Islamabad
	Brand Name +Dosage Form + Strength	Neso 375/20mg tablet
	Composition	Each delayed release tablet contains: Naproxen (acid resistant granules)….375mg Esomeprazole as magnesium….20mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 1758 dated 20-01-2011 (**Verified from R&I)** Rs.15000/- (Photocopy) Rs.5000/- (Original) Dy. No. 25150 dated 25-09-2020
	Pharmacological Group	Beta Blocker
	Finished product Specifications	Wilson's specs
	Pack size & Demanded Price	
	RRA status	USFDA
	Me-too status	Eznepo of M/s Wnsfeild

	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Stability data not submitted • As per manufacturing method firm has manufactured bi-layer tablet while RRA approved formulation is Core Coated.
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
217.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Iminox Plus Injection 250mg/250mg
	Composition	Each vial contains: Imipenem as monohydrate…...250mg Cilastatin as sodium……..…250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1467 dated 30-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30125 dated 13-01-2020 (Original)
	Pharmacological Group	Antibacterial, Carbapenem
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1's, As per SRO
	RRA status	USFDA
	Me-too status	Nemcil by Wallace
	GMP status	
	Remarks of the Evaluator	**Container Closure Type-III Clear glass Vial**
	Decision: Registration Board rejected the instant application since the firm does not possess approval of required manufacturing facility / section from Licensing Division, DRAP.	
218.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Iminox Plus Injection 500mg/500mg
	Composition	Each vial contains: Imipenem as monohydrate…...500mg Cilastatin as sodium……..…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1466 dated 30-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30126 dated 13-01-2020 (Original)
	Pharmacological Group	Antibacterial, Carbapenem
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1's, As per SRO
	RRA status	USFDA

	Me-too status	Nemcil by Wallace
	GMP status	
	Remarks of the Evaluator	**Container Closure Type-III Clear glass Vial**
	Decision: Registration Board rejected the instant application since the firm does not possess approval of required manufacturing facility / section from Licensing Division, DRAP.	
219.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sitapin Tablets 50mg
	Composition	Each film-coated tablet contains: Sitagliptin phosphate monohydrate …….50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1454 dated 30-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30139 dated 13-01-2020 (Original)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	14's, As per SRO
	RRA status	USFDA
	Me-too status	Sita-K of M/s Schazoo
	GMP status	
	Remarks of the Evaluator	RRA approved label claim is as: **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** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 37000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	
220.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sitapin Tablets 100mg
	Composition	Each film-coated tablet contains: Sitagliptin phosphate monohydrate …….100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1453 dated 30-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30140 dated 13-01-2020 (Original)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs

	Pack size & Demanded Price	14's, As per SRO
	RRA status	USFDA
	Me-too status	Sita-K of M/s Schazoo
	GMP status	
	Remarks of the Evaluator	RRA approved label claim is as: **Each film-coated tablet contains:** **Sitagliptin (as phosphate monohydrate) …….100mg**
	Decision: Approved with following label claim: **Each film-coated tablet contains:** **Sitagliptin (as phosphate monohydrate) …….100mg** **Moreover, Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **submission of fee Rs. 37000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications.** • **latest GMP inspection report conducted within period of three years.**	
221.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metormin Tablets 250mg
	Composition	Each film-coated tablet contains: Metformin Hydrochloride……250 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 385 dated 29-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30136 dated 13-01-2020 (Original)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	PMDA Japan approved
	Me-too status	Glucophage of M/s Martin Dow
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
222.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metormin Tablets 500mg
	Composition	Each film-coated tablet contains: Metformin Hydrochloride……500 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5

		(Duplicate dossier) verified vide Dy. No 387 dated 29-06-2011 from R&I Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30137 dated 13-01-2020 (Original)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Glucophage of M/s Martin Dow
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
223.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metormin Tablets 850mg
	Composition	Each film-coated tablet contains: Metformin Hydrochloride……850 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 384 dated 29-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30138 dated 13-01-2020 (Original)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Metfor tablets of M/s Valor pharmaceuticals
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
224.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Leflin Tablets 10mg
	Composition	Each film coated tablet contains: Leflunomide…….10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 265 dated 21-06-2011 from R&I**

		Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30129 dated 13-01-2020 (Original)
	Pharmacological Group	Selective Immunosuppressant
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	Lunit of M/s Woodwards
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
225.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Leflin Tablets 20mg
	Composition	Each film coated tablet contains: Leflunomide…….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 261 dated 21-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30130 dated 13-01-2020 (Original)
	Pharmacological Group	Selective Immunosuppressant
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	Lunit of M/s Woodwards
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
226.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Tenovit Tablets 300mg
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil as Fumarate…300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1461 dated 30-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30127 dated 13-01-2020 (Original)

	Pharmacological Group	Antiviral
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Paniv of M/s S.J&G
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
227.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Redox Tablets 35mg
	Composition	Each film coated tablet contains: Risedronate sodium……35mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1408 dated 28-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30132 dated 13-01-2020 (Original)
	Pharmacological Group	Bisphosphonate
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Osocyte of Brookes
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** **latest GMP inspection report conducted within period of three years.**	
228.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Redox Tablets 150mg
	Composition	Each film coated tablet contains: Risedronate sodium……150mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1409 dated 28-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30133 dated 13-01-2020 (Original)
	Pharmacological Group	Bisphosphonate

	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Sedron of Evolution
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** **latest GMP inspection report conducted within period of three years.**	
229.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Clofen Tablet 100 mg
	Composition	Each film coated tablet contains: Aceclofenac……..…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 171 dated 27-12-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30128 dated 13-01-2020 (Original)
	Pharmacological Group	NSAID
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	Alfenac of Bio-Labs
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
230.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Laclin Syrup 3.335gm/5ml
	Composition	Each 5ml contains: Lactulose……3.335gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 391 dated 29-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 31604 dated 27-01-2020 (Original)
	Pharmacological Group	Laxative
	Finished product Specifications	USP specs

	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	Duphalac
	GMP status	
	Remarks of the Evaluator	**Source Lacsa (Pty) Ltd, South Africa.** **Fee for imported is source required.**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.** • **Differential fee of Rs. 280000/- being imported source of Lactulose along with GMP of Lactulose manufacturer and stability of lactulose.**	
231.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Nevitix Tablets 500mcg
	Composition	Each sugar-coated tablet contains: Mecobalamin……500mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 1406 dated 28-08-2012 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30131 dated 13-01-2020 (Original)
	Pharmacological Group	Vitamin B12
	Finished product Specifications	JP specs
	Pack size & Demanded Price	As per SRO
	RRA status	PMDA
	Me-too status	Methycobal
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
232.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metifen Tablet 20mg/120mg
	Composition	Each tablet contains: Artemether…….....20mg Lumefantrine…….120mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 266 dated 21-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30134 dated 13-01-2020 (Original)

	Pharmacological Group	Antimalarial
	Finished product Specifications	Intl. Ph. Specs
	Pack size & Demanded Price	As per SRO
	RRA status	WHO PQ
	Me-too status	Am-Invo of Invotek
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
233.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metifen DS Tablet 40mg/240mg
	Composition	Each tablet contains: Artemether…….....40mg Lumefantrine…….240mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 264 dated 21-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 30135 dated 13-01-2020 (Original)
	Pharmacological Group	Antimalarial
	Finished product Specifications	Intl. Ph. Specs
	Pack size & Demanded Price	As per SRO
	RRA status	WHO PQ
	Me-too status	Mefaran of UDL
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board** • **latest GMP inspection report conducted within period of three years.**	
234.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Metifen Dry Suspension 15mg/90mg
	Composition	Each 5ml contains: Artemether…….....15mg Lumefantrine…….90mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier) verified vide Dy. No 263 dated 21-06-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 31605 dated 27-01-2020 (Original)

	Pharmacological Group	Antimalarial
	Finished product Specifications	Intl. Ph. Specs
	Pack size & Demanded Price	30ml, As per SRO
	RRA status	WHO PQ
	Me-too status	Malnate of Evolution
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
235.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1 -A2, Phase 1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Alfadol 0.50µg Tablets
	Composition	Each tablet contains: Alfacalcidol….0.50µg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 1315 dated 22-01-2024 (**Duplicate dossier)** Dy. No. nil dated 31-03-2014 Rs.20000/- dated 31-03-2014 (photo copy) **verified vide Dy. No 137 dated 31-03-2014 from R&I**
	Pharmacological Group	Vitamin D analogue
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1 x 10's, Rs. 15.00 per tablet
	RRA status	One-alfa UK
	Me-too status	Alfa-D Platinum
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 20,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
236.	Name and address of manufacturer / Applicant	M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Tizsave tablet 2mg
	Composition	Each tablet contains: Tizanidine hydrochloride eq. to Tizanidine….2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 12208 dated 18-05-2023 (Duplicate dossier) **Verified from record of R&I DRAP** vide Dy.No 5059 dated 07-06-2017 Rs.20,000/- dated 06-06-2017 (**duplicate challan attached**)
	Pharmacological Group	Skeletal muscle relaxant/ anti spastic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10s, As per SRO

	RRA status	Zanaflex UK
	Me-too status	Movax tablets of Sami pharmaceuticals
	GMP status	GMP certificate dated 01-10-2021 based upon evaluation conducted on 18-09-2021
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 20,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
237.	Name and address of manufacturer / Applicant	M/s. Welwrd Pharmaceuticals, Plot No. 3, Block-A, Pharse V, Hattar Industrial estate, Hattar.
	Brand Name +Dosage Form + Strength	Tedro 2mg tablet
	Composition	Each film coated tablet contains: Tolterodine tartarate...2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 23470 dated 22-09-2023 (Duplicate dossier) **Verified from record of R&I DRAP** vide Dy. No 16163 dated 07-03-2019 Rs.20,000/- dated 06-03-2019 (**duplicate challan attached**)
	Pharmacological Group	Cholinergic
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Tolterodine Tartarate 2mg tablets MHRA
	Me-too status	Toltura 2mg tablet of Hilton pharma
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 20,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
238.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi (Plant-I)
	Brand Name +Dosage Form + Strength	Ornox 4 Tablet
	Composition	Each film coated tablet contains: Lornoxicam…4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 648 dated 08-05-2012 **verified from R&I** Rs.12000/- (Original) Dy. No 26997 dated 13-12-2019
	Pharmacological Group	NSAIDs
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	Xefo EMA
	Me-too status	LRN 4mg tablet of M/s Seraph
	GMP status	

	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
239.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi (Plant-I)
	Brand Name +Dosage Form + Strength	Ornox 8 Tablet
	Composition	Each film coated tablet contains: Lornoxicam…8mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 698 dated 08-05-2012 verified from R&I Rs.12000/- (Original) Dy. No 26996 dated 13-12-2019
	Pharmacological Group	NSAIDs
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	Xefo EMA
	Me-too status	LRN 8mg tablet of M/s Seraph
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
240.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi (Plant-I)
	Brand Name +Dosage Form + Strength	Qmetem 20/120mg Tablet
	Composition	Each dispersible tablet contains: Artemether…20mg Lumefantrine…120mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 192 dated 27-12-2010 verified from R&I Rs.12000/- (Original) Dy. No 27001 dated 13-12-2019
	Pharmacological Group	Antimalarial
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	WHO PQ
	Me-too status	Am-Invo of Invotek
	GMP status	
	Remarks of the Evaluator	

	Decision: Approved with Intl. Ph. Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
241.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi (Plant-I)
	Brand Name +Dosage Form + Strength	Lezol 400mg Tablet
	Composition	Each film coated tablet contains: Linezolid…400mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 186 dated 18-07-2007 verified from R&I Rs.12000/- (Original) Dy. No 26055 dated 04-12-2019
	Pharmacological Group	Oxazolidinones
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	Zyvox UK
	Me-too status	Linzoheim 400mg Tablet Reg. No. 118854
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan of Rs. 8,000 will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	

b. Duplicate dossiers with photocopies of R&I receiving (to be verified from R&I DRAP) and with incomplete evidence for fee challans and R&I receiving:

242.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Amroplus -F Tablet
	Composition	Each chewable tablet contains: Iron Polymaltose Complex eq. to elemental Iron …100mg Folic Acid ….0.35mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25406 dated 19-10-2023 **(Duplicate dossier)** Dy. No 224 dated 27-10-2010 Rs.8000/- (photo copy) to be verified from R&I Rs.12000/- 19-07-2017 (photo copy)
	Pharmacological Group	Iron/folic acid
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	Ran-F of M/s Daneen

	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
243.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Antimal Oral Syrup
	Composition	Each 5ml contains: Artemether …….15 mg Lumefantrine ……..…90 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25414 dated 19-10-2023 **(Duplicate dossier)** Dy. No 222 dated 17-10-2010 Rs.8000/- (photo copy) to be verified from R&I Rs.12000/- 19-07-2017 (photo copy)
	Pharmacological Group	Anti-Malarial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	WHO PQ
	Me-too status	Malnate of Evolution
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with International Pharmacopoeia Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
244.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Vitamin B12 Injection
	Composition	Each ml contains: Cyanocobalamin ……500 mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25411 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 346 dated 17-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy)
	Pharmacological Group	Vitamins
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml, As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Cynosel 1000mcg/2ml of M/s Selmore

	GMP status	
	Remarks of the Evaluator	**Shortcomings:** RRA status could not be confirmed
	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.	
245.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Amroplus Tablet
	Composition	Each chewable tablet contains: Iron Polymaltose Complex eq. to elemental Iron…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25407 dated 19-10-2023 **(Duplicate dossier)** Dy. No 225 dated 17-10-2010 Rs.8000/- (photo copy) to be verified from R&I Rs.12000/- 19-07-2017 (photo copy)
	Pharmacological Group	Anti Anaemic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	-
	Me-too status	Trimose of M/s Trillium
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
246.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Amroplus Syrup
	Composition	Each 5ml contains: Iron Polymaltose Complex eq. to elemental Iron…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25405 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 226 dated 27-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	Anti Anaemic
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	As per SRO
	RRA status	Maltofer syrup TGA
	Me-too status	Ferosoft syrup of Hilton
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following:	

	• **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
247.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Frusem 20mg injection
	Composition	Each 2ml contains: Furosemide….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25412 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 345 dated 17-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	Diuretic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml, As per SRO
	RRA status	UK
	Me-too status	Lasix Sanofi
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
248.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Oxin infusion
	Composition	Each 100ml contains: Ofloxacin ……..200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25409 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 219 dated 27-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	Antibacterial
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	UK
	Me-too status	Triflox Bosch
	GMP status	
	Remarks of the Evaluator	

	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** **latest GMP inspection report conducted within period of three years.**	
249.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Amvinate injection
	Composition	Each ml contains: Dimenhydrinate…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25413 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 343 dated 17-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	Antiemetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1ml x 25's, As per SRO
	RRA status	FDA
	Me-too status	Gravinate Injection
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
250.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Roxic 20mg tablet
	Composition	Each tablet contains: Piroxicam Beta cyclodextrin eq. to Piroxicam…20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25410 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 342 dated 17-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	NSAID
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2 x 10's, As per SRO
	RRA status	AIFA Italy
	Me-too status	Ripex 20mg Tablet, Hilton
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following:	

	• **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
251.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.
	Brand Name +Dosage Form + Strength	Futon syrup
	Composition	Each 15ml contains: Iron protein sucinylate 800mg eq. to elemental iron…40mg Folic acid…5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 25410 dated 19-10-2023 **(Duplicate dossier) verified vide Dy. No 344 dated 17-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
	Pharmacological Group	Antianemic
	Finished product Specifications	Amros specs
	Pack size & Demanded Price	120ml, As per SRO
	RRA status	
	Me-too status	Sucofer-F CCL
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
252.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1 -A2, Phase 1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Biscor 5mg tablet
	Composition	Each film coated tablet contains: Bisoprolol fumarate …… 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No 20560 dated 21-10-2023 AD R-I has informed letter vide No.F.6-10/2013-Reg-II dated 12-12-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **R&I Verified vide Dy. No 138 dated 31-03-2014** Rs.20000/- (photo copy) to be verified
	Pharmacological Group	Beta Blocker
	Finished product Specifications	USP specs
	Pack size & Demanded Price	14's, As per SRO
	RRA status	FDA
	Me-too status	Camdrova 10mg Tablet Martin Dow
	GMP status	
	Remarks of the Evaluator	

	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
253.	Name and address of manufacturer / Applicant	Dr. Raza Pharma, 44-C industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Mylenol-C suspension
	Composition	Each 5ml contains: Paracetamol …120mg Chlorpheniramine maleate …1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 6405 dated 07-03-2023 **(Duplicate dossier) verified vide Dy. No 18 dated 08-03-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- vide Dy. No. 44 dated 15-01-2015 (photo copy) to be verified
	Pharmacological Group	Antipyretics, Antihistamine
	Finished product Specifications	USP specs
	Pack size & Demanded Price	60ml, As per SRO
	RRA status	
	Me-too status	Olidol syrup of M/s Olive
	GMP status	
	Remarks of the Evaluator	**Official monograph not available in USP** **Case was previously considered in 265th meeting of Registration Board and the Board Deferred for evidence of approval of applied formulation by reference regulatory authorities.**
	Decision: Deferred for evidence of approval of applied formulation by reference regulatory authorities.	
254.	**Deleted since the application had already been approved.**	
255.	Name and address of manufacturer / Applicant	Dr. Raza Pharma, 44-C industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Nervigor-plus Capsule
	Composition	Each capsule contains: Exsiccated Ferrous Sulphate …100mg Vitamin B1….2mg Vitamin B2 …2mg Vitamin B6…1mg Vitamin C ….50mg Folic Acid ….0.50mg Nicotinamide ….10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 6407 dated 07-03-2023 **(Duplicate dossier) verified vide Dy. No 20 dated 08-03-2011 from R&I** Rs.8000/- (photo copy)

		Rs.12000/- vide Dy. No. 44 dated 15-01-2015 (photo copy) to be verified
	Pharmacological Group	Multivitamin
	Finished product Specifications	Dr Raza's specs
	Pack size & Demanded Price	10s, 20's, 30's, 50's, 100's, 500's, 1000's As per SRO
	RRA status	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	**Case was previously considered in 265th meeting of Registration Board and the Board Deferred for evidence of approval of applied formulation by reference regulatory authorities.**
	Decision: Deferred for evidence of approval of applied formulation by reference regulatory authorities	
256.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Neogeral 5mg tablet
	Composition	Each film coated tablet contains Prasugrel (as Hydrochloride) …… 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5248 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 176 dated 19-10-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, As per SRO
	RRA status	MHRA
	Me-too status	Mepigril of M/s Maple
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
257.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Neogeral 10mg tablet
	Composition	Each film coated tablet contains Prasugrel (as Hydrochloride) …… 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5249 dated 23-02-2023

		(Duplicate dossier) verified vide Dy. No 173 dated 19-10-2010 from R&I Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, As per SRO
	RRA status	MHRA
	Me-too status	Mepigril of M/s Maple
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
258.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Neogrel -AP 5/150 Tablet
	Composition	Each tablet contains Prasugrel (as hydrochloride) …… 5mg Aspirin (enteric coated) …… 150mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5251 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 259 dated 19-04-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's As per SRO
	RRA status	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
259.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Neogrel -AP 10/150 Tablet

	Composition	Each tablet contains Prasugrel (as hydrochloride) …… 10mg Aspirin (enteric coated) …… 150mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5253 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 256 dated 19-04-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's As per SRO
	RRA status	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
260.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Neogrel -AP 10/75 Tablet
	Composition	Each tablet contains Prasugrel (as hydrochloride) …… 10mg Aspirin (enteric coated) …… 75mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5252 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 253 dated 19-04-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's As per SRO
	RRA status	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
261.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi

	Brand Name +Dosage Form + Strength	Neogrel -AP 5/75 Tablet
	Composition	Each tablet contains Prasugrel (as hydrochloride) …… 5mg Aspirin (enteric coated) …… 75mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5250 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 254 dated 19-04-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	P2Y12 platelet inhibitor
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's As per SRO
	RRA status	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
262.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi **Contract Manufactured By M/s. Surge Laboratories, Sheikhupura.**
	Brand Name +Dosage Form + Strength	Zucloact 50mg/ml injection
	Composition	Each ml ampoule contains Zuclopenthixol Acetate ……. 50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5238 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 25 dated 04-01-2011 from R&I** Rs.8000/- (photo copy) Rs.42000/- dated 14-05-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Antipsychotic
	Finished product Specifications	BP specs
	Pack size & Demanded Price	1ml x 1's, 1ml x 5's As per SRO
	RRA status	MHRA
	Me-too status	Zufen of M/s Standpharm
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
263.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi **Contract Manufactured By M/s. Surge Laboratories, Sheikhupura.**

	Brand Name +Dosage Form + Strength	Lincobact Injection 300mg/1ml
	Composition	Each 1ml ampoule contains: Lincomycin HCl Monohydrate eq. to Lincomycin USP….300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5243 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 203 dated 18-03-2009 from R&I** Rs.8000/- (photo copy) Rs.42000/- dated 14-05-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Macrolide
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1ml x 5's As per SRO
	RRA status	TGA approved
	Me-too status	Incomy of M/s Inventor
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
264.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi **Contract Manufactured By M/s. Surge Laboratories, Sheikhupura.**
	Brand Name +Dosage Form + Strength	Lincobact Injection 300mg/1ml
	Composition	Each 2ml ampoule contains: Lincomycin HCl Monohydrate eq. to Lincomycin USP….600mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5244 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 201 dated 18-03-2009 from R&I** Rs.8000/- (photo copy) Rs.42000/- dated 14-05-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Macrolide
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2ml x 1's As per SRO
	RRA status	TGA approved
	Me-too status	Incomy of M/s Inventor
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
265.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Sart 20mg tablet

	Composition	Each film coated tablet contains: Olmesartan Medoxomol ….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5241 dated 23-02-2023 **(Duplicate dossier)** Dy. No 50 dated 09-12-2010 to be confirmed from R&I Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Angiotensin-II receptor blocker
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's As per SRO
	RRA status	MHRA
	Me-too status	Olmelod of M/s Welwrd
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
266.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	G-Active 320mg tablet
	Composition	Each film coated tablet contains: Gemifloxacin (as Mesylate) …… 320mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5240 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 26 dated 04-01-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Antimicrobial
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	5's, 7's As per SRO
	RRA status	Factive USFDA with status **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Me-too status	Crohit 320mg tablet of M/s Horizon Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
267.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Simva-N 20/1000mg Tablet

	Composition	Each film coated tablet contains: Simvastatin USP …20mg Niacin …….1000mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5247 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 76 dated 11-11-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 22-01-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Cholesterol lowering agent
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's As per SRO
	RRA status	Simcor USA (as extended-release tablet)
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
268.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Simva-N 20/500mg Tablet
	Composition	Each film coated tablet contains: Simvastatin USP …20mg Niacin …….500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5245 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 78 dated 11-11-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 22-01-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Cholesterol lowering agent
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's;As per SRO
	RRA status	Simcor USA (as extended-release tablet)
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
269.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi

	Brand Name +Dosage Form + Strength	Simva-N 20/750mg Tablet
	Composition	Each film coated tablet contains: Simvastatin USP …20mg Niacin …….750mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5246 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 77 dated 11-11-2010 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 22-01-2020 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Cholesterol lowering agent
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's; As per SRO
	RRA status	Simcor USA (as extended-release tablet)
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
270.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi
	Brand Name +Dosage Form + Strength	Flugone Sachet
	Composition	Each Sachet contains Paracetamol ……..500mg Mepyramine maleate…13mg Pheniramine Maleate …13mg Pseudoephedrine HCl …30mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5239 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 134 dated 23-02-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 12-11-2018 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Antihistamine, Analgesic, sympathomimetic
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's, 20's;As per SRO
	RRA status	
	Me-too status	Flueze Sachets
	GMP status	
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
271.	Name and address of manufacturer / Applicant	M/s NabiQasim industries (Pvt) Ltd. 17/24, Korangi Industrial Area, Korangi Karachi

	Brand Name +Dosage Form + Strength	Acenex Cream 0.1%
	Composition	Each gram contains: Adapalene ……. 0.1% W/w
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 5242 dated 23-02-2023 **(Duplicate dossier) verified vide Dy. No 132 dated 23-02-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- dated 31-12-2019 to be confirmed from R&I (Photocopy)
	Pharmacological Group	Anti-Acne
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10gm, 15gm, 30gm 45gm; As per SRO
	RRA status	USFDA
	Me-too status	Adaplex of M/s Life pharma
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
272.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1 -A2, Phase 1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Spasmocare tablet
	Composition	Each film coated tablet contains: Phloroglucinol hydrate…80mg Trimethyphloroglucinol…80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 20564 dated 21-08-2023 (**Duplicate dossier)** Rs.8000/- (Photocopy) **verified vide Dy. No 704 dated 23-07-2012 from R&I** Rs.52000/- (photo copy) dated 06-02-2013 to be verified from R&I
	Pharmacological Group	Antispasmodic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	ANSM approved
	Me-too status	Ploro-T of M/s Fynk
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	

273.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1 -A2, Phase 1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Sudofen Forte Tablet
	Composition	Each film coated tablet contains: Ibuprofen……..…400mg Pseudoephedrine HCl …60mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 1313 dated 22-01-2024 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No 704 dated 27-05-2011 to be verified from R&I Rs.12000/- not attached
	Pharmacological Group	NSAID, Decongestant
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	Dimetapp Children Cold and Fever USFDA
	Me-too status	Rhinoff Atco
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
274.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Zeflam 50mg tablet
	Composition	Each tablet contains: Diclofenac potassium….50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19443 dated 04-08-2023 **(Duplicate dossier)** DD R-II has informed vide letter No.F.1-11/2019-Reg-II dated 15-01-2024 that duplicate dossier is verified from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. **Verified vide Dy. No 5603 dated 18-05-2011 from R&I** Rs.8000/- (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Analgesic, anti-inflammatory
	Finished product Specifications	BP specs
	Pack size & Demanded Price	Not demanded
	RRA status	MHRA
	Me-too status	Infast of M/s Inventor
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML

		Shortcomings: Form-5 and Rs. 12,000/- challan are not attached, only annexures are submitted
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
275.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Artecom DS tablet
	Composition	Each tablet contains: Artemether…80mg Lumefantrine…480mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19443 dated 04-08-2023 **(Duplicate dossier)** **Dy. No. nil dated nil to be verified from R&I** Rs.20000/- dated 29-05-2014 (photo copy)
	Pharmacological Group	Antimalarial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1 x 4's, Rs. 320./-
	RRA status	WHO PQ
	Me-too status	Exafal of M/s Novartis
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** **Receiving of application in DRAP** is not attached
	Decision: Approved with Intl. Ph. Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
276.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Aproxen 550mg tablet
	Composition	Each tablet contains: Naproxen sodium 550mg eq. to naproxen…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19453 dated 04-08-2023 **(Duplicate dossier)** Verified vide Dy. No 5601 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Anti-inflammatory

	Finished product Specifications	BP specs
	Pack size & Demanded Price	20's, Rs. 143./-
	RRA status	USFDA
	Me-too status	Nepox of M/s Batala
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP is not attached Aproved formulation is film coated in RRA
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision from uncoated to film coated tablet.**	
277.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Arthocap 100mg capsule
	Composition	Each capsule contains: Diclofenac sodium (enteric coated pellets)…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19447 dated 04-08-2023 **(Duplicate dossier) Verified vide Dy. No 5583 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- dated 25-04-2013 (photo copy)
	Pharmacological Group	Analgesic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2 x 10's, Rs. 90./-
	RRA status	NA
	Me-too status	Volfenac 100mg capsules of M/s Aries
	GMP status	
	Remarks of the Evaluator	**Capsule General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Source of pellets not mentioned Rs.12,000/- submission in DRAP is not attached
	Decision: Deferred for submission of following; • **evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.**	
278.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.

	Brand Name +Dosage Form + Strength	Bezix 10mg Tablet
	Composition	Each tablet contains: Loratadine….10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19452 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5610 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Antihistamine
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1 x 10's, Rs. 11./- per tablet
	RRA status	USFDA
	Me-too status	Fozil 10mg tablets of M/s Harmann pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
279.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Begix 10mg tablet
	Composition	Each tablet contains: Cetirizine 2HCl….10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19446 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5608 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Antihistamine
	Finished product Specifications	BP specs
	Pack size & Demanded Price	1 x 10's, Rs. 30./- per 10 tablet
	RRA status	USFDA
	Me-too status	Sapizine tablets of M/s Sapient pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following:	

	• **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
280.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Belden 20mg tablet
	Composition	Each tablet contains: Piroxicam….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19445 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5587 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	NSAID
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2 x 10's, Rs. 149.0/- per 20 tablet
	RRA status	ANSM approved
	Me-too status	Orthram tablets of M/s Davis pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP is not attached
	Decision: Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
281.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Zadol 500mg tablet
	Composition	Each tablet contains: Paracetamol….500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19444 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5596 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- to be verified)
	Pharmacological Group	Analgesic/ antipyretic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Panadol of GSK

	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Form-5, Rs. 12,000/- challan and its submission in DRAP are not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
282.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Blufen 100mg tablet
	Composition	Each tablet contains: Flurbiprofin…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19451 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5578 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Anti-inflammatory
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5 x 6's, Rs. 175.0/- per 30 tablet
	RRA status	USFDA
	Me-too status	Sapid tablets of Sapient pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP are not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
283.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Befam 40mg tablet
	Composition	Each tablet contains: Famotidine…40mg
	Type of Form, Diary No. Date of R&	Form-5 Dy. No. 19448 dated 04-08-2023 **(Duplicate dossier)**

	I & fee	**Verified vide Dy. No 5597 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	H-2 receptor antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2 x 10's, Rs. 20/- per tablet
	RRA status	MHRA
	Me-too status	Famot 40mg tablets of Shaigan pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** Rs. 12,000/- challan and its submission in DRAP are not attached Film coated tablet in RRA
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of formulation from uncoated to film coated tablet.**	
284.	Name and address of manufacturer / Applicant	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.
	Brand Name +Dosage Form + Strength	Biclo-SR 100mg tablet
	Composition	Each enteric coated tablet contains: Diclofenac sodium…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 19449 dated 04-08-2023 **(Duplicate dossier)** **Verified vide Dy. No 5598 dated 18-05-2011 from R&I** Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (**to be verified**)
	Pharmacological Group	Analgesic, anti-inflammatory
	Finished product Specifications	BP specs
	Pack size & Demanded Price	2 x 15's, Rs. 99/- per 30 tablet
	RRA status	MHRA
	Me-too status	Lopran SR tablets of Lowitt pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Tablet General section** verified vide panel inspection report dated 16-03-2023 for renewal of DML **Shortcomings:** • Rs. 12,000/- challan and its submission in DRAP are not attached • Clarification regarding applied formulation since **SR is mentioned with brand name while enteric coated tablet is mentioned in label claim and specifications.**

	Decision: Deferred for clarification of formulation SR is mentioned with brand name while enteric coated tablet is mentioned in label claim and specifications.	
285.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat
	Brand Name +Dosage Form + Strength	Vorizole 200mg tablet
	Composition	Each film coated tablet contains: Voriconazole ….200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 6452 dated 27-06-2024 (**Duplicate dossier)** Fee 8000/- dated 20-12-2010 (Photocopy) Fee 12000- dated 28-10-2015 (photocopy)
	Pharmacological Group	Triazole antifungal agent
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Vfend UK
	Me-too status	Vorif of M/s Ferozsons
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	**Submitted after the deadline** **Shortcomings:** • verification is required from R&I section • Section approval from CLB is required????
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
286.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat
	Brand Name +Dosage Form + Strength	Magfast -D Dry Suspension
	Composition	Each 5ml contains after reconstitution: Omeprazole …40mg Sodium Bicarbonate…1100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 1456 dated 29-06-2022 (**Duplicate dossier)** Fee 8000/- dated 04-06-2011 (Photocopy) **Fee 12000/- challan and its receiving in DRAP is not attached**
	Pharmacological Group	PPI/ antacids
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	60ml, 90ml, 120ml, As per SRO
	RRA status	Zegrid USA
	Me-too status	Ruling + of M/s High-Q
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	**Shortcomings:** • verification of 8000/- fee is required from R&I section • Fee Rs. 12000/- challan and its receiving in DRAP • Section approval from CLB is required????
	Decision: Registration Board rejected instant application as approved formulation in RRA is Sachet while applied dosage form is Dry Powder Suspension.	

287.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat
	Brand Name +Dosage Form + Strength	Diacin Capsule 50mg
	Composition	Each capsule contians: Diacerein ….50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 1455 dated 29-06-2022 (**Duplicate dossier)** Fee 8000/- dated 20-12-2010 (Photocopy challan) **Fee 12000/- challan and its receiving in DRAP is not attached**
	Pharmacological Group	Anthraquinone
	Finished product Specifications	As per Innovator's specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Atrodar capsules
	Me-too status	Diarox 50mg capsules of M/s Atco
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	**Shortcomings:** • verification of 8000/- fee is required from R&I section • Fee Rs. 12000/- challan and receiving of both 8000/- and 12000/- in DRAP.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
288.	Name and address of manufacturer / Applicant	Maple Pharma Pvt. Ltd. Plot No.147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lumart 80mg /ml IM injection
	Composition	Each ml contians: Artemether ….80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Fee 8000/- dated 13-10-2010 (Photocopy) Fee 12,000/- dated 16-03-2015 (Photocopy)
	Pharmacological Group	Anti-malarial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5's, Rs. 125.80 per injection
	RRA status	
	Me-too status	Artem inj. of M/s Hilton
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • verification is required from R&I section
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following:	

	• **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP Specifications.**	
289.	Name and address of manufacturer / Applicant	Maple Pharma Pvt. Ltd. Plot No.147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Laronic Tablet
	Composition	Each bilayered tablet contians: Nicotinic Acid.....1000mg Laropiprant …20mg
	Type of Form, Diary No. Date of R& I & fee	Form-**5D** (**Duplicate dossier)** Fee 15000/- dated 18-10-2010 (Photocopy) Fee 12,000/- + 23000/- dated nil (Photocopy)
	Pharmacological Group	Anti-lipidemic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	10's, As per SRO
	RRA status	Tredaptive modified release tablets (**suspended across EU**)
	Me-too status	NA
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • verification of 8000/- fee is required from R&I section • receiving of both 12000/- and 23000/- in DRAP and their verification from DRAP • Section approval from CLB is required????
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
290.	Name and address of manufacturer / Applicant	Maple Pharma Pvt. Ltd. Plot No.147, Sector 23, Korangi Industrial Area, Karachi. **Contract manufactured by:** M/n Nexus Pharma Pvt. Ltd., 4/19-4/36 Sector 21 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Levolife injection 500mg/100ml IV
	Composition	Each 100ml contains: Levofloxacin (as hemihydrate) …500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Fee 8000/- dated 13-10-2010 (Photocopy) Dy. No. nil. Dated 01-08-2016; Fee 12,000/- (Photocopy)
	Pharmacological Group	Quinolone antibacterial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1's, Rs. 660 per vial
	RRA status	MHRA
	Me-too status	Tavanic of Ms Sanofi Aventis

	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • verification of both 8000/- and 12000/- is required from R&I section • Section approval from CLB is required????
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP Specifications.**	
291.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Abowin 80mg/2ml Injection
	Composition	Each 2ml contains: Tobramycin as sulfate…80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23132 dated 16-08-2022 Rs.8000/- dated 15-07-2009 (**photo copy**) **verified from R&I** Rs.12000/- Dy No.29727 -R&I dated 07-01-2020, (original)
	Pharmacological Group	Aminoglycoside antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Tobracin 80mg injection of M/s Swiss pharma
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
292.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Abowin 20mg/2ml Injection
	Composition	Each 2ml contains: Tobramycin as sulfate…20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23132 dated 16-08-2022 Rs.8000/- dated 15-07-2009 (**photo copy**) **verified from R&I** Rs.12000/- Dy No.29727 -R&I dated 07-01-2020, (original)

	Pharmacological Group	Aminoglycoside antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Tobracin 20mg injection of M/s Swiss pharma
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
293.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Amex Injection 50mg
	Composition	Each ml contains: Amikacin sulfate…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23130 dated 16-08-2022 Rs.8000/- dated 06-06-2009 (photo copy) **verified from R&I** Rs.12000/- Dy No.31558 -R&I dated 27-01-2020, (original)
	Pharmacological Group	Aminoglycoside antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed in applied 1ml pack size**
	Me-too status	Grasil 50mg Injection of M/s Sami Karachi
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024 along with evidence of approval of applied formulation in filled volume of 1ml, in any of the reference regulatory authority adopted by Registration Board in its 275th meeting.	
294.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.

	Brand Name +Dosage Form + Strength	Amex Injection 100mg/2ml
	Composition	Each 2ml contains: Amikacin as sulfate…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23130 dated 16-08-2022 Rs.8000/- dated 06-06-2009 (photo copy) **verified from R&I** Rs.12000/- Dy No.31558 -R&I dated 27-01-2020, (original)
	Pharmacological Group	Aminoglycoside antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Ekasin 100mg injection of M/s Epharm Karachi
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
295.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Amex Injection 250mg/ml
	Composition	Each 2ml contains: Amikacin as sulfate…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23131 dated 16-08-2022 Rs.8000/- dated 06-06-2009 (photo copy) **verified from R&I** Rs.12000/- Dy No.31558 -R&I dated 27-01-2020, (original)
	Pharmacological Group	Aminoglycoside antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Ekasin 250mg injection of M/s Epharm Karachi
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached

	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
296.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Diclox Plus Injection 2ml
	Composition	Each 2ml contains: Diclofenac Sodium…….75mg Lidocaine Hydrochloride……20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23129 dated 16-08-2022 Rs.8000/- dated 14-04-2009 (photo copy) **verified from R&I** Rs.12000/- Dy No.29727 -R&I dated 07-01-2020, (original)
	Pharmacological Group	NSAID & local anesthetic
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	Diclofenac-Mepha 75 ampoules, AG approved by Switzerland
	Me-too status	Dilarm-L injection of M/s Fynk pharmaceuticals
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
297.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Mipram Tablet 10mg
	Composition	Each film coated tablet contains: Clomipramine HCl …10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 12695 dated 24-05-2022 Rs.8000/- dated 02-06-2010 (photo copy) **verified from R&I** Rs.12000/- dated 14-10-2015 (photo copy) **verified from R&I**
	Pharmacological Group	Tricyclic antidepressants
	Finished product Specifications	JP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Clonil tablet of M/s Schazoo Laboratories
	GMP status	
	Remarks of the Evaluator	**Shortcomings:**

		• Fee challan for 8000/- and 12,000/- are not attached
	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.	
298.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Mipram Tablet 25mg
	Composition	Each film coated tablet contains: Clomipramine HCl …25mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 12696 dated 24-05-2022 Rs.8000/- dated 02-06-2010 (photo copy) **verified from R&I** Rs.12000/- dated 14-10-2015 (photo copy) **verified from R&I**
	Pharmacological Group	Tricyclic antidepressants
	Finished product Specifications	JP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Clonil tablet of M/s Schazoo Laboratories
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Fee challan for 8000/- and 12,000/- are not attached
	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.	
299.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Zomatawin injection
	Composition	Each vial contains: Zoledronic Acid as monohydrate …5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 12690 dated 24-05-2022 Rs.8000/- dated 08-08-2009 (photo copy) **verified from R&I** Rs.12000/- dated 14-10-2015 (photo copy) **verified from R&I**
	Pharmacological Group	Bisphosphonates
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA approved
	Me-too status	Edonax injection of Ms S.J&G
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- and 12,000/- are not attached
	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self	

	manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024 along with details of filled volume applied.	
300.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Le-4 Infusion
	Composition	Each 100ml contains: Levofloxacin as hemihydrate…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 23809 dated 23-08-2022 Rs.8000/- dated 14-04-2009 (photo copy) **verified from R&I** Rs.12000/- Dy No.31558 -R&I dated 27-01-2020, (original)
	Pharmacological Group	Fluoroquinolones antibiotics
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA approved
	Me-too status	Aksolox infusion 100ml of Ms Akson pharma (316670)
	GMP status	
	Remarks of the Evaluator	Initially the firm has applied for Contract manufacturing by M/s Welwrd Pharmaceuticals Hattar due to non-availability of Liquid General Section Facility. Later on the firm has revised its request to self-manufacturing with submission of 12,000/- differential fee. **Shortcomings:** • Fee challan for 8000/- is not attached
	Decision: Decision: Registration Board while considering the fact that the requested change in type of manufacturing from contract manufacturing to self manufacturing reuires submission of Form 5F, hence Board deferred the instant application for either submission of Fomr 5F for self manufacturing or else firm shall submit differenatial fee for the contract manufacturing as per SRO1324 (I)/2024 dated 30-08-2024.	
301.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Ferremia capsule 150mg
	Composition	Each capsule contains: Elemental iron eq. to iron polysaccharide Complex….150mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 1268P dated 24-05-2022 Rs.8000/- dated 29-02-2011 (photo copy) to be verified from R&I Rs.12000/- dated 14-10-2015 (photo copy) to be verified from R&I
	Pharmacological Group	Iron in combination with folic acid
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	
	Me-too status	Sakride 150mg capsule of Ms Winthrox pharmaceuticals (080536)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:**

		• Fee challan for 8000/- and 12,000/- are not attached • verification is required from R&I section • Section approval from CLB is required
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
302.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Phosmin tablet 667mg
	Composition	Each uncoated tablet contains: Calcium acetate monohydrate 667mg eq. to elemental calcium..... 169mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 12692 dated 24-05-2022 Rs.8000/- dated 14-06-2010 (photo copy) to be verified from R&I No R&I and challan of 12,000/- submitted
	Pharmacological Group	Phosphate binders
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved (**as coated tablet**)
	Me-too status	Lophos tablet of M/s English pharma (084829)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Fee challan for 8000/- and challan and R&I of RS. 12,000/- are not attached • Section approval from CLB is required
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
303.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd., W-33, Industrial Area, Hayatabad Peshawar.
	Brand Name +Dosage Form + Strength	Lepride 50mg Tablet
	Composition	Each film coated tablet contains: Levosulpride…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy.No nil dated 25-10-2023 Dy.No 13614 dated 07-03-2019 (**to be verified from R&I, DRAP**) Rs.20,000/- (photocopy challan) dated 07-03-2019
	Pharmacological Group	Antipsychotic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2 x 10's; As per SRO
	RRA status	Levopraid AIFA Italy approved
	Me-too status	Motrol tablet of M/s Wilshire (045836)

	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
304.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd., W-33, Industrial Area, Hayatabad Peshawar.
	Brand Name +Dosage Form + Strength	Lepride 25mg Tablet
	Composition	Each film coated tablet contains: Levosulpride…25mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy.No nil dated 25-10-2023 Dy.No 13612 dated 07-03-2019 (**to be verified from R&I, DRAP**) Rs.20,000/- (photocopy challan) dated 07-03-2019
	Pharmacological Group	Antipsychotic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2 x 10's; As per SRO
	RRA status	Levopraid AIFA Italy approved
	Me-too status	Motrol 25mg tablet of M/s Wilshire
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
305.	Name and address of manufacturer / Applicant	M/s Saffron pharmaceuticals (pvt) ltd. 19km sheikhpura road, Faisalabad.
	Brand Name +Dosage Form + Strength	Neurica 50mg capsule
	Composition	Each capsule contains: Pregabalin …50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy.No nil dated 06-08-2020 Rs. 8000/-dated 28-06-2012 (photocopy) Rs.12000/-dated 07-11-2018 (photocopy) **(to be verified from R&I, DRAP)**
	Pharmacological Group	GABA analogue (Anti-epileptic)
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	14's; Rs. 400/-
	RRA status	Lyrica
	Me-too status	Gabica of M/s Getz
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Section approval from CLB is required

	Decision: Approved with BP Specifications. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
306.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ostat Capsule
	Composition	Each capsule contains: Orlistat (**powder**) ….60mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy.No 26842 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/-dated 25-06-2018 (photocopy)
	Pharmacological Group	Gastric and pancreatic lipase inhibitor
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved (**as pellets**)
	Me-too status	Xenical capsules
	GMP status	
	Remarks of the Evaluator	**Capsule (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Registration Board rejected the instant application as applied formulation is in powder form while approved formulation in RRA is Pellets.	
307.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Diva Tablets 5mg
	Composition	Each tablet contains: Diazepam…5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32398 dated.31-01-2020 Rs.12000/- dated 31-01-2020 (original)
	Pharmacological Group	Benzodiazepine
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	Valpam TGA Australia approved (as uncoated tablet)
	Me-too status	Valium of Roche
	GMP status	
	Remarks of the Evaluator	**Tablet (psychotropic/ narcotic) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 14-06-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**

	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000/- within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challan of Rs.8000/- will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.**	
308.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T-Fed DM Tablets
	Composition	Each tablet contains: Triprolidine HCl…1.25mg Pseudoephedrine HCl…30mg Dextromethorphan Hydrobromide…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32396 dated.31-01-2020 Rs.12000/- dated 31-01-2020 (original)
	Pharmacological Group	Antihistamine/ sympathomimetic/antitussive
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Actifed DM tablets of GSK
	GMP status	
	Remarks of the Evaluator	**Tablet (psychotropic/ narcotic) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 14-06-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	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.	
309.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T-Val tablet 250mg
	Composition	Each tablet contains: Sodium Valproate ….250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 26844 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
	Pharmacological Group	Carboxylic acid derivative
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Epival tablets of Abbott
	GMP status	

	Remarks of the Evaluator	**Tablet (psychotropic/ narcotic) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 14-06-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Registration Board approved the formulation as per following label claim: **Each enteric coated tablet contains:** **Divalproex sodium eq. to Sodium Valproate …. 250mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval variation in label claim.**	
310.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T-Val tablet 500mg
	Composition	Each tablet contains: Sodium Valproate ….500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 26845 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
	Pharmacological Group	Carboxylic acid derivative
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Epival tablets of Abbott
	GMP status	
	Remarks of the Evaluator	**Tablet (psychotropic/ narcotic) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 14-06-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached** **RRA approved label claim is as;** **Each enteric coated tablet contains:** **Divalproex sodium eq. to Sodium Valproate …. 500mg**
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
311.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Sheen Tablet
	Composition	Each tablet contains: Procyclidine HCl…5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 26843 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
	Pharmacological Group	Anticholinergic

	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	TGA approved
	Me-too status	Kemadrin tablets of GSK
	GMP status	
	Remarks of the Evaluator	**Tablet (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
312.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fiden Tablet 30mg
	Composition	Each tablet contains: Ephedrine HCl…30mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32391 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
	Pharmacological Group	Adrenergic agonist
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA
	Me-too status	Ephedrine tablets of Karachi Chemical
	GMP status	
	Remarks of the Evaluator	**Tablet (psychotropic/ narcotic) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 14-06-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
313.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Risdone Tablet
	Composition	Each tablet contains: Risperidone…2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 26840 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)

	Pharmacological Group	Antipsychotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA
	Me-too status	Persch tablets of Barrett Hodgson
	GMP status	
	Remarks of the Evaluator	**Tablet (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
314.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Amdol-P Tablet
	Composition	Each tablet contains: Tramadol HCl …37.5mg Paracetamol….325mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No 26841 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
	Pharmacological Group	Opiate analogue
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA
	Me-too status	Tonoflex-P tablets of Sami
	GMP status	
	Remarks of the Evaluator	**Tablet (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
315.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	T Cap M Tablets

	Composition	Each tablet contains: Vitamin A …5000 IU Vitamin D …500 IU Vitamin B1 …2.5mg Vitamin B2 …2.5mg Vitamin B6 …0.5mg Vitamin B12 …2mcg Nicotinamide….20mg Vitamin C …50mg Calcium Pentothenate….5mg Magnesium (as oxide) …6mg Iron (as Ferrous fumarate) ….10mg Copper (as sulphate) ….1mg Manganese (as sulphate) ….1mg Iodine (as Potassium iodide) ….0.15mg Potassium (as sulphate) ….5mg Calcium (as carbonate) 35mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32390 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
	Pharmacological Group	Vitamin and minerals combination
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Unicap-M tablets of Johnsons & Johnsons
	GMP status	
	Remarks of the Evaluator	**Tablet (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **Submission of Rs. 8000/- not verified from R&I**
	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.	
316.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Derminone Cream
	Composition	Each gram contains: Hydroquinone.....20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32393 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
	Pharmacological Group	Skin bleaches
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10gm; As per SRO
	RRA status	Superfade original cream tube TGA approved
	Me-too status	Clariderm cream of Stiefel
	GMP status	

	Remarks of the Evaluator	**Cream/ointment (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
317.	Name and address of manufacturer / Applicant	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Felix Ointment
	Composition	Each gram contains: Diflucortolone Valerate.....0.1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Rs. 8000/- (photocopy challan) Dy.No.32392 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
	Pharmacological Group	Corticosteroid
	Finished product Specifications	BP specs
	Pack size & Demanded Price	10gm; As per SRO
	RRA status	MHRA
	Me-too status	Nerisone of Bayer Schering
	GMP status	
	Remarks of the Evaluator	**Cream/ointment (General) section** confirmed vide letter No. F. 1-8/94-Lic (Vol-III) dated 27-04-2018 **Shortcomings:** • **R&I of Rs. 8000/- is not attached**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
318.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Veflex 37.5mg Tablet
	Composition	Each film coated extended release tablet contains: Venlafaxine Hydrochloride….37.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10861 dated 29-04-2022 **(Duplicate dossier)** Rs.8000/- dated 06-05-2010 (photo copy) Rs.12000/- R&I Dy No..nil dated 29-01-2020, (photocopy)
	Pharmacological Group	SSNRI

	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO
	RRA status	Venlafaxine UK
	Me-too status	Venalax tab (Reg. No. 038206)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved as per following label claim; **Each film coated extended release tablet contains:** **Venlafaxine as Hydrochloride….37.5mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change in label claim.**	
319.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Recyclo SR 15mg Capsules
	Composition	Each capsule contains: Cyclobenzaprine HCl…..15mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26352 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Dy.No.1746 Rs.12,000/- 09-10-2015 (photocopy)
	Pharmacological Group	Muscle relaxant
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Mezrel of M/s PharmEvo
	GMP status	
	Remarks of the Evaluator	**Label claim correction is required along with source of pellets.**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.37000/- for change of label claim along with source of pellets and for change of title to M/s. Global Pakistan.**	
320.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Recyclo SR 30mg Capsules
	Composition	Each capsule contains: Cyclobenzaprine HCl…..30mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26349 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I

		Dy.No.1746 Rs.12,000/- 09-10-2015 (photocopy)
	Pharmacological Group	Muscle relaxant
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Mezrel of M/s PharmEvo
	GMP status	
	Remarks of the Evaluator	**Label claim correction is required along with source of pellets.**
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.37000/- for change of label claim along with source of pellets and for change of title to M/s. Global Pakistan.**	
321.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Nimfast 100mg Tablets
	Composition	Each tablet contains: Nimsulide …….. 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 26350 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Dy.No.1746 Rs.12,000/- 09-10-2015 (photocopy)
	Pharmacological Group	NSAID
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x10's As per SRO
	RRA status	EMA
	Me-too status	Nims of M/s Sami
	GMP status	
	Remarks of the Evaluator	
	Decision: Keeping in view the approval status of Nimesulide 100mg tablet in EMA, Registration Board approved the applied formulation of Nimesulide tablet 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • **Treatment of acute pain** • **Primary dysmenorrhea** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.37000/- for change of title to M/s. Global Pakistan.**	
322.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Glopram 5mg Tablets

	Composition	Each tablet contains: Escitalopram …… 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 26345 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Dy.No.1746 Rs.12,000/- 09-10-2015 (photocopy)
	Pharmacological Group	Anti-Depressant
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	10's As per SRO
	RRA status	MHRA
	Me-too status	Belexa of Lisko
	GMP status	
	Remarks of the Evaluator	**Fee of standardization of label claim**
	Decision: Approved as per following label claim; **Each tablet contains:** **Escitalopram as Oxalate …… 5mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change in label claim and for change of title to M/s. Global Pakistan.**	
323.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Mycin Ointment
	Composition	Each gm contains: Gentamycin as Sulphate …0.1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 26348 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Dy.No.1746 Rs.12,000/- 09-10-2015 (photocopy) to be verified form R& I
	Pharmacological Group	Antibiotics
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	15gm As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and Mee-too status.	
324.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Rexit 40mg Tablets

	Composition	Each tablet contains: Febuxostat …… 40mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26347 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	xanthine oxidase inhibitor
	Finished product Specifications	inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA (**as film coated tablet**)
	Me-too status	Buxotat of Epharm
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved as per following label claim; **Each film coated tablet contains:** **Febuxostat …… 40mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change in label claim and for change of title to M/s. Global Pakistan.**	
325.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Rexit 80mg Tablets
	Composition	Each tablet contains: Febuxostat …… 80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D Dy. No 26346 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	xanthine oxidase inhibitor
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA (**as film coated tablet**)
	Me-too status	Buxotat of Epharm
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved as per following label claim; **Each film coated tablet contains:** **Febuxostat …… 40mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 37000/- for pre-approval change in label claim and for change of title to M/s. Global Pakistan.**	

326.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Fesolin 4mg Tablets
	Composition	Each tablet contains: Fesoterodine Fumarate ….4mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26354 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Alpha receptor blocker
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	**Not available**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
327.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Fesolin 8mg Tablets
	Composition	Each tablet contains: Fesoterodine Fumarate ….8mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26353 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Alpha receptor blocker
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	**Not available**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
328.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Fesolin XR 4mg Tablets

	Composition	Each tablet contains: Fesoterodine Fumarate ….4mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26351 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Alpha receptor blocker
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	**Not available**
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
329.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Rezole 30mg Capsules
	Composition	Each capsule contains: Dexlansoprazole ……. 30mg
	Type of Form, Diary No. Date of R& I & fee	**Form-5D** Dy. No 26357 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Xanprol of M/s Winbrain
	GMP status	
	Remarks of the Evaluator	**Label claim correction is required along with source of pellets.**
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
330.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Rezole 60mg Capsules
	Composition	Each capsule contains: Dexlansoprazole ……. 60mg
	Type of Form, Diary No. Date of R&	**Form-5D** Dy. No 26356 dated 19-09-2022 (**Duplicate dossier)**

	I & fee	Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Xanprol of M/s Winbrain
	GMP status	
	Remarks of the Evaluator	**Label claim correction is required along with source of pellets.**
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
331.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Transo 250mg Capsules
	Composition	Each capsule contains: Tranexamic Acid …… 250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D Dy. No 26344 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Antifibrinolytic agent
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	RRA status	PMDA
	Me-too status	Transamin capsules of M/s Hilton
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 37000/- for pre-approval change of title to M/s. Global Pakistan.**	
332.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Transo 500mg Capsules
	Composition	Each capsule contains: Tranexamic Acid …… 500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D Dy. No 26358 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I

		Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Antifibrinolytic agent
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	RRA status	PMDA
	Me-too status	Transamin capsules of M/s Hilton
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change of title to M/s. Global Pakistan.**	
333.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Rawat.
	Brand Name +Dosage Form + Strength	Myzith 500mg Capsules
	Composition	Each capsule contains: Azithromycin as Dihydrate…….500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D Dy. No 26355 dated 19-09-2022 (**Duplicate dossier)** Rs.8000/- dated 25-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 09-10-2015 (photocopy) to be verified from R&I
	Pharmacological Group	Macrolide
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	RRA status	**Not available**
	Me-too status	**NA**
	GMP status	
	Remarks of the Evaluator	**RRA could not be confirmed.**
	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.	
334.	Name and address of manufacturer / Applicant	M/s. MKB Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Telsa 40mg Tablets
	Composition	Each tablet contains: Telmisartan……..40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 594 dated 28-06-2012 verified from R&I Rs.12000/- (Photocopy) dated 31-12-2015 to be verified from R&I
	Pharmacological Group	Angiotensin-II receptor blocker
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, As per SRO
	RRA status	USFDA

	Me-too status	Mesartin of M/s Shrooq
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
335.	Name and address of manufacturer / Applicant	M/s. MKB Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Amloval Tablets
	Composition	Each film coated tablet contains: Amlodipine besylate eq. to Amlodipine……5mg Valsartan ……..80mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 587 dated 28-06-2012 **verified from R&I** Rs.12000/- (Photocopy) dated 31-12-2015 to be verified from R&I
	Pharmacological Group	Cardiovascular
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	14's, As per SRO
	RRA status	USFDA
	Me-too status	Valdosar Tablet 5mg+80mg of M/s Pinnacle Biotech (Pvt.) Ltd., Karachi. 114647
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications**	
336.	Name and address of manufacturer / Applicant	M/s. MKB Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Amloval Tablets
	Composition	Each film coated tablet contains: Amlodipine besylate eq. to Amlodipine……10mg Valsartan ……..160mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- (Photocopy) Dy. No. 590 dated 28-06-2012 **verified from R&I**

		Rs.12000/- (Photocopy) dated 31-12-2015 to be verified from R&I
	Pharmacological Group	Cardiovascular
	Finished product Specifications	inhouse
	Pack size & Demanded Price	14's, As per SRO
	RRA status	USFDA approved
	Me-too status	Valdosar Tablet 10mg+160mg of M/s Pinnacle Biotech (Pvt.) Ltd., Karachi. 114647
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications**	
337.	Name and address of manufacturer / Applicant	M/s Stand pharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Samide 10mg/ml Injection
	Composition	Each Ampoule Contains: Lacosamide…10mg/ml
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 3776 dated 05-03-2024 (**Duplicate dossier)** Rs.20000/- (Photocopy) dated 10-09-2018 to be verified from R&I
	Pharmacological Group	antiepileptic drug
	Finished product Specifications	inhouse
	Pack size & Demanded Price	20ml, As per SRO
	RRA status	Vimpat Belgium
	Me-too status	Winspat of Wnsfeild
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications**	
338.	Name and address of manufacturer / Applicant	M/s Mediceena Pharma Pvt Ltd 27-KM, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Medicoline Tablet 500mg
	Composition	Each tablet contains: Citicoline as Sodium…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10670 dated 27-04-2023 Rs. 12,000/- Dy. No. 32430 dated 31-01-2020 (original)

		Fee. 8,000, dated 18-04-2009 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Neurotonic
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's, As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Cercolin, Schazoo
	GMP status	
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
339.	Name and address of manufacturer / Applicant	M/s Mediceena Pharma Pvt Ltd 27-KM, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Medicoline Syrup
	Composition	Each 5ml contains: Citicoline as Sodium…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 10671 dated 27-04-2023 Rs. 12,000/- Dy. No. 32430 dated 31-01-2020 (original) Fee. 8,000, dated 18-04-2009 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Neurotonic
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	30ml, 45ml, 60ml, 90ml, 120ml As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Cercolin, Schazoo
	GMP status	
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
340.	Name and address of manufacturer / Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi.
	Brand Name +Dosage Form + Strength	Ponstapharm tablet
	Composition	Each film coated tablet contains: Mefenamic Acid…250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 13631 dated 01-06-2023 (**Duplicate dossier)** Dy. No nil dated 14-02-2017 Rs.20,000/- dated14-02-2017 (Photocopy) to be verified from R&I
	Pharmacological Group	NSAID
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	BNF
	Me-too status	Doloran tablet of Ms Epla
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following:	

	• **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
341.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Erythro tablet 250mg
	Composition	Each film coated tablet contains: Erythromycin as Stearate…..250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24859 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 26-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Macrolide antibiotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10x10'sAs per SRO
	RRA status	MHRA
	Me-too status	Erithrin 250mg of Ms Ferozsons
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
342.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Diclofast -P tablet 50mg
	Composition	Each film coated tablet contains: Diclofenac Potassium …50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24868 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	NSAID
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x10's, 3x10's;As per SRO
	RRA status	MHRA
	Me-too status	Spon K 50mg of Ms Davis
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following:	

	• **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
343.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Diclofast tablet 50mg
	Composition	Each film coated tablet contains: Diclofenac Sodium …50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24864 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	NSAID
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x10's, 3x10's;As per SRO
	RRA status	MHRA
	Me-too status	Rodic 50mg of Ms Rock Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
344.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Medisulide Tablet 100mg
	Composition	Each tablet contains: Nimesulide….100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24862 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Selective COX-2 inhibitors
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1x10's, 2x10's;As per SRO
	RRA status	EMA
	Me-too status	Nims tablet of Ms Sami Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached

	Decision: Keeping in view the approval status of Nimesulide 100mg tablet in EMA, Registration Board approved the applied formulation of Nimesulide tablet 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • **Treatment of acute pain** • **Primary dysmenorrhea** **Registration Board further decided that Registration letter shall be issued after the following:** • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
345.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Lomeflo tablet 200mg
	Composition	Each film coated tablet contains: Lomefloxacin Hydrochloride eq. to Lomefloxacin ….200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24860 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Fluoroquinolones
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1x10's;As per SRO
	RRA status	TGA Australia
	Me-too status	Maxaquin tablet of Ms Searle Pakistan Pvt. Ltd.
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
346.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore. **Contract manufactured by:** M/s Dyson Research Laboratories Pvt. Ltd., 28 Km Ferozpur Road Lahore.
	Brand Name +Dosage Form + Strength	Medipram Tablet 10mg
	Composition	Each film coated tablet contains: Escitalopram as Oxalate ….10mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- dated 18-07-2009 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Antidepressant/SSRI
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x7's, 1x10's;As per SRO
	RRA status	MHRA
	Me-too status	Citanew tablet of Ms Hilton Pharma Pvt. Ltd.
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Receiving of Rs.12000/- is not attached
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of submitted differential fee of contract manufacturing within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
347.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Clomimed tablet 50mg
	Composition	Each tablet contains: Clomiphene Citrate.....50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24863 dated 08-09-2021 (**Duplicate dossier)** Dy. No. 4645 dated 20-04-2011; Rs.8000/- dated 20-04-2011 (Photocopy) **to be verified form R& I** **R&I and fee challan of Rs.12,000/- are not attached**
	Pharmacological Group	Ovulatory stimulants
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	1x10's;As per SRO
	RRA status	TGA Australia
	Me-too status	Ovafin tablet of Ms OBS pharma.
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Fee challan and receiving of Rs.12000/- in R&I DRAP is not attached.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
348.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.

	Brand Name +Dosage Form + Strength	Biovirin capsule 200mg
	Composition	Each capsule contains: Ribavirin ….200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24867 dated 08-09-2021 (**Duplicate dossier)** Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I **R&I and fee challan of Rs.12,000/- are not attached**
	Pharmacological Group	Anti-viral
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1x10's;As per SRO
	RRA status	USFDA
	Me-too status	Ribazole of Ms Getz Pharma
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Fee challan and receiving of Rs.12000/- in R&I DRAP is not attached.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
349.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Tamsul capsule 0.4mg
	Composition	Each capsule contains: Tamsulosin HCl (as modified release pellets 0.2% w/w eq. to Tamsulosin HCl….0.4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- dated 31-08-2012 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Alpha-adrenoreceptor antagonist
	Finished product Specifications	BP specs
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's;As per SRO
	RRA status	MHRA
	Me-too status	Maylan of Ms McOlson Research Laboratories.
	GMP status	
	Remarks of the Evaluator	**Source of pellets:** M/s Vision Pharmaceuticals Pvt. Ltd. Islamabad **Shortcomings:** Receiving of Rs.12000/- in R&I DRAP is not attached.
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	

350.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Meditol Solution 4.8% w/v
	Composition	Each 100ml contains: Chloroxylenol ….4.8% w/v
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 24866 dated 08-09-2021 (**Duplicate dossier)** **No fee challan and R&I receiving of the applied product are submitted**
	Pharmacological Group	Antiseptic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	60/50ml, 100/100ml, 600/100ml;As per SRO
	RRA status	Dettol Antiseptic solution 48mg/ml TGA Australia
	Me-too status	Shrexol solution 4.8% w/v of Ms Sgarex Laboratories.
	GMP status	
	Remarks of the Evaluator	**External preparation section confirmed.** **Shortcomings:** Fee challans and receiving of both Rs. 8000/- and Rs.12000/- in R&I DRAP are not attached.
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
351.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Iroplex Syrup
	Composition	Each 15ml contains: Elemental Iron as Iron Protein Succinylate…40 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- dated 31-08-2012 (Photocopy) to be verified form R& I **Fee challan and R&I receiving of Rs. 12,000/- are not submitted**
	Pharmacological Group	Anti-anemic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	60ml, 120ml;As per SRO
	RRA status	Spain
	Me-too status	Fero-Slim syrup of Ms Fynk Pharmaceutical
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Fee challan and R&I receiving of Rs. 12,000/- are not submitted
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
352.	Name and address of manufacturer / Applicant	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.
	Brand Name +Dosage Form + Strength	Palen 1g cream

	Composition	Each gram contains: Adapalene …1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Rs.8000/- dated 21-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
	Pharmacological Group	Retinoid
	Finished product Specifications	BP specs
	Pack size & Demanded Price	15gm, 30gm, 45gm;As per SRO
	RRA status	MHRA
	Me-too status	Redap 0.1% cream of Ms Evolution Pharmaceutical
	GMP status	
	Remarks of the Evaluator	**External preparation section confirmed.** **Shortcomings:** R&I receiving of Rs. 12,000/- is not submitted
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
353.	Name and address of manufacturer / Applicant	M/s Winlet Pharma, 30Km, Lahore Sargodha Road, Sargodha **contract manufacturing from** M/s Bio-Labs(Pvt) Ltd., Plot No 145, Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Spasmolet Injection
	Composition	Each ampoule contains: Phloroglucinol Hydrate ….40mg Trimethylphloroglucinol ….0.04mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4619 dated 24-04-2024 Rs.50000/- dated 07-03-2019 (Photocopy) to be verified form R& I
	Pharmacological Group	Spasmolytic agent
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	4mlx10's ;As per SRO
	RRA status	ANSM approved
	Me-too status	Spadix injection of Ms Tabros
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs.50000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
354.	Name and address of manufacturer / Applicant	M/s Allmed (pvt) Ltd, Plot No.590 Sunder Estate Lahore
	Brand Name +Dosage Form + Strength	Gablika 150mg capsule

	Composition	Each capsule contains: Pregabalin…..150mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4175 dated 26-03-2024 and Dy. No. nil dated 03-02-2023 Fee. 8,000, Date: 28-01-2009 (Photocopy)(Challan Shows for M/s Ever Green pharma) Rs.12000/- dated 11-10-2012(Photocopy)
	Pharmacological Group	Anti-epileptic
	Finished product Specifications	BP specs
	Pack size & Demanded Price	14's;As per SRO
	RRA status	MHRA
	Me-too status	Gabica of Ms Getz
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
355.	Name and address of manufacturer / Applicant	M/s Allmed (pvt) Ltd, Plot No.590 Sunder Estate Lahore
	Brand Name +Dosage Form + Strength	Gablika 75mg capsule
	Composition	Each capsule contains: Pregabalin…..75mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4176 dated 26-03-2024 and Dy. No. nil dated 03-02-2023 Fee. 8,000, Date: 28-01-2009 (Photocopy)(Challan Shows for M/s Ever Green pharma) Rs.12000/- dated 11-10-2012(Photocopy)
	Pharmacological Group	Anti-epileptic
	Finished product Specifications	BP specs
	Pack size & Demanded Price	14's;As per SRO
	RRA status	MHRA
	Me-too status	Gabica of Ms Getz
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
356.	Name and address of manufacturer / Applicant	M/s Maxitech pharma Pvt Ltd, Plot No. E-178, S.I.T.E, Super Highway Karachi.
	Brand Name +Dosage Form + Strength	Mezox 250mg IM/IV injection
	Composition	Each vial contains: Ceftizoxime sodium eq. to ceftizoxime...250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 25710 dated 02-12-2019 Dy. No. nil dated 07-12-2018, Rs.20000/-dated 07-12-2018 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Cephalosporin antibiotic

	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	**Could not be confirmed**
	Me-too status	Cefizox injection 250mg of Ms GSK
	GMP status	
	Remarks of the Evaluator	**Dry Powder vial injectable (Cephalosporin) section** confirmed vide N0. F. 2-12/2012-Lic (Vol-I) dated 03-12-2018
	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.	
357.	Name and address of manufacturer / Applicant	M/s Maxitech pharma Pvt Ltd, Plot No. E-178, S.I.T.E, Super Highway Karachi.
	Brand Name +Dosage Form + Strength	Clin-max Cream 1%
	Composition	Each gram contains: Clindamycin as phosphate..1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. nil dated 09-12-2016, Rs.20000/-dated 09-12-2016 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	antibiotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	
	Me-too status	acnesafe of Ms Epla
	GMP status	
	Remarks of the Evaluator	**Ointment/cream/lotion (General) section** confirmed vide N0. F. 2-12/2012-Lic dated 25-11-2016 **Deferred in M-269** for consideration on its turn as firm has already availed priority quota of products against this section.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
358.	Name and address of manufacturer / Applicant	M/s Maxitech pharma Pvt Ltd, Plot No. E-178, S.I.T.E, Super Highway Karachi.
	Brand Name +Dosage Form + Strength	Primicef 100mg/1ml drops dry powder suspension
	Composition	Each 1ml contains: Cephalexin monohydrate eq. to Cephalexin....100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 25709 dated 02-12-2019 Dy. No. nil dated 07-12-2018, Rs.20000/-dated 07-12-2018 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antibiotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	USFDA
	Me-too status	Keflex of Ms AGP

	GMP status	
	Remarks of the Evaluator	**Oral Dry Powder suspension (Cephalosporin) section** confirmed vide N0. F. 2-12/2012-Lic (Vol-I) dated 03-12-2018
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
359.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ragnid 0.5mg Tablet
	Composition	Each film coated tablet contains: Repaglinide…0.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4232 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	USFDA
	Me-too status	Reugax of Axis
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
360.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ravzol 50mg Tablet
	Composition	Each film-coated tablet contains: Voriconazole …..50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4240 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	antifungal
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	USFDA
	Me-too status	Vorif
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following:	

	• **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
361.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Relnate 70mg tablet
	Composition	Each tablet contains: Alendronate (as sodium)….70mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4238 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Bisphosphonate
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2's, 4's, 6's, 12's; As per PRC
	RRA status	Fosamax once weekly 70mg tablet **UK**
	Me-too status	Alendro Flex (Reg. No. 042387)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
362.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Royze 600mg Tablet
	Composition	Each film-coated tablet contains: Oxcarbazepine …..600mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4239 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antiepileptic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 60's, 100's, 200's; As per PRC
	RRA status	Mylan 600mg film coated tablets **UK**
	Me-too status	Neutozep 600mg Tablet of M/s Neutro Pharma (Pvt) Ltd., Lahore. (Reg. No.109556)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
363.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.

	Brand Name +Dosage Form + Strength	Ropiron 25mg tablet
	Composition	Each film coated tablet contains: Eplerenone …..25mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4237 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Mineralocorticoid receptor antagonist
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	10's, 20's, 28's, 30's, 50's, 90's, 100's, 200's; As per PRC
	RRA status	Eplerenone 25mg film coated tablets **UK**
	Me-too status	Epliron (Reg. No.080484) of M/s Highnoon
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
364.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ragnid 2mg Tablet
	Composition	Each tablet contains: Repaglinide…2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4236 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per PRC; As per PRC
	RRA status	USFDA
	Me-too status	Rugex of Axis
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
365.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Royze 300mg Tablet
	Composition	Each film-coated tablet contains: Oxcarbazepine …..300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4235 dated 02-04-2024

		Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antiepileptic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 60's, 100's, 200's; As per PRC
	RRA status	Oxcarbazepine Mylan 600mg film coated tablets **UK**
	Me-too status	Neutozep 300mg Tablet of M/s Neutro Pharma (Pvt) Ltd., Lahore. (Reg. No.109557)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
366.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Rastazic Tablet 50mg
	Composition	Each film coated tablet contains: Cilostazol …..50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4231 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Anti-thrombotic agent
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x14's, 4x14's; As per PRC
	RRA status	Cilostazol 50mg Ireland
	Me-too status	Neutocil 50mg Tablet of M/s Neutro Pharma (Pvt) Ltd., Lahore. (Reg. No. 108203)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
367.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Roldi 2mg Tablet
	Composition	Each film-coated tablet contains: Tolterodine tartrate 2mg corresponding to tolterodine.....1.37 mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4234 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antimuscarinic

	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	14's, 20's, 28's, 50's, 56's, 60's, 90's, 100's; As per PRC
	RRA status	Tolterodine tartrate 2mg film coated tablet, Ireland
	Me-too status	Uratonyl Tablet 2mg of M/s High-Q Pharmaceuticals, Karachi. (Reg. No. 100963)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
368.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Relsa Tablet
	Composition	Each film-coated tablet contains: Amlodipine as besylate ….5mg Valsartan ……..160mg Hydrochlorothiazide ……12.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4233 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Antihypertensive
	Finished product Specifications	USP specs
	Pack size & Demanded Price	14's, 28's, 30's, 56's, 90's, 98's, 280's; As per PRC
	RRA status	Copalia HCT film coated tablet, Ireland
	Me-too status	Avsar Plus 160/5/12.5Tablets of M/s Pharmevo (Pvt) Ltd. (Reg. No. 076357)
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
369.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Aspamerz 3mg Sachet
	Composition	Each sachet contains: L-Ornithine L Aspartate…..3gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 4241 dated 02-04-2024 Dy. No. nil dated 07-03-2019, Rs.20000/-dated 07-03-2019 (photocopy) to be verified from R&I DRAP
	Pharmacological Group	Amino acids
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO; As per SRO

	RRA status	Hepa Merz granules for sachet, Germany
	Me-too status	Hepaser Sachet 3gm of M/s Panacea Pharmaceuticals (Reg. No. 075403)
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs.20000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
370.	Name and address of manufacturer / Applicant	M/s Pacific Pharmaceuticals Limited., 30 km, Multan Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Melomin XR Tablet 1000mg
	Composition	Each film coated extended release tablet contains: Metformin HCl…1000mg
	Type of Form, Diary No. Date of R& I & fee	Form-**5D (Duplicate dossier)** Dy. No. 13660 dated 20-12-2024 R&I and fee challan of Rs. 15000/- is **not attached** Dy. No. nil dated 25-10-2018, Rs.5000/-dated 25-10-2018 (photocopy) to be verified from R&I DRAP **1st reminder**: Dy. No. 21104 dated 17-01-2019 (original) **2nd reminder**: Dy. No. nil dated 25-10-2021 (photocopy) **3rd reminder**: Dy. No. nil dated 11-11-2022 (photocopy) **4th reminder**: Dy. No. nil dated 07-03-2023 (photocopy)
	Pharmacological Group	Antidiabetic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	Glucophage XR tablets
	Me-too status	Himet XR 1000mg Tablet of M/s Himont Pharmaceuticals (Pvt) Ltd (Reg. No. 113899)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** **R&I and fee challan of Rs. 15000/- is not attached**
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs.15000/- and Rs.5000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
371.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Z-Grow Tablet
	Composition	Each film coated contains: Zinc as Zinc Sulphate …. 22.5mg Vitamin E …… 30IU Vitamin C ……..500mg Folic Acid …… 150mcg Vitamin B1 …….. 15mg Vitamin B2 …….. 15mg Nicotinamide ……... 100mg Vitamin B6 …….. 20mg Vitamin B12 …….. 12mcg Pantothenic acid as calcium pantothenate …… 20mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. Nil dated 09-12-2019 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Multivitamin
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Surbex Z Abbott
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved with change of brand name. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
372.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Viodol Injection 2ml
	Composition	Each 2ml ampoule contains: Paracetamol …… 300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier) Dy. No. 3966** dated 14-03-2024. Rs.60000/- (photocopy) dated 11-02-2014 **no receiving attached; to be confirmed from R&I DRAP**
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Bofalgan 300mg/2ml Injection
	GMP status	
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs.60000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
373.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, Plot 527, Sunder Industrial Estate Lahore.
	Brand Name +Dosage Form + Strength	Bocep tablet
	Composition	Each film coated tablet contains: Memantine Hydrochloride.....5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. nil dated 22-03-2024. Dy. No. nil dated 06-07-2017, Rs.20000/- dated 06-07-2017 (photocopy) to be verified from R&I
	Pharmacological Group	Glutamate receptor antagonist
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	14's, 30's and 56's; As per SRO
	RRA status	Ebixa MHRA
	Me-too status	Afdol of M/s AGP

	GMP status	
	Remarks of the Evaluator	Receiving of Rs. 20,000/- to be verified from R&I DRAP
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
374.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Ranit 50mg/2ml Injection
	Composition	Each 2ml contains: Ranitidine as HCl …….. 50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 8266 dated 07-08-2012 **(Original dossier)** Rs.8000/- (Original) Rs.12000/- (**Photocopy**) Dy No.970 -R&I dated 23-08-2016, to be verified from R&I DRAP
	Pharmacological Group	H2 Blocker
	Finished product Specifications	USP specs
	Pack size & Demanded Price	5's x 2ml, As per SRO
	RRA status	
	Me-too status	Zantec
	GMP status	
	Remarks of the Evaluator	Receiving of Rs. 12,000/- to be verified from R&I DRAP
	Decision: Registration Board rejected instant application as product is not available in RRA.	
375.	Name and address of manufacturer / Applicant	Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura, Lahore.
	Brand Name +Dosage Form + Strength	Nuzar 25mg Tablet
	Composition	Each film coated tablet contains: Losartan Potassium….25mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 9912 dated 19-04-2022 **(Duplicate dossier)** Dy. No 8179 dated 31-08-2010 to be verified from R&I Rs.8000/- (photo copy) Rs.12000/- Dy No.32042 -R&I dated 29-01-2020, (original)
	Pharmacological Group	Angiotensin-II Receptor Antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA
	Me-too status	Thaitan of Jaens
	GMP status	
	Remarks of the Evaluator	Receiving of Rs. 8,000/- to be verified from R&I DRAP
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.**	

	• **latest GMP inspection report conducted within period of three years.**

c Duplicate dossiers submitted after the deadline:

376.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Hepalac syrup
	Composition	Each 5ml contains: Lactulose….3.335gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11128 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 12-06-2017 (photocopy)
	Pharmacological Group	Laxative
	Finished product Specifications	USP specs
	Pack size & Demanded Price	60ml, 120ml;As per SRO
	RRA status	MHRA
	Me-too status	Lilac of Ms Getz
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** **Shortcomings:** Source of Bulk Lactulose is required along with differential fee.
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
377.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Osamin-D 830mg tablets
	Composition	Each film coated tablet contains: Ossein mineral complex i.e. Hydroxyapatite compound….830mg Equivalent to Calcium .....177.6mg Phosphorus.....82.2mg Residual mineral salts.....24.9mg Collagen.....224mg Other proteins.....66.4mg Trace elements.....Fl, Mg, Fe, Ni, Cu Vitamin D.....400IU
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11127 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 28-11-2016 (photocopy)
	Pharmacological Group	Multivitamins and supplements
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	30's;As per SRO
	RRA status	
	Me-too status	Osnate-D AGP
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**

	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
378.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Osamin Suspension
	Composition	Each 5ml contains: Ossein mineral complex i.e. Hydroxyapatite compound….400mg Equivalent to Calcium .....85.59mg Phosphorus.....39.61mg Residual mineral salts.....12mg Collagen.....107.95mg Other proteins.....32.0mg Trace elements.....Fl, Mg, Fe, Ni, Cu
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11129 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 12-06-2017 (photocopy)
	Pharmacological Group	Multivitamins and supplements
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	60ml;As per SRO
	RRA status	
	Me-too status	Osnate of AGP
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
379.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Osamin 830mg tablets
	Composition	Each film coated tablet contains: Ossein mineral complex i.e. Hydroxyapatite compound….830mg Equivalent to Calcium .....177.6mg Phosphorus.....82.2mg Residual mineral salts.....24.9mg Collagen.....224mg Other proteins.....66.4mg Trace elements.....Fl, Mg, Fe, Ni, Cu
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11124 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 28-11-2016 (photocopy)
	Pharmacological Group	Multivitamins and supplements
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	30's;As per SRO

	RRA status	
	Me-too status	Osnate Tablet AGP
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
380.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Romlus 5mg capsule
	Composition	Each capsule contains: Tacrolimus as monohydrate.....5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11130 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 21-12-2017 (photocopy)
	Pharmacological Group	Immunosuppressant
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10's & 30's;As per SRO
	RRA status	USFDA
	Me-too status	Tacgraf CCL
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
381.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Acidonil suspension
	Composition	Each 5ml contains: Famotidine.....40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11131 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 12-06-2017 (photocopy)
	Pharmacological Group	H2 blocker
	Finished product Specifications	USP specs
	Pack size & Demanded Price	60ml, 120ml;As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

382.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Gavicon Liquid
	Composition	Each 10ml contains: Sodium Alginate.....500mg Sodium bicarbonate.....267mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11126 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 12-06-2017 (photocopy)
	Pharmacological Group	Antacids
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	120ml;As per SRO
	RRA status	
	Me-too status	Not confirmed
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
383.	Name and address of manufacturer / Applicant	Crystolite pharmaceuticals, Plot No. 1,2 street S-2 National Inductrial zone Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Gavicon Double action Liquid
	Composition	Each 10ml contains: Sodium Alginate.....500mg Calcium Carbonate.....325mg Sodium bicarbonate.....213mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 11125 dated 21-10-2024 **(Duplicate dossier)** Rs.20,000/- Dy No..nil dated 12-06-2017 (photocopy)
	Pharmacological Group	Antacids
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	120ml;As per SRO
	RRA status	
	Me-too status	Gaviscon double action liquid
	GMP status	GMP certificate dated 19-08-2022 based on inspection conducted on 08-08-2022
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
384.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Pregaba 100 Capsules
	Composition	Each capsule contains: Pregabalin …… 100mg
	Type of Form, Diary No. Date of R&	Form-5 (**Duplicate dossier)** Dy. No. 13517 dated 19-12-2024

	I & fee	Rs.8000/- (photocopy) dated 11-01-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	In-house
	Pack size & Demanded Price	10's, As per PRC
	RRA status	FDA
	Me-too status	Gabica 100mg Capsule Getz
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
385.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Pregaba 300 Capsules
	Composition	Each capsule contains: Pregabalin …… 300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13511 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	In-house
	Pack size & Demanded Price	10's, As per PRC
	RRA status	FDA
	Me-too status	Gabica 300mg Capsule Getz
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

386.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	L-Fox Suspension 125mg
	Composition	Each 5ml contains: Levofloxacin …… 125mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13504 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	antibiotics
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	**Not found**
	Me-too status	Levox Dry Suspension 125mg Reg. No. 075394
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
387.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	L-Fox Suspension 250mg
	Composition	Each 5ml contains: Levofloxacin …… 250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13508 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	antibiotics
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	**Not found**
	Me-too status	Levox Dry Suspension 250mg Reg. No. 075395
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section

		Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
388.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa Suspension
	Composition	Each 5ml contains: Domperidone …… 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13528 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	**FDA**
	Me-too status	Motillium Syrup
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
389.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa tablet
	Composition	Each film coated tablet contains: Domperidone as maleate …… 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13526 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- receiving not attached
	Pharmacological Group	antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Motillium V Tablet

	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
390.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa C tablet
	Composition	Each film coated tablet contains: Domperidone as maleate …… 15mg Cinnarizine ……. 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13525 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	Antiemetic, antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 30, 50 As per PRC
	RRA status	**FDA**
	Me-too status	Pelton C Tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
391.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Pacid Tablet
	Composition	Each film coated tablet contains: Flurbiprofen …… 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13510 dated 19-12-2024 Rs.8000/- (photocopy) dated 21-06-2011 to be verified from R&I DRAP

		Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	30 As per PRC
	RRA status	**FDA**
	Me-too status	Ansaid tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
392.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Ribra 10mg Tablet
	Composition	Each enteric coated tablet contains: Rabeprazole …… 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13524 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	PPI
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 14 As per PRC
	RRA status	**FDA**
	Me-too status	Promoto tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
393.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore

	Brand Name +Dosage Form + Strength	Ribra 20mg Tablet
	Composition	Each enteric coated tablet contains: Rabeprazole …… 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13523 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	PPI
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 14 As per PRC
	RRA status	**FDA**
	Me-too status	Promoto tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
394.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther Tablet
	Composition	Each film coated tablet contains: Artemether …… 20mg Lumefantrine …… 120mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13527 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	8 As per PRC
	RRA status	**FDA**
	Me-too status	Aertem tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section

		Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
395.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther DS ablet
	Composition	Each film coated tablet contains: Artemether …… 40mg Lumefantrine ……. 240mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13512 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	8 As per PRC
	RRA status	**WHO PQ**
	Me-too status	Aertem tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
396.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther Forte ablet
	Composition	Each film coated tablet contains: Artemether …… 80mg Lumefantrine ……. 480mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13515 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	4 As per PRC

	RRA status	**WHO PQ**
	Me-too status	Aertem tablet
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
397.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther suspension
	Composition	Each 5ml contains: Artemether …… 15mg Lumefantrine ……. 90mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13514 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, As per PRC
	RRA status	
	Me-too status	Aertem plus suspension
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
398.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Epril 5mg Tablet
	Composition	Each film coated tablet contains: Enalapril …… 5mg
	Type of Form, Diary No. Date of R&	Form-5 (**Duplicate dossier)** Dy. No. 13521 dated 19-12-2024

	I & fee	Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	ACE inhibitor
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 20 As per PRC
	RRA status	**FDA**
	Me-too status	Cardace zafa
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
399.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Epril 10mg Tablet
	Composition	Each film coated tablet contains: Enalapril …… 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13522 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	ACE inhibitor
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 20 As per PRC
	RRA status	**FDA**
	Me-too status	Cardace zafa
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

400.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Fonza M Tablet
	Composition	Each film coated tablet contains: Sumatriptan as succinate …… 85mg Naproxen sodium …… 500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13520 dated 19-12-2024 Rs.8000/- (photocopy) dated 26-12-2010 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	5HT agonist, NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Synflex M
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
401.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Afelo 100mg Tablet
	Composition	Each film coated tablet contains: Aceclofenac …… 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13519 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Acenac
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section

		Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
402.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Volima Tablet
	Composition	Each film coated tablet contains: Activated Attapulgite …… 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13519 dated 19-12-2024 Rs.8000/- (photocopy) dated 21-06-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	ENTOX-P TAB
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
403.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Codofen Tablet
	Composition	Each film coated tablet contains: Ibuprofen …… 200mg Codeine Phosphate ……. 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13506 dated 19-12-2024 Rs.8000/- (photocopy) dated 20-12-2010 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	Opioid, NSAID
	Finished product Specifications	In-house

	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Brufen Plus Tablets Abbott
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
404.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Moxidal Lotion
	Composition	Each ml contains: Minoxidil ……. 0.05mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13509 dated 19-12-2024 Rs.8000/- (photocopy) dated 23-05-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antihypertensive
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Minoxi plus solution Danas
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
405.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Scape Lotion
	Composition	Each ml contains: Permethrin ……. 10mg
	Type of Form, Diary No. Date of R&	Form-5 (**Duplicate dossier)** Dy. No. 13516 dated 19-12-2024

	I & fee	Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Scabicide
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Lotrix lotion GSK
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
406.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Scape Cream
	Composition	Each gm contains: Permethrin ……. 50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13507 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Scabicide
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Lotrix cream GSK
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

407.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Porex Syrup
	Composition	Each 5ml contains: Codeine Phosphate ……. 10mg Chlorpheniramine maleate ……. 4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13518 dated 19-12-2024 Rs.8000/- (photocopy) dated 23-05-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Cough suppressant, anti-allergic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Not confirmed
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
408.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Shapex Gel
	Composition	Each gm contains: Isotretinoin ……. 0.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13505 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Retinoid
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**FDA**
	Me-too status	Isotin gel Shaigan
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line** Capsule General Section Tablet General Section

		Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
409.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reozine Syrup
	Composition	Each 5ml contains: Levocetirizine Dihydrochloride ……. 2.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12857 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml As per PRC
	RRA status	
	Me-too status	Neo-Sedil Syrup Sami
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
410.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reotolin Syrup
	Composition	Each 5ml contains: Salbutamol as sulphate ……. 2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12856 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Bronchodilator
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**MHRA**
	Me-too status	Ventolin syrup
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
411.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore

	Brand Name +Dosage Form + Strength	Reotalin Syrup
	Composition	Each ml contains: Terbutaline sulphate ……. 0.3mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12854 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Selective B2 Stimulant
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**MHRA**
	Me-too status	Britanyl Syrup Barrett Hodgson
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
412.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodine Syrup
	Composition	Each ml contains: Desloratadine ……. 0.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12855 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**MHRA**
	Me-too status	Neo-Antial 0.5mg/ml Syrup
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
413.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reoton Syrup
	Composition	Each 5ml contains: Ondansetron as HCl Dihydrate ……. 4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12853 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Selective 5HT-3 Receptor antagonist
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC

	RRA status	**FDA**
	Me-too status	Onset
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
414.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riocoline Syrup
	Composition	Each 5ml contains: Citicoline ……. 500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12858 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Psychostimulant
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Cercolin syrup
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
415.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Roecetam Syrup
	Composition	Each 5ml contains: Piracetam ……. 1gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12852 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Nootropic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**Spain**
	Me-too status	Ceremin Syrup Schazoo
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
416.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore

	Brand Name +Dosage Form + Strength	Reolid Suspension
	Composition	Each 5ml contains: Linezolid ……. 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12851 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antibiotic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**MHRA**
	Me-too status	Nazkil suspension SJ&G
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
417.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodon Suspension
	Composition	Each 5ml contains: Domperidone ……. 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12850 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	**MHRA**
	Me-too status	Domel
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
418.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riocone Cream
	Composition	Each gm contains: Miconazole nitrate ……. 2%
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12849 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antifungal
	Finished product Specifications	In-house
	Pack size & Demanded Price	20gm As per PRC

	RRA status	MHRA
	Me-too status	Micoral Cream Elko
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
419.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riofenac Gel
	Composition	Each gm contains: Diclofenac Dimethylamine eq. to Diclofenac sodium .. 1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12846 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	20gm As per PRC
	RRA status	**MHRA**
	Me-too status	Voltral gel
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
420.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riocam Gel
	Composition	Each gm contains: Piroxicam …… 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12847 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	25gm As per PRC
	RRA status	MHRA
	Me-too status	Xorip Gel 5mg Reliance
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
421.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore

	Brand Name +Dosage Form + Strength	Riofuse Cream
	Composition	Each gm contains: Fusidic Acid ……. 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12848 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Steroidal antibiotic
	Finished product Specifications	In-house
	Pack size & Demanded Price	15gm As per PRC
	RRA status	MHRA
	Me-too status	Baxidin Cream 2% Baxter
	GMP status	
	Remarks of the Evaluator	**Submitted after dead line**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
422.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat
	Brand Name +Dosage Form + Strength	Post Eye Drops 0.004%
	Composition	Each ml opthalmic Solution contains: Travoprost ….0.04mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 6451 dated 27-06-2024 (**Duplicate dossier)** Fee 20000- dated 07-03-2019 (photocopy)
	Pharmacological Group	Antiglaucoma preparations and miotics prostaglandin analogues
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Travatan USFDA UK
	Me-too status	Travost of M/s Sante Pvt. Ltd., Karachi
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	**Submitted after the deadline** **Shortcomings:** • verification is required from R&I section • Section approval from CLB is required????
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
423.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Merotyl Injection 1gm
	Composition	Each vial contains: Meropenem as Trihydrate……1gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)**

		Dy. No. 30124 dated 13-01-2020 Rs.12000/- dated 13-01-2020 (Original) Rs.8000/- dated 30-06-2011 (photo copy challan only)
	Pharmacological Group	Antibacterial, Carbapenem
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1's, As per SRO
	RRA status	FDA
	Me-too status	Merfuge Rotex
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • R&I of Rs. 8,000/- is **not attached** • Container Closure Type-III Clear glass Vial
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
424.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories, 136-138 Sector-15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Merotyl Injection 500mg
	Composition	Each vial contains: Meropenem as Trihydrate……500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No. 30123 dated 13-01-2020 Rs.12000/- dated 13-01-2020 (Original) Rs.8000/- dated 30-06-2011 (photo copy challan only)
	Pharmacological Group	Antibacterial, Carbapenem
	Finished product Specifications	USP specs
	Pack size & Demanded Price	1's, As per SRO
	RRA status	FDA
	Me-too status	Merfuge Rotex
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • R&I of Rs. 8,000/- is **not attached** • Container Closure Type-III Clear glass Vial
	Decision: Registration Board rejected the instant application since the firm does not possess approval of required manufacturing facility / section from Licensing Division, DRAP.	
425.	Name and address of manufacturer / Applicant	M/s. Pharmedic labs (Pvt) Ltd, 16-KM Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Butacin tablets
	Composition	Each tablet contains: Oxybutynin…..5mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No. 409 dated **06-02-2020** Rs.12000/- dated 30-01-2020 (Original) Rs.8000/- (photo copy challan)
	Pharmacological Group	Antispasmodic
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Ditropan USA
	Me-too status	Cystrin AJ&Co
	GMP status	
	Remarks of the Evaluator	Fee endorsement on 30-01-2020 while submission in DRAP dated 06-02-2020 **Shortcomings:** • R&I of Rs. 8,000/- is **not attached**
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
426.	Name and address of manufacturer / Applicant	M/s. Pharmedic labs (Pvt) Ltd, 16-KM Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Topican Injection
	Composition	Each vial contains: Topotecan ….4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No. 405 dated **06-02-2020** Rs.12000/- dated 30-01-2020 (Original) Rs.8000/- (photo copy challan)
	Pharmacological Group	Immunosupressant
	Finished product Specifications	
	Pack size & Demanded Price	1's, As per SRO
	RRA status	Hycamtin UK, Australia
	Me-too status	Hycamtin GSK
	GMP status	
	Remarks of the Evaluator	Fee endorsement on 30-01-2020 while submission in DRAP dated 06-02-2020 **Shortcomings:** • R&I of Rs. 8,000/- is **not attached**
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
427.	Name and address of manufacturer / Applicant	M/s. Pharmedic labs (Pvt) Ltd, 16-KM Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Ketolac 10mg Injection
	Composition	Each ampoule contains: Ketorolac….10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No. 410 dated **06-02-2020** Rs.12000/- dated 30-01-2020 (Original)

		Rs.8000/- (photo copy challan)
	Pharmacological Group	NSAID
	Finished product Specifications	
	Pack size & Demanded Price	5x1ml; As per SRO
	RRA status	Toradol UK, USA
	Me-too status	Toradol, Roche
	GMP status	
	Remarks of the Evaluator	Fee endorsement on 30-01-2020 while submission in DRAP dated 06-02-2020 **Shortcomings:** • R&I of Rs. 8,000/- is **not attached**
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	
428.	Name and address of manufacturer / Applicant	M/s. Pharmedic labs (Pvt) Ltd, 16-KM Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Terosin tablets 2mg
	Composition	Each tablet contains: Tolterodine….2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy. No. 407 dated **06-02-2020** Rs.12000/- dated 30-01-2020 (Original) Rs.8000/- (photo copy challan)
	Pharmacological Group	Cholinergic
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Tolterodine Tartarate 2mg tablets MHRA
	Me-too status	Toltura 2mg tablet of Hilton pharma
	GMP status	
	Remarks of the Evaluator	Fee endorsement on 30-01-2020 while submission in DRAP dated 06-02-2020 **Shortcomings:** • R&I of Rs. 8,000/- is **not attached**
	Decision: Registration board rejected the instant application as differential fee was submitted after the deadline for submission of differential fee i.e., 31-01-2020 notified vide notification No. Dy. 3013/2018-Add: Dir. (PE&R) dated 01-10-2019.	

d. Duplicate dossiers not verified by R&I section of DRAP:

429.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Dermigen Cream
	Composition	Each gram contains: Fusidic Acid.....2%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31871 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original)

		Fee. 8,000, dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Steroid Antibiotics
	Finished product Specifications	BP specs
	Pack size & Demanded Price	15gm, As per SRO
	RRA status	MHRA
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **Verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **Latest GMP inspection report conducted within period of three years.** • **Fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
430.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Dermigen H Cream
	Composition	Each gram contains: Fusidic Acid.....2% Hydrocortisone.....1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31875 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antibiotics and hydrocortisone
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	15gm, As per SRO
	RRA status	Fucidin H UK
	Me-too status	Fusac H cream
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
431.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Dermigen B Cream 2%

	Composition	Each gram contains: Fusidic Acid.....2% Betamethasone.....1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31874 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antibiotics and corticosteroid
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Fucibet cream UK
	Me-too status	Fusil B cream
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
432.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Maxiderm Cream 20%
	Composition	Each gram contains: Azelaic Acid.....20%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31881 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Aromatic organic compound
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Dermatica 20% cream UK
	Me-too status	Skinoren 20% cream
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	

433.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Isopex Gel 0.5%
	Composition	Each gram contains: Isotretinoin…0.5%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31882 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 12-12-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Vitamin analogue
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
434.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Clomizole Vaginal Cream 10%
	Composition	Each gram contains: Clotrimazole 10%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31880 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antifungal
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	

435.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Gynogen Vaginal Cream
	Composition	Each gram contains: Isoconazole Nitrate ……. 1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31883 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antifungal
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
436.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Apequine Cream 4%
	Composition	Each gram contains: Hydroquinone……. 4%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31885 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Benzene derivative
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.**	

	• **latest GMP inspection report conducted within period of three years.**	
437.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Adalene Cream 0.1%
	Composition	Each gram contains: Adapalene.....0.1% w/w
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31884 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Retinoid like compounds (oxygenated derivative)
	Finished product Specifications	BP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Differin 0.1% cream US
	Me-too status	Acne lene 0.1% cream of Ms Valor pharmaceuticals
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
438.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Minazole V Vaginal Cream
	Composition	Each gram contains: Miconazole Nitrate.....2%
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31872 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antifungal
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Monistate 2% cream USA
	Me-too status	Gyno Daktarin 2% cream of Ms Johnson & Johnson
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.**	

	• **latest GMP inspection report conducted within period of three years.**	
439.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Apepram Capsule 20mg
	Composition	Each capsule contains: Escitalopram…20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31878 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	SSRI
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Registration Board rejected instant application due to non-availability of approval status in Reference regulatory authorities as adopted by Registration Board in its 275th meeting.	
440.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Apetor Tablet 10mg
	Composition	Each film coated tablet contains: Atorvastatin as calcium…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31863 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 15-09-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	HMG Co reductase inhibitor
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Atorlip 10mg tablet FDA
	Me-too status	Lipitor of M/s Pfizer
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
441.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.

	Brand Name +Dosage Form + Strength	Apetor Tablet 40mg
	Composition	Each film coated tablet contains: Atorvastatin as calcium…40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31864 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 01-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	HMG Co reductase inhibitor
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Atorlip 40mg tablet FDA
	Me-too status	Lipitor of M/s Pfizer
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
442.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Mecoba Tablet 500mcg
	Composition	Each film coated tablet contains: Mecobalamin…500mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31859 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 28-02-2012 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Vitamin B12
	Finished product Specifications	JP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Methycobal 500mcg tablet USA
	Me-too status	G-cobal 500mcg tablet of M/s Glitz
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval change from film coated to sugar coated tablet.**	

443.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Tiptin Tablet 50mg
	Composition	Each film coated tablet contains: Sitagliptin as phospate…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31858 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 28-02-2012 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Januvia 50mg tablet UK
	Me-too status	Silo 50mg tablet of M/s Macter
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for change in label claim.**	
444.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Tiptin Tablet 100mg
	Composition	Each film coated tablet contains: Sitagliptin as phospate…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31857 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 28-02-2012 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Januvia 100mg tablet UK
	Me-too status	Silo 100mg tablet of M/s Macter
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.**	

	• **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for change in label claim.**	
445.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Tiptin Met Tablet 50/500mg
	Composition	Each film coated tablet contains: Sitagliptin as phospate…50mg Metformin HCl…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31856 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 28-02-2012 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Janumet 50/500mg tablet USFDA
	Me-too status	Silo M 50/500mg tablet of M/s Macter
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for change in label claim.**	
446.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Tiptin Met Tablet 50/1000mg
	Composition	Each film coated tablet contains: Sitagliptin as phospate…50mg Metformin HCl…1000mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 37742 dated 26-12-2022 (**Duplicate dossirer**) Rs. 12,000/- dated 29-01-2020 (**photocopy**) to be verified from R&I DRAP Fee. 8,000 , dated 28-02-2012 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitor
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Janumet 50/1000mg tablet USFDA
	Me-too status	Silo M 50/1000mg tablet of M/s Macter
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance

	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 37000/- for change in label claim.**	
447.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Montekast Tablet 4mg
	Composition	Each tablet contains: Monteleukast as Sodium…4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31870 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 01-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Leukotriene receptor antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Montelukast Apotex 4mg tablet Canada
	Me-too status	Be Easy 4mg tablet of M/s Bosch
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Registration Board deferred the product for revision of formulation as per reference regulatory authorities adopted by Registration Board in 275th meeting. **Firm shall also submit original receipt of fee of Rs.8000/-.**	
448.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Montekast Tablet 10mg
	Composition	Each tablet contains: Monteleukast Sodium…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31862 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 01-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Leukotriene receptor antagonist
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance

	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for change in label claim.**	
449.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Pregaline Capsule 100mg
	Composition	Each capsule contains: Pregabalin…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31879 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 12-12-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Pregablin capsule 100mg UK
	Me-too status	Gabolest 100mg capsules of Ms Aspin
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.9000/- for revision of FPP Specifications**	
450.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Pregaline Capsule 75mg
	Composition	Each capsule contains: Pregabalin…75mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31873 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 12-12-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO, As per SRO

	RRA status	Pregablin capsule 75mg UK
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.9000/- for revision of FPP Specifications**	
451.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Aprocin Tablet 500mg
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31869 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 23-09-2011 (**photo copy**)
	Pharmacological Group	Antibiotic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
452.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Aprocin Tablet 250mg
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl…250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31868 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 01-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	Antibiotic
	Finished product Specifications	USP specs

	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
453.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Lowcid Capsule 40mg
	Composition	Each capsule contains: Omeprazole (enteric coated pellets)…40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31876 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 03-11-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	PPI
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Losec 40mg capsules UK
	Me-too status	Risek 40mg capsule
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Source of pellets.**	
454.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Lefomide Tablet 10mg
	Composition	Each tablet contains: Leflunomide…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31861 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 23-09-2011 (**photo copy**) to be verified from R&I DRAP

	Pharmacological Group	DMARDs
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
455.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Lefomide Tablet 100mg
	Composition	Each tablet contains: Leflunomide…100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31860 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 23-09-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	DMARDs
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	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.	
456.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Lefomide Tablet 20mg
	Composition	Each tablet contains: Leflunomide…20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31866 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 , dated 23-09-2011 (**photo copy**) to be verified from R&I DRAP
	Pharmacological Group	DMARDs
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO

	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021: good GMP compliance
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** **latest GMP inspection report conducted within period of three years.**	
457.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Amloval Tablet 5/160mg
	Composition	Each tablet contains: Amlodipine…5mg Valsartan…160mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31854 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000, (Photocopy) dated 01-11-2011 to be verified from R&I DRAP
	Pharmacological Group	Antihypertensive
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** **latest GMP inspection report conducted within period of three years.**	
458.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Amloval Tablet 10/160mg
	Composition	Each tablet contains: Amlodipine…10mg Valsartan…160mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31853 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000, (Photocopy) dated 01-11-2011 to be verified from R&I DRAP
	Pharmacological Group	Antihypertensive
	Finished product Specifications	USP specs

	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** **latest GMP inspection report conducted within period of three years.**	
459.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Apiflox Tablet 500mg
	Composition	Each tablet contains: Levofloxacin…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31865 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 (Photocopy), dated 01-11-2011 to be verified from R&I DRAP
	Pharmacological Group	Antibiotics
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.37000/- for correction in label claim.**	
460.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Artidol Tablet 40/240mg
	Composition	Each tablet contains: Artemether…40mg Lumefantrine….240mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31877 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 (Photocopy), dated 01-11-2011 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	Inhouse

	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Fee of Rs.9000/- for revision of FPP Specifications**	
461.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Artidol Tablet 80/480mg
	Composition	Each tablet contains: Artemether…80mg Lumefantrine….480mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31867 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 (Photocopy), dated 01-11-2011 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **Fee of Rs.9000/- for revision of FPP Specifications**	
462.	Name and address of manufacturer / Applicant	M/s Apex Pharmaceuticals Pvt Ltd., D-21-A/1, S.I.T.E, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Zestress Tablet 10mg
	Composition	Each tablet contains: Loratadine…10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No 31852 dated 29-01-2020 Rs. 12,000/- dated 29-01-2020 (original) Fee. 8,000 (Photocopy), dated 28-02-2012 to be verified from R&I DRAP
	Pharmacological Group	Antihistamine

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	RRA status	
	Me-too status	
	GMP status	GMP inspection report dated 30-11-2021.
	Remarks of the Evaluator	**No record found in R&I Section for year 2011 and available record of Registration-I Section.**
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
463.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals (Pvt) Ltd., Plot No. 2 Street N-4 National Industrial zone, Rawat.
	Brand Name +Dosage Form + Strength	Betamed N Cream
	Composition	Each gram contains: Betamethasone as Valerate ...0.1% Neomycin Sulphate ...0.5%
	Type of Form, Diary No. Date of R& I & fee	Form-5 **(Duplicate dossier)** Dy.No 7076 dated 10-03-2023 Rs. 8000/-dated 10-06-2011 (photocopy) Dy. No. 31590 dated 27-01-2020; Rs.12000/-dated 27-01-2020 (original)
	Pharmacological Group	Corticosteroid, antibiotic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5gm, 15gm; As per SRO
	RRA status	
	Me-too status	Betnovate N of M/s GSK
	GMP status	
	Remarks of the Evaluator	**No record found** in R&I register/ section against the product Betamed N cream.
	Decision: Deferred for following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	

e Intimation with only original/copies of R&I receiving and fee challans:

Following firms have submitted only photocopies of covering letters of initial applications and photocopies/ original fee challans without attaching duplicate dossiers on form-5.

Sr. No.	Name of Firm	Name of Drug Product	Type of Form, Diary No. Date of R& I & fee
1.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Cincet 30mg Tablet Cinacalcet as HCl…30mg	Form 5, Dy. No Nil. dated 26-12-2018 Rs.20,000/-.
2.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Ticalor 90mg Tablet Ticagrelor … 90mg	Form 5, Dy. No Nil. dated 31-12-2018 Rs.20,000/-.
3.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Panxib 30mg Tablet Valdecoxib as HCl…20mg	Form 5, Dy. No Nil. dated 26-12-2018 Rs.20,000/-.

4.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Naprox Tablet Naproxen … 375mg Esomeprazole … 20mg	Rs. 15000/- Dy. No Nil. dated 29-10-2010 Rs. 35000/- Dy. No Nil. dated 25-06-2014
5.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Naprox Tablet Naproxen … 500mg Esomeprazole … 20mg	Rs. 15000/- Dy. No Nil. dated 16-09-2010 Rs. 35000/- Dy. No Nil. dated 25-06-2014
6.	M/s. Pharmix Laboratories (Pvt) Ltd., Lahore.	Durol Capsule 30mg Duloxetine as HCl … 30mg	Rs. 8000/- Dy. No Nil. dated 16-09-2010 Rs. 12000/- Dy. No 21447. dated 21-10-2019 (Original)
7.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Cometh fort tablet contains: Artemether ….80mg Lumefantrine…480mg	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- (Photocopy)
8.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Omanatab-OB capsule omeprazole …40mg Sodium ….1100Mg	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- (Photocopy)
9.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Pifob Syp 120ml Pizotifin	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- (Photocopy)
10.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Pifob plus Syp 120ml Pizotifin	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- dated (Photocopy)
11.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Ciprob Suspension 125mg/5ml ciprofloxacin	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- dated (Photocopy)
12.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Ciprob Suspension 250mg/5ml ciprofloxacin	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- dated (Photocopy)
13.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Oblonec capsule 50mg Diclofenac Sodium	Fee. 8,000, Date: 23-06-2011 (Photocopy) Rs.12000/- dated (Photocopy)
14.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Ortizin Syrup 5mg/5ml Cetrizine ….5mg	Fee. 8,000, not attached Rs.12000/- dated 23-02-2015
15.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Clopidob Plus tablet 75mg+75mg Clopidogrel +Aspirin	Fee. 8,000, Date: 22-06-2011 (Photocopy) Rs.12000/- dated (Photocopy
16.	M/s Obsons Pharmceuticals , 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore	Gemob Tablet 320mg Gemifloxacin	Fee. 8,000, Date: 22-06-2011 (Photocopy) Rs.12000/- dated (Photocopy)

17.	M/s Medicaids Pakistan (pvt) Ltd. Plot No 10, Sector-27 Korangi Industrial Area, Karachi	Cobac 2g IM/IV Injection Each injection contains: Cefeprazone…1g Sulbactam…1g	Rs.8000/- dated 29-01-2011 (photo copy) Dy.No 26209 dated 05-12-2019 Rs.12,000/- Dated 28-11-2019 (original)
18.	M/s Medicaids Pakistan (pvt) Ltd. Plot No 10, Sector-27 Korangi Industrial Area, Karachi	Cobac 1g IM/IV Injection Each injection contains: Cefeprazone…500mg Sulbactam…500mg	Rs.8000/- dated 29-01-2011 Dy.No 26208 dated 05-12-2019 Rs.12,000/- Dated 28-11-2019 (original)
19.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Dilin Syrup Diphenhydramine Hcl…8mg Aminophylline…32mg Ammonium chloride…30mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
20.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Preg 50mg Capsule Pregabalin…50mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020(original)
21.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Preg 75mg Capsule Pregabalin…75mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020(original)
22.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Preg 100mg Capsule Pregabalin…100mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
23.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Prin 75mg Capsule Aspirin 75mg enteric coated	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
24.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Prin 150mg Capsule Aspirin 150mg enteric coated	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
25.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Cay Ris 2mg Tablet Risperidone…2mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
26.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Prolol 2.5mg tablet Bisoprolol Fumarate…2.5mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
27.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Prolol 10mg tablet Bisoprolol Fumarate…10mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
28.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Fosfo Syrup Fosfomycin Sodium 250mg/5ml	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
29.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Hypocard 5mg Tablet Amlodipine Besylate…5mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)

30.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Raabzo 10mg Tablet Rabeprazole sodium…10mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
31.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Raabzo 20mg Tablet Rabeprazole sodium…20mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
32.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Ribalex 600mg Tablet Ribavirin…600mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
33.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Ribalex 200mg Tablet Ribavirin…200mg	Dy.No.32436 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
34.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Ribalex 400mg Tablet Ribavirin…400mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
35.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Gabalex 100mg Tablet Gabapentin…100mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
36.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Gabalex 200mg Tablet Gabapentin…200mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
37.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Artmether Suspension Artemether 15mg/5ml	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
38.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Cay Enema Biphosphate 19.2mg Sodium phospate 7.2mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
39.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Fapa 50mg Capsule Diclofenac potassium…50mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
40.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Lazole 30mg Capsule Pantoprazole 30mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
41.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	Parotin 20mg Tablet Paroxetine Hcl…20mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)
42.	M/s Caylex Pharmaceuticals Pvt Ltd 27-KM, Raiwind Road, Lahore	No Depris 20mg Tablet Escitalopram …20mg	Dy.No.32429 dated.31-01-2020 Rs.12,000 dated 31-01-2020 (original)

43.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Tamosin D capsules Tamsulosin HCl …0.4mg Dutasteride …0.5mg	Dy. No. 13716 dated 23-12-2024 Dy.No.nil dated.03-11-2016 Rs.20,000 dated 31-10-2016 (photocopy)
44.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Alinz 50mg capsules Pregabalin …50mg	Dy. No. 13715 dated 23-12-2024 Photocopy of covering letter with only fee endorsement of Rs. 8000/- dated 30-07-2011
45.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Alinz 75mg capsules Pregabalin …75mg	Dy. No. 13715 dated 23-12-2024 Photocopy of covering letter with only fee endorsement of Rs. 8000/- dated 30-07-2011
46.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Alinz 100mg capsules Pregabalin …100mg	Dy. No. 13715 dated 23-12-2024 Photocopy of covering letter with only fee endorsement of Rs. 8000/- dated 30-07-2011
47.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Alinz 150mg capsules Pregabalin …150mg	Dy. No. 13715 dated 23-12-2024 Photocopy of covering letter with only fee endorsement of Rs. 8000/- dated 30-07-2011
48.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Dare 5mg tablet Desloratadine …5mg	Dy. No. 13678 dated 20-12-2024 Dy.No.nil dated.17-02-2009 Rs.8,000 dated 17-02-2009 (photocopy)
49.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trisem 3g Sachet Dioctehedral Smectite ……3g	Dy. No. 12769-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
50.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Triviga Sachet Vigabatrin ….500mg	Dy. No. 12768-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
51.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Tricook Sachet (pre-Cooked Rice Powder 6gm+Sodium Citrate 0.580Gm+Sodium Chloride 0.35+Potassium Chloride 0.300	Dy. No. 12767-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
52.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Tricalbic Sachet 685/200/500mg) Calcium Carbonate ….685mg Calcium lactate …..20mg Ascorbic Acid …..500mg Ascorbic Acid …..500mg	Dy. No. 12766-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
53.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trisolat sachet Strontium ranelate…2gm	Dy. No. 12778-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018

			No STO stamp in covering letter and Fee Challan
54.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Tricyst Sachet Acetyl cysteine 200mg	Dy. No. 12777-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
55.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trifen sachet 600mg Ibuprofen (effervescent granules)…600mg	Dy. No. 12776-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
56.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trifosin sachetrifosin sachetFosfomycin (as trometamol)…3g	Dy. No. 12775-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
57.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trigol sachet Macrogol …13.125 Sodium Chloride….0.3507gm Potassium Chloride …0.466gm Sodium Bicarbonate ….0.1785	Dy. No. 12774-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
58.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trikast sachet 4mg Montelukast as Sodium eq. to montelukast….4mg	Dy. No. 12773-R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
59.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Trimb sachet rimb sachet mebeverine as HCl ….135mg Ispaghula husk …..3.5gm	Dy. No. 12772 R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
60.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Triom Sachet 20mg Omeprazole ….20mg Sodium Bicarbonate …..1680mg	Dy. No. 12771 R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
61.	Trillium Pharmaceuticals Pvt Ltd.td.C-3& C-4, Value Addition city , Kharrianwala, Faisalabad.	Triom Sachet 40mg Omeprazole ….40mg Sodium Bicarbonate …..1680mg	Dy. No. 12771 R&I(DRAP) dated 29-11-2024 Firm has submitted old intimation dated 31-10-2018 **No STO stamp in covering letter and Fee Challan**
62.	Noa Hemis Pharmaceuticals,	Silodosin 4mg Each capsule contains: Silodosin …4mg	Dy. No. 20555 R&I(DRAP) dated 14-10-2019

	Plot No.154, Sector 23,Koarangi Industrial Area, Karachi		Dy.No.nil dated.29-05-2015 Rs.20000 dated 29-05-2015 (photocopy)
63.	Noa Hemis Pharmaceuticals, Plot No.154, Sector 23, Koarangi Industrial Area, Karachi	Extam 250mg capsule Each capsule contains: Tranexamic Acid ….250mg	Dy. No. 20555 R&I(DRAP) dated 14-10-2019 Dy.No.nil dated.15-12-2015 Rs.20000 dated 14-12-2015 (photocopy)
64.	Noa Hemis Pharmaceuticals, Plot No.154, Sector 23,Koarangi Industrial Area, Karachi	Sovelusa tablet 400mg/100mg Each tablet contains: Sofosbuvir….400mg Velpatasvir …100mg	**Form 5D,** Dy. No. 20555 R&I(DRAP) dated 14-10-2019 Dy.No.nil dated.04-08-2016 Rs.50000 dated 04-08-2016 (photocopy)
65.	Noa Hemis Pharmaceuticals, Plot No.154, Sector 23,Koarangi Industrial Area, Karachi	Hepatier tablet Each tablet contains: Elbasvir …..50mg Grazoprevir…100mg	**Form 5D,** Dy. No. 20555 R&I(DRAP) dated 14-10-2019 Dy.No.nil dated.03-02-2017 Rs.50000 dated 03-02-2017 (photocopy)
66.	Noa Hemis Pharmaceuticals, Plot No.154, Sector 23,Koarangi Industrial Area, Karachi	Tusivit Syrup Each tablet contains::terpin, Chlorpheniramine, pot bicarbonate, Ammonium chloride menthol Flavort Etc	Dy. No. 20555 R&I(DRAP) dated 14-10-2019 No evidence of fee Rs. 8000/- and 12,000/- and R&I submission in DRAP is attached.

Registration Board decided as under:

i. **Deferred the applications of products at Sr. No. 01- 42 & 49-66 for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.**

ii. **For products at Sr. No. 43-48, The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.**

f. M/s. Mediceena Pharma Lahore

M/s. Mediceena Pharma Lahore had submitted following applications (mentioned in **column I** of below table) for registration of drugs. Now, the firm has requested to withdraw these formulations and submitted revised formulations (mentioned in **column III** of below table) in lieu of these applications.

Sr. No.	**Name of Drug Product and composition in Previously submitted application**	**Dy. No. & Date of**	**Proposed Drug Product and composition**
	I	**II**	**III**
1.	Acyclovir Injection Lyophilized Powder for IV Infusion	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	V-zol 200mg Tablet Vorconazole
2.	Anaspas Plus Phloroglucinol ……..40mg TrimethylPhloroglucinol ……..40mg	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Medioxil Plus Tablet Each vial contains: Amoxycillin as sodium…….500mg Sulbactam as sodium……500mg
3.	Kanacil Injection 1gm Each injection contains:	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Colidox Injection Colistimethate 2MIU

	Kanamycin as HCl……1gm		
4.	Kanacil Injection 500mg Each injection contains: Kanamycin as HCl……500mg	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Naprocil Advance Tablet Supatriptan Succinate eq. to Sumatriptan 85mg Naproxen Sodium 550mg
5.	Trobidox Injection Spectinomycin as 2HCl 5H2O 2gm	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Bactam Fast 250mg Injection Each vial contains: Ceftazidime……..2gm Avibactum ……500mg
6.	Tinidazole Tablets 500mg Each vaginal tablet contains: Tinidazole……500mg	Nil	Medispan 200mg/5ml Suspesnion Cefixime
7.	Medicoline 500mg/2ml Injection Each 2ml contains: Citicoline as Sodium…500mg	Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Tiga-Fast 50mg Injection Tigecycline
8.	Eporare 500mg/ml Injection Sodium Valproate	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Osteonil-D Tablet Alendronic Acid as Alendronate Sodium Trihydrate …. 70mg Cholecalciferol … 70mcg
9.	Vecuron 4mg injection Vacuronium Bromide	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Spasrex Plus Capsule Alverine Citrate 60mg Simethicon … 300mg
10.	Vecuron 10mg injection Vacuronium Bromide	Rs.8000/- dated 01-12-2010 Rs.12000/- Dy. No. 32430 dated 31-01-2020 (Original)	Nil-Cid Chewable Tablet Famotidine … 10mg Calcium Carbonate … 800mg Magnesium Hydroxide…165mg

Registration Board did not accede to request of the firm for change of formulation. The Board further decided that if firm desired to get registration of previously applied formulations mentioned above in column-I, then firm shall submit the following:

i. **Original receipt for submission of fee of fee of Rs.8000/- for product at Sr. No. 01-05 & 07-10 within 6 months of publication of minutes of instant meeting on DRAP website.**

ii. **Original receipt for submission of fee of Rs. 8,000 and Rs.12000/- for product at Sr. No. 06 within 6 months of publication of minutes of instant meeting on DRAP website.**

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

464.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Tylosafe Powder
	Composition	Each gram contains: Tylosin tartate …100mg Doxycycline HCL…200mg Colistin Sulphate …0.5MIU Bromhexine HCl…6mg

	Type of Form, Diary No. Date of R& I & fee	Form-5; **Duplicate dossier** Dy. No. 23173 dated 25-08-2021 **No evidence of fee Rs. 8000/- and 12,000/- and R&I submission in DRAP is attached.**
	Pharmacological Group	Antibiotic
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm: Decontrolled
	RRA status	
	Me-too status	Pulmomats
	GMP status	
	Remarks of the Evaluator	**Powder (General) Section** confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007 **Target species:** poultry **Shortcomings:** • **Fee challans of Rs. 8000/- and 12,000/- and R&I submission in DRAP is not attached.**
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
465.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Gumbo Stop Powder
	Composition	Each gram contains: Ammonium Chloride …650mg Methionine …100mg Sorbitol …50mg Vitamin A …250IU Vitamin C …100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5; **Duplicate dossier** Dy. No. 23172 dated 25-08-2021 Dy. No. nil dated 30-07-2013 Rs.12000/- dated 30-07-2013 (Photocopy) Rs.8000/- (photo copy challan)
	Pharmacological Group	Antibiotic
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100g,500g,1000g,5kg: Decontrolled
	RRA status	
	Me-too status	Gumbovit of M/s Intervac Pvt Ltd.,
	GMP status	
	Remarks of the Evaluator	**Powder (General) Section** confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007 **Target species:** poultry **Shortcomings:** • **R&I submission of Rs. 8000/- in DRAP is not attached.**.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.**	

	• **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP.**	
466.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Lincomall powder
	Composition	Each gram contains: Lincomycin HCL 100mg Colistin Sulphate…800000I.U
	Type of Form, Diary No. Date of R& I & fee	Form-5; **Duplicate dossier** Dy. No. 23175 dated 25-08-2021 Dy. No. nil dated 30-07-2013 Rs.12000/- dated 30-07-2013 (Photocopy) Rs.8000/- (photo copy challan)
	Pharmacological Group	Antibiotic
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1000g, 2.5Kg, 5kg: Decontrolled
	RRA status	
	Me-too status	Lincosole of M/s A&K Pharma
	GMP status	
	Remarks of the Evaluator	**Powder (General) Section** confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007 **Target species:** poultry **Shortcomings:** • **R&I submission of Rs. 8000/- in DRAP is not attached.**.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP.**	
467.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	TC Doxin 200 Liquid
	Composition	Each ml contains: Tylosin tartrate …100mg Doxycyline HCl…200mg Colistin Sulphate …480000IU Bromhexine HCl …6mg
	Type of Form, Diary No. Date of R& I & fee	Form-5; **Duplicate dossier** Dy. No. 23174 dated 25-08-2021 Dy. No. nil dated 30-07-2013 Rs.12000/- dated 30-07-2013 (Photocopy) Dy. No. nil, dated 18-06-2012 Rs.8000/- dated 18-06-2012 (photocopy)

	Pharmacological Group	Antibiotic
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2.5L: Decontrolled
	RRA status	
	Me-too status	Pulmomats
	GMP status	
	Remarks of the Evaluator	**Liquid (General) Section** confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007 **Target species:** Poultry, calves **Shortcomings:** • Clarification regarding quantity of Bromhexine since 6mg is mentioned on covering letter while 60mg is mentioned on Form-5.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP.**	
468.	Name and address of manufacturer / Applicant	M/s Zumars Pharma FTY. Pvt. Ltd 02 Malir Industiral Area, Karachi
	Brand Name +Dosage Form + Strength	Fendamars 10% (Oral Suspension)
	Composition	Each ml contains: Fenbendazole …… 25mg Triclabendazole …. 50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5; **Duplicate dossier** Dy. No. 23920 dated 31-08-2021 Rs. 8000/- (Photocopy) dated 28-05-2011 dated to be verified from R &I. Rs.12000/- (Photocopy) **receiving not attached**
	Pharmacological Group	Anthelmintic, Dewermer
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	RRA status	
	Me-too status	Trifen Act Liquid Reg. No. 063776 Arbenmol TF Reg. No. 046524
	GMP status	
	Remarks of the Evaluator	**Vet Liquid (General) Section** confirmed vide letter No. F. 2-7/89-Lic (Vol-I) dated 14-04-2009 **Target species:** Cattle
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.**	

	• **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** **fee Rs. 9000/- for pre-approval variation in FPP.**	
469.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Cefur-Duo Injection
	Composition	Each ml contains: Ceftiofur as HCl…50mg **Ketoprofen**…150mg
	Type of Form, Diary No. Date of R& I & fee	**Form 5D,** Dy. No 9918 dated 16-09-2024 **(Duplicate dossier)** Rs. 75000/-dated 29-06-2022 (photocopy) **verified from R&I DRAP vide Dy. No. 25070 dated 05-09-2022**
	Pharmacological Group	Combination of Cephalosporin antibiotic and NSAID
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	RRA status	Curacef Duo has been **approved by EU** under authorization number CY00485V with date of authorization status 02/00/2014. **Authorized in France** Reference: https://medicines.health.europa.eu/veterinary/en/600000029458 accessed dated 27-12-2024
	Me-too status	NA
	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	• **Ketoprofen containing formulations** already referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters • Firm has submitted 06 months accelerated and 06 months long term stability data of FPP as per zone IV-A conditions.
	Decision: Registration Board deferred and decided to refer the formulation to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	

Agenda of Ms. Saima Hussain

470.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Esli Tablets 200mg
	Composition	Each tablet contains: Eslicarbazepine Acetate…… 200mg
	Diary No. Date of R& I & fee	Dy.No 8827 dated 27-02-2019 Rs.50,000/- dated 26-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5 D

	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	APTIOM tablets 200mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	Me-too status	Not Available
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA			
Drug	Esli Tablets 200mg (Eslicarbazepine Acetate)		
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.		
Manufacturer of API	M/s. CTX Lifesciences Pvt. Ltd. Block no. 251/P-252/P-253 to 255 ,256/P-258/P-276/P-277,278/P-279 TO 282,283/P,284/P GIDC,City-Sachin,Dist.-Surat Gujarat India.		
API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported		
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: TR-076 (6 months), TR-077 (6 months), TR-078 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TR-076	TR-077	TR-078
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	16-02-2021	16-02-2021	16-02-2021
No. of Batches	03		
Date of Submission	25-01-2022		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Stability study conditions:
Long term: 30°C ± 2° C / 65% ± 5% RH for 48 months
Accelerated: 40°C ± 2°C / 75% ± 5% RH for 06 months
Eslicarbazepine Acetate:
Batches #: (ES183001, ES183002, ES183003)</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>Copy of GMP certificate No. 19061470 dated 02/07/2019 which remain valid until 01/07/2022.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has provided the copy of procurement invoices of API; details are as follow.<table><tr><td>API Name</td><td>Invoice No. & Date</td></tr><tr><td>Eslicarbazepine Acetate</td><td>EI/3002100560 18/12/2020</td></tr></table></td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not Applicable</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Esli Tablet 200mg</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>TR-076</td><td>1000 tablets</td><td>16-02-2021</td></tr><tr><td>TR-077</td><td>1000 tablets</td><td>16-02-2021</td></tr><tr><td>TR-078</td><td>1000 tablets</td><td>16-02-2021</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted (against the product Zebinix Tablet 200mg of M/s. Bial Portela & Ca. S.A. Portugal)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>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 the Evaluator<table><tr><td>Sr.no.</td><td>Shortcoming/Deficiencies</td><td>Response of the Firm</td></tr></table></td></tr>
</table>

1.	Provide method used for analysis of API from API Manufacturer.	Submitted
2.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing .	Submitted
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

471.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Esli Tablets 400mg
	Composition	Each tablet contains: Eslicarbazepine Acetate…… 400mg
	Diary No. Date of R& I & fee	Dy.No 8828 dated 27-02-2019 Rs.50,000/- dated 26-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	APTIOM tablets 400mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	Me-too status	Not Available
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA

Drug	Esli Tablets 400mg (Eslicarbazepine Acetate)
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.
Manufacturer of API	M/s. CTX Lifesciences Pvt. Ltd. Block no. 251/P-252/P-253 to 255 ,256/P-258/P-276/P-277,278/P-279 TO 282,283/P,284/P GIDC,City-Sachin,Dist.-Surat Gujarat India.
API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported
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: TR-076 (6 months), TR-077 (6 months), TR-078 (6 months) Accelerated: 6 months

Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TR-073	TR-074	TR-075
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	15-02-2021	15-02-2021	15-02-2021
No. of Batches	03		
Date of Submission	25-01-2022		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Stability study conditions: Long term: 30˚C ± 2˚ C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Eslicarbazepine Acetate: Batches #: (ES183001, ES183002, ES183003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 dated 02/07/2019 which remain valid until 01/07/2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has provided the copy of procurement invoices of API; details are as follow. API Name: Eslicarbazepine Acetate — Invoice No. & Date: EI/3002100560 18/12/2020
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Not Applicable

10.	Complete batch manufacturing record of three stability batches.	The firm has been submitted copy of Trial batch manufacturing record. Details are as under: Esli Tablet 200mg Batch No. / Bach size / Mfg. Started TR-073 / 1000 tablets / 15-02-2021 TR-074 / 1000 tablets / 15-02-2021 TR-075 / 1000 tablets / 15-02-2021
11.	Record of comparative dissolution data (where applicable)	Submitted (against the product Zebinix Tablet 200mg of M/s. Bial Portela & Ca. S.A. Portugal)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Provide method used for analysis of API from API Manufacturer.	Submitted
2.	Justify for not adopting the same dissolution acceptance criteria for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA.Since the innovator recommend two sampling time point for dissolution of eslicarbazepine acetate tablet 400mg,600mg & 800mg, while you have mentioned the single time point acceptance criteria for the applied product.	Firm submitted the revised acceptance limit of dissolution test i.e. Q after 15 minutes and Q after 45 minutes for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA. Accordingly submitted the updated specification and testing method of finished product along with commitment letter that they will perform stability study of first three commercial batches as per the updated specification and testing method of finished product.
3.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing .	Submitted
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

472.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Esli Tablets 600mg
	Composition	Each tablet contains: Eslicarbazepine Acetate…… 600mg

	Diary No. Date of R& I & fee	Dy.No 8829 dated 27-02-2019 Rs.50,000/- dated 26-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	APTIOM tablets 600mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	Me-too status	Not Available
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA			
Drug	Esli Tablets 600mg (Eslicarbazepine Acetate)		
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.		
Manufacturer of API	M/s. CTX Lifesciences Pvt. Ltd. Block no. 251/P-252/P-253 to 255 ,256/P-258/P-276/P-277,278/P-279 TO 282,283/P,284/P GIDC,City-Sachin,Dist.-Surat Gujarat India.		
API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported		
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: TR-070 (6 months), TR-071 (6 months), TR-072 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TR-070	TR-071	TR-072
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	26-02-2021	26-02-2021	26-02-2021
No. of Batches	03		
Date of Submission	25-01-2022		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Stability study conditions:
Long term: 30˚C ± 2˚ C / 65% ± 5% RH for 48 months
Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months
Eslicarbazepine Acetate:
Batches #: (ES183001, ES183002, ES183003)</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>Copy of GMP certificate No. 19061470 dated 02/07/2019 which remain valid until 01/07/2022.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has provided the copy of procurement invoices of API; details are as follow.<table><tr><td>API Name</td><td>Invoice No. & Date</td></tr><tr><td>Eslicarbazepine Acetate</td><td>EI/3002100560 18/12/2020</td></tr></table></td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not Applicable</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Esli Tablet 200mg</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>TR-070</td><td>1000 tablets</td><td>02-2021</td></tr><tr><td>TR-071</td><td>1000 tablets</td><td>02-2021</td></tr><tr><td>TR-072</td><td>1000 tablets</td><td>02-2021</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted (against the product Zebinix Tablet 200mg of M/s. Bial Portela & Ca. S.A. Portugal)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>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>
</table>

Remarks of the Evaluator

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Provide method used for analysis of API from API Manufacturer.	Submitted
2.	Justify for not adopting the same dissolution acceptance criteria for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA.Since the innovator recommend two sampling time point for dissolution of eslicarbazepine acetate tablet 400mg,600mg & 800mg, while you have mentioned the single time point acceptance criteria for the applied product.	Firm submitted the revised acceptance limit of dissolution test i.e. Q after 15 minutes and Q after 45 minutes for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA. Accordingly submitted the updated specification and testing method of finished product along with commitment letter that they will perform stability study of first three commercial batches as per the updated specification and testing method of finished product.
3.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing .	Submitted
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

473.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Esli Tablets 800mg
	Composition	Each tablet contains: Eslicarbazepine Acetate…… 800mg
	Diary No. Date of R& I & fee	Dy.No 8830 dated 27-02-2019 Rs.50,000/- dated 26-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	APTIOM tablets 800mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	Me-too status	Not Available
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA

Drug	Esli Tablets 800mg (Eslicarbazepine Acetate)
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.
Manufacturer of API	M/s. CTX Lifesciences Pvt. Ltd. Block no. 251/P-252/P-253 to 255 ,256/P-258/P-276/P-277,278/P-279 TO 282,283/P,284/P GIDC,City-Sachin,Dist.-Surat Gujarat India.

API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported		
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: TR-070 (6 months), TR-071 (6 months), TR-072 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TR-055	TR-056	TR-057
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	05.2021	05.2021	05.2021
Date of Initiation	26-02-2021	26-02-2021	26-02-2021
No. of Batches	03		
Date of Submission	25-01-2022		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Stability study conditions: Long term: 30˚C ± 2˚ C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Eslicarbazepine Acetate: Batches #: (ES183001, ES183002, ES183003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 dated 02/07/2019 which remain valid until 01/07/2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has provided the copy of procurement invoices of API; details are as follow. API Name: Eslicarbazepine Acetate — Invoice No. & Date: EI/3002100560 18/12/2020

<table>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not Applicable</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Esli Tablet 200mg</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>TR-055</td><td>1000 tablets</td><td>05-2021</td></tr>
<tr><td>TR-056</td><td>1000 tablets</td><td>05-2021</td></tr>
<tr><td>TR-057</td><td>1000 tablets</td><td>05-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted (against the product Zebinix Tablet 200mg of M/s. Bial Portela & Ca. S.A. Portugal)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>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>
</table>

Remarks of the Evaluator

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Provide method used for analysis of API from API Manufacturer.	Submitted
2.	Justify for not adopting the same dissolution acceptance criteria for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA.Since the innovator recommend two sampling time point for dissolution of eslicarbazepine acetate tablet 400mg,600mg & 800mg, while you have mentioned the single time point acceptance criteria for the applied product.	Firm submitted the revised acceptance limit of dissolution test i.e. Q after 15 minutes and Q after 45 minutes for strength 400mg,600mg & 800mg tablet, as recommended by the innovator product approved in USFDA. Accordingly submitted the updated specification and testing method of finished product along with commitment letter that they will perform stability study of first three commercial batches as per the updated specification and testing method of finished product.
3.	Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing .	Submitted
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

474.	Name and address of manufacturer / Applicant	**M/s. Highnoon Laboratories Ltd.17.5 km, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Ertu 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Ertugliflozin (as L-Pyroglutamic Acid)….5mg
	Diary No. Date of R& I & fee	Dy.No 35885 dated 30-10-2018 Rs.50,000/- dated 29-10-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved.
	Me-too status	Eglaro Tablet of M/s. Pharm Evo
	GMP status	Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.

STABILITY STUDY DATA			
Drug	Ertu 5mg Tablet (Ertugliflozin)		
Name of Manufacturer	M/s. Highnoon Laboratories Ltd.17.5 km, Multan Road, Lahore		
Manufacturer of API	M/s. Fuxin Long Rui Pharmaceutical CO., Ltd.		
API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported		
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: RD-22147 (6 months), RD-22152 (6 months), RD-22153 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	RD-22147	RD-22152	RD-22153
Batch Size	2777 Tablets	2777 Tablets	2777 Tablets
Manufacturing Date	20-05-2022	20-05-2022	20-05-2022
Date of Initiation	24-05-2022	24-05-2022	24-05-2022
No. of Batches	03		
Date of Submission	26-10-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

<table>
<tr><td>Sr. No.</td><td>Documents To Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Firm has referred to product specific inspection of product Apiban Tablet 2.5mg & Apiban Tablet 5mg conducted on 26-July-2019.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Stability study conditions:
Long term: 30˚C ± 2˚ C / 65% ± 5% RH for 36 months
Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months
Ertugliflozin L-Pyroglutamic acid:
Batches #: (20150328, 20150406, 20150513)</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>Copy of GMP certificate of M/s. Fuxin Long Rui Pharmaceutical CO., Ltd. which remain valid until 16/11/2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has provided the copy of procurement invoices of API; details are as follow.
<table>
<tr><td>API Name</td><td>Invoice No. & Date</td></tr>
<tr><td>Ertugliflozin L-Pyroglutamic acid</td><td>HN21090901-L dated 09-Sep-2021</td></tr>
</table></td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Submitted</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Ertu Tablet 5mg</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>RD-22147</td><td>2777 tablets</td><td>20-05-2022</td></tr>
<tr><td>RD-22152</td><td>2777 tablets</td><td>20-05-2022</td></tr>
<tr><td>RD-22153</td><td>2777 tablets</td><td>20-05-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted (against the product Steglatro 5mg tablet of M/s. Pfizer Manufacturing Deutschland)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
</table>

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 the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

475.	Name and address of manufacturer / Applicant	**M/s. Highnoon Laboratories Ltd.17.5 km, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Ertu 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Ertugliflozin (as L-Pyroglutamic Acid)…..15mg
	Diary No. Date of R& I & fee	Dy.No 35884 dated 30-10-2018 Rs.50,000/- dated 29-10-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	USFDA Approved.
	Me-too status	Eglaro Tablet of M/s. Pharm Evo
	GMP status	Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.

STABILITY STUDY DATA

Drug	Ertu 15mg Tablet (Ertugliflozin)
Name of Manufacturer	M/s. Highnoon Laboratories Ltd.17.5 km, Multan Road, Lahore
Manufacturer of API	M/s. Fuxin Long Rui Pharmaceutical CO., Ltd.
API Lot No.	As per invoice no. EI/3002100560 attested by DRAP batch no.20EP00010 has been imported
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: RD-22148 (6 months), RD-22154 (6 months), RD-22155 (6 months)

	Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	RD-22148	RD-22154	RD-22155
Batch Size	2777 Tablets	2777 Tablets	2777 Tablets
Manufacturing Date	20-05-2022	20-05-2022	20-05-2022
Date of Initiation	24-05-2022	24-05-2022	24-05-2022
No. of Batches	03		
Date of Submission	26-10-2022		

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 product specific inspection of product Apiban Tablet 2.5mg & Apiban Tablet 5mg conducted on 26-July-2019.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Stability study conditions: Long term: 30˚C ± 2˚ C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Ertugliflozin L-Pyroglutamic acid: Batches #: (20150328, 20150406, 20150513)
5.	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. Fuxin Long Rui Pharmaceutical CO., Ltd. which remain valid until 16/11/2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has provided the copy of procurement invoices of API; details are as follow. API Name: Ertugliflozin L-Pyroglutamic acid Invoice No. & Date: HN21090901-L dated 09-Sep-2021
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Not Applicable

10.	Complete batch manufacturing record of three stability batches.	The firm has been submitted copy of Trial batch manufacturing record. Details are as under: Ertu Tablet 15mg Batch No. / Bach size / Mfg. Started RD-22148 / 2777 tablets / 20-05-2022 RD-22154 / 2777 tablets / 20-05-2022 RD-22155 / 2777 tablets / 20-05-2022
11.	Record of comparative dissolution data (where applicable)	Submitted (against the product Steglatro 15mg tablet of M/s. Pfizer Manufacturing Deutschland GmbH, Germany)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
2.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

476.	Name and address of manufacturer/ Applicant	**M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan.**
	Brand Name + Dosage Form + Strength	Ertumet 2.5mg/500mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic Acid) …….2.5mg Metformin HCl ……500mg
	Diary No. Date of R & I & fee	Dy. No. 35879 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET 2.5mg/500mg film coated tablet approved in US FDA
	Me-too status	Ertuvia-M 2.5mg/500mg Tablet (112542) by Ferozsons Laboratories Limited
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance

	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		Ertugliflozin (as L-Pyroglutamic Acid) Metformin HCl		
Manufacturer of API		Ertugliflozin L-Pyroglutamic Acid: M/s 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, MIDC, WALUJ, AURANGABAD – 431136 Maharashtra State, India		
API Lot No.		Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Metformin HCl: 21041ML2AMMI		
Description of Pack (Container closure system)		Alu-Alu Blister in Unit Carton with leaf 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, 6months		
Batch No.		RD-22165	RD-22171	RD-22172
Batch Size		2500 tablets	2500 tablets	2500 tablets
Manufacturing Date		Jun-2022	Jun-2022	Jun-2022
Date of Initiation		20-Jul-2022	20-Jul-2022	20-Jul-2022
No. of Batches		03		
Date of Submission		15-May-2023		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	Documents to Be Provided		Details	
1.	Reference of previous approval of applications with stability study data of the firm.		Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th meeting of Registration Board	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.		The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer		The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.	
4.	Stability study data of API from API manufacturer		The firm has submitted 6 months accelerated and 36 months real time stability study data of 3 batches of Ertugliflozin API and the firm has submitted 6 months	

<table>
<tr><td></td><td></td><td>accelerated and 60 months real time stability study data of 3 batches of Metformin HCl API.</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>Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027.
The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027.

Metformin HCl:
The firm has submitted a copy of the GMP Certificate for M/s IPCA LABORATORIES LIMITED issued by Central Drugs Standard Control Organisation, FDA Bhawan, Kotla Road, New Delhi-110 002, India. It is valid up to 02-07-2025.
The firm has submitted a copy of the DML Certificate for M/s IPCA LABORATORIES LIMITED issued by Licensing Authority, Food & Drug Administration, Aurangabad Division Maharashtra State. It is valid up to 31-03-2029.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice for the purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Metformin HCl (2025Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 27-01-2022.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted copy of method used for analysis of finished Product Ertumet 2.5mg/500mg Tablet.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The firm has submitted compatibility studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>RD-22165</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
<tr><td>RD-22171</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
<tr><td>RD-22172</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>The firm has submitted pharmaceutical equivalence of their product against Ertuvia-M 2.5mg/500mg Tablets (Batch # 2L33). Firm has submitted CDP results of their product against Ertuvia-M 2.5mg/500mg Tablets (Batch # 2L33) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable f2 values.</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.	The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

477.	Name and address of manufacturer/ Applicant	**M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan.**
	Brand Name + Dosage Form + Strength	Ertumet 2.5mg/1000mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic Acid) …….2.5mg Metformin HCl ……1000mg
	Diary No. Date of R & I & fee	Dy. No. 35880 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET 2.5mg/1000mg film coated tablet approved in US FDA
	Me-too status	Ertuvia-M 2.5mg/1000mg Tablet (112543) by Ferozsons Laboratories Limited
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ertugliflozin (as L-Pyroglutamic Acid) Metformin HCl
Manufacturer of API	Ertugliflozin L-Pyroglutamic Acid: M/s 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, MIDC, WALUJ, AURANGABAD – 431136 Maharashtra State, India
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Metformin HCl: 21041ML2AMMI
Description of Pack	Alu-Alu Blister in Unit Carton with leaf insert.

(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, 6months		
Batch No.	RD-22161	RD-22167	RD-22169
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Jun-2022	Jun-2022	Jun-2022
Date of Initiation	26-Jul-2022	26-Jul-2022	26-Jul-2022
No. of Batches	03		
Date of Submission	15-May-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th meeting of Registration Board
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.
4.	Stability study data of API from API manufacturer	The firm has submitted 6 months accelerated and 36 months real time stability study data of 3 batches of Ertugliflozin API and the firm has submitted 6 months accelerated and 60 months real time stability study data of 3 batches of Metformin HCl API.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027. The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027. Metformin HCl: The firm has submitted a copy of the GMP Certificate for M/s IPCA LABORATORIES LIMITED issued by Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110 002, India. It is valid up to 02-07-2025. The firm has submitted a copy of the DML Certificate for M/s IPCA LABORATORIES LIMITED issued by Licensing Authority, Food & Drug Administration, Aurangabad Division Maharashtra State. It is valid up to 31-03-2029.

<table>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice for the purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Metformin HCl (2025Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 27-01-2022.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted copy of method used for analysis of finished Product Ertumet 2.5mg/1000mg Tablet.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The firm has submitted compatibility studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>RD-22161</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
<tr><td>RD-22167</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
<tr><td>RD-22169</td><td>2500 Tablets</td><td>Jun-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>The firm has submitted pharmaceutical equivalence of their product against Ertuvia-M 2.5mg/1000mg Tablets (Batch # 2L35). Firm has submitted CDP results of their product against Ertuvia-M 2.5mg/1000mg Tablets (Batch # 2L35) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable f2 values.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of applied product.</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>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product</td></tr>
<tr><td colspan="3">Remarks of the Evaluator:
<table>
<tr><td>Sr.no.</td><td>Shortcoming/Deficiencies</td><td>Response of the Firm</td></tr>
<tr><td>1.</td><td>Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.</td><td>Firm submitted the revised, updated specification and testing method of finished products including disintegration test.</td></tr>
</table></td></tr>
<tr><td colspan="3">Decision: Approved.</td></tr>
<tr><td>478.</td><td>Name and address of manufacturer/ Applicant</td><td>M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan.</td></tr>
<tr><td></td><td>Brand Name + Dosage Form + Strength</td><td>Ertusit 5mg/100mg Tablet</td></tr>
<tr><td></td><td>Composition</td><td>Each film coated tablet contains:
Ertugliflozin (as L-Pyroglutamic Acid) …….5mg
Sitagliptin (as Phosphate Monohydrate) ……100mg</td></tr>
</table>

	Diary No. Date of R & I & fee	Dy. No. 35883 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	STEGLUJAN 5mg/100mg film coated tablet approved in US FDA
	Me-too status	Ertuglu-S 5mg/100mg Tablet (117430) by Horizon Pharma
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Ertugliflozin (as L-Pyroglutamic Acid) Sitagliptin (as Phosphate Monohydrate)		
Manufacturer of API	Ertugliflozin L-Pyroglutamic Acid: M/s Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China Sitagliptin: Zhejiang Yongtai Pharmaceutical Co., Ltd. Address: No.1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China		
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Sitagliptin: 1827-0001-21051		
Description of Pack (Container closure system)	Alu-Alu Blister in Unit Carton with leaf 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, 6months		
Batch No.	RD-22146	RD-22158	RD-22159
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	18-May-2022	18-May-2022	18-May-2022
Date of Initiation	19-Jun-2022	19-Jun-2022	19-Jun-2022
No. of Batches	03		
Date of Submission	27-Jan-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents to Be Provided	Details

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm.</td><td>Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th 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>The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted 6 months accelerated and 36 months real time stability study data of 3
batches of both API.</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>Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027.

The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027.

Sitagliptin:
The firm has submitted a copy of the DML Certificate for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. issued by Zhejiang Medical Products Administration. It is valid up to 31-05-2027.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice for the
purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Sitagliptin (275Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 15-12-2021.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted copy of method used for analysis of finished Product Ertusit 5mg/100mg Tablet.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The firm has submitted compatibility studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>RD-22146</td><td>2500 Tablets</td><td>18-May-2022</td></tr>
<tr><td>RD-22158</td><td>2500 Tablets</td><td>18-May-2022</td></tr>
<tr><td>RD-22159</td><td>2500 Tablets</td><td>18-May-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP studies against the reference product of STEGLUJAN 5mg/100mg Tablets (Batch # U025008) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable f2 values</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.	The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

479.	Name and address of manufacturer/ Applicant	**M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan.**
	Brand Name + Dosage Form + Strength	Ertusit 15mg/100mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic Acid) …….15mg Sitagliptin (as Phosphate Monohydrate) ……100mg
	Diary No. Date of R & I & fee	Dy. No. 35886 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	STEGLUJAN 15mg/100mg film coated tablet approved in US FDA
	Me-too status	Ertuglu-S 15mg/100mg Tablet (117431) by Horizon Pharma
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ertugliflozin (as L-Pyroglutamic Acid) Sitagliptin (as Phosphate Monohydrate)
Manufacturer of API	Ertugliflozin L-Pyroglutamic Acid: M/s Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China Sitagliptin: Zhejiang Yongtai Pharmaceutical Co., Ltd. Address: No.1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China

API Lot No.	Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Sitagliptin: 1827-0001-21051		
Description of Pack (Container closure system)	Alu-Alu Blister in Unit Carton with leaf 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, 6months		
Batch No.	RD-22145	RD-22156	RD-22157
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	17-May-2022	17-May-2022	17-May-2022
Date of Initiation	19-Jun-2022	19-Jun-2022	19-Jun-2022
No. of Batches	03		
Date of Submission	27-Jan-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th meeting of Registration Board
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.
4.	Stability study data of API from API manufacturer	The firm has submitted 6 months accelerated and 36 months real time stability study data of 3 batches of both API.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027. The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027. Sitagliptin: The firm has submitted a copy of the DML Certificate for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. issued by Zhejiang Medical Products Administration. It is valid up to 31-05-2027.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the

		purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Sitagliptin (275Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 15-12-2021.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted copy of method used for analysis of finished Product Ertusit 15mg/100mg Tablet.
9.	Drug-excipients compatibility studies (where applicable)	The firm has submitted compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches: Batch No. / Batch Size / Mfg. Date RD-22144 / 2500 Tablets / 17-May-2022 RD-22156 / 2500 Tablets / 17-May-2022 RD-22157 / 2500 Tablets / 17-May-2022
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies against the reference product of STEGLUJAN 15mg/100mg Tablets (Batch # W022904) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable *f2* values
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

480.	Name and address of manufacturer/ Applicant	**M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan**.
	Brand Name + Dosage Form + Strength	Ertumet 7.5mg/500mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic Acid) …….7.5mg Metformin HCl ……500mg
	Diary No. Date of R & I & fee	Dy. No. 35881 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D

	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET 7.5mg/500mg film coated tablet approved in US FDA
	Me-too status	Ertuvia-M 7.5mg/500mg Tablet (112540) by Ferozsons Laboratories Limited
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ertugliflozin (as L-Pyroglutamic Acid) Metformin HCl		
Manufacturer of API	Ertugliflozin L-Pyroglutamic Acid: M/s 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, MIDC, WALUJ, AURANGABAD – 431136 Maharashtra State, India		
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Metformin HCl: 21041ML2AMMI		
Description of Pack (Container closure system)	Alu-Alu Blister in Unit Carton with leaf 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, 6months		
Batch No.	RD-22166	RD-22173	RD-22174
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Jun-2022	Jun-2022	Jun-2022
Date of Initiation	20-Jul-2022	20-Jul-2022	20-Jul-2022
No. of Batches	03		
Date of Submission	15-May-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th meeting of Registration Board
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted 6 months accelerated and 36 months real time stability study data of 3 batches of Ertugliflozin API and the firm has submitted 6 months accelerated and 60 months real time stability study data of 3 batches of Metformin HCl API.</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>Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027.
The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027.

Metformin HCl:
The firm has submitted a copy of the GMP Certificate for M/s IPCA LABORATORIES LIMITED issued by Central Drugs Standard Control Organisation, FDA Bhawan, Kotla Road, New Delhi-110 002, India. It is valid up to 02-07-2025
The firm has submitted a copy of the DML Certificate for M/s IPCA LABORATORIES LIMITED issued by Licensing Authority, Food & Drug Administration, Aurangabad Division Maharashtra State. It is valid up to 31-03-2029.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice for the purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Metformin HCl (2025Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 27-01-2022.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>The firm has submitted protocols for conduction of stability studies.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>The firm has submitted copy of method used for analysis of finished Product Ertumet 7.5mg/500mg Tablet.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The firm has submitted compatibility studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches:

<table><tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr><tr><td>RD-22166</td><td>2500 Tablets</td><td>Jun-2022</td></tr><tr><td>RD-22173</td><td>2500 Tablets</td><td>Jun-2022</td></tr><tr><td>RD-22174</td><td>2500 Tablets</td><td>Jun-2022</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>The firm has submitted pharmaceutical equivalence of their product against Ertuvia-M 7.5mg/500mg Tablets (Batch # 2L34). Firm has submitted CDP results of their product against Ertuvia-M 2.5mg/1000mg Tablets (Batch # 2L34) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable f2 values.</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.	The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

481.	Name and address of manufacturer/ Applicant	**M/s Highnoon Laboratories Ltd. 17.5km, Multan Road, Lahore-53700, Pakistan.**
	Brand Name + Dosage Form + Strength	Ertumet 7.5mg/1000mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic Acid) …….7.5mg Metformin HCl ……1000mg
	Diary No. Date of R & I & fee	Dy. No. 35882 dated 30-10-2018 (50000/-)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs /Anti-diabetic
	Type of Form	Form 5D
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	1's, 5's, 7's, 10's, 14's, 20's, 21's, 28's, 30's, 40's, 50's, 60's, 100's, 120's
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET 7.5mg/1000mg film coated tablet approved in US FDA
	Me-too status	Ertuvia-M 7.5mg/1000mg Tablet (112541) by Ferozsons Laboratories Limited
	GMP status	Last GMP inspection conducted on 12-06-2024, and the report concludes that the firm was considered to be operating at a satisfactory level of cGMP compliance
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ertugliflozin (as L-Pyroglutamic Acid) Metformin HCl
Manufacturer of API	Ertugliflozin L-Pyroglutamic Acid: M/s. 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, MIDC, WALUJ, AURANGABAD – 431136 Maharashtra State, India

API Lot No.	Ertugliflozin L-Pyroglutamic Acid: L-IG-20210612-D01-IG06-01 Metformin HCl: 21041ML2AMMI		
Description of Pack (Container closure system)	Alu-Alu Blister in Unit Carton with leaf 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, 6months		
Batch No.	RD-22162	RD-22168	RD-22170
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Jun-2022	Jun-2022	Jun-2022
Date of Initiation	26-Jul-2022	26-Jul-2022	26-Jul-2022
No. of Batches	03		
Date of Submission	15-May-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Emplina (Diajard-L) 5mg/25mg Tablet approved in Minutes of 339th meeting of Registration Board
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	The firm has submitted certificate of analysis of both API from both API manufacturer and drug product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	The firm has submitted methods used for analysis of both API from both API manufacturer and drug product manufacturer.
4.	Stability study data of API from API manufacturer	The firm has submitted 6 months accelerated and 36 months real time stability study data of 3 batches of Ertugliflozin API and the firm has submitted 6 months accelerated and 60 months real time stability study data of 3 batches of Metformin HCl API.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L-Pyroglutamic Acid: The firm has submitted a copy of the GMP Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-04-2027. The firm has submitted a copy of the DML Certificate for M/s Fuxin Long Rui Pharmaceutical CO., Ltd. issued by Liaoning Medical Products Administration. It is valid up to 17-11-2027. Metformin HCl: The firm has submitted a copy of the GMP Certificate for M/s IPCA LABORATORIES LIMITED issued by Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110 002, India. It is valid up to 02-07-2025.The firm has submitted a copy

		of the DML Certificate for M/s IPCA LABORATORIES LIMITED issued by Licensing Authority, Food & Drug Administration, Aurangabad Division Maharashtra State. It is valid up to 31-03-2029.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of Ertugliflozin (3Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-09-2021 and Metformin HCl (2025Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 27-01-2022.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted copy of method used for analysis of finished Product Ertumet 7.5mg/1000mg Tablet.
9.	Drug-excipients compatibility studies (where applicable)	The firm has submitted compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopies of complete batch Manufacturing records s of following 03 Batches: Batch No. | Batch Size | Mfg. Date RD-22162 | 2500 Tablets | Jun-2022 RD-22168 | 2500 Tablets | Jun-2022 RD-22170 | 2500 Tablets | Jun-2022
11.	Record of comparative dissolution data (where applicable)	The firm has submitted pharmaceutical equivalence of their product against Ertuvia-M 7.5mg/1000mg Tablets (Batch # 2L36). Firm has submitted CDP results of their product against Ertuvia-M 7.5mg/1000mg Tablets (Batch # 2L36) in three dissolution media of pH 1.2, 4.5, 6.8, with acceptable *f2* values.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted stability study data of 03 batches along with chromatograms, raw data sheets, COA, and summary data sheet.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not including the disintegration test in the specification of finished product, since the innovator review literature revealed that disintegration test one of the critical quality parameter of drug product.	Firm submitted the revised, updated specification and testing method of finished products including disintegration test.

Decision: Approved.

482.	Name and address of manufacturer/ Applicant	**M/s High-Q Pharmaceuticals, Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi**

	Brand Name + Dosage Form + Strength	Satril 24mg + 26mg Tablet
	Composition	Each Film coated tablet contains: Sacubitril……....24mg Valsartan……..…26mg
	Diary No. Date of R & I & fee	Dy.No 3206 dated 20-12-2016 Rs.50,000/- dated 20-12-2016
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Entresto 24mg + 26mg Tablet by Novartis Pharmaceutical , USFDA Approved
	Me-too status	Savesto 24mg + 26mg Tablet by Getz Pharma
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Satril (Sacubitril 24mg + Valsartan 26mg) Tablet		
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.		
API Lot No.	Batch no. 57319030802		
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 / 75% ± 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.	5SVPD01/21	5SVPD02/21	5SVPD03/21
Batch Size	3508 Tablets	3508 Tablets	3508 Tablets
Manufacturing Date	Jul, 2021	Jul, 2021	Jul, 2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	28-10-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th meeting. • Date of inspection: 12th July, 2018 • The HPLC is 21 CFR Compliant Audit trail on the testing were available.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted 3 batches stability study data of API at:
Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance &
Long Term, 24 months at Zone IV B</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>Copy of Drug Manufacturing License No.
YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration.

GMP Certificate is valid till 15-09-2026</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 commercial invoice (Invoice No: RD2019051401-1) cleared dated 12-06-2019 specifying 2Kg. The invoice is cleared by AD (I&E) DRAP.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Firm has submitted protocols followed for conduction of stability study</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Firm has provided detailed method for analysis of FPP</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted drug excipient compatibility studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the batches</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP results of their product against comparator product, Savesto tablet. The details are follows:
<table>
<tr><td>Feature</td><td>Comparator Product</td><td>Product of High-Q</td></tr>
<tr><td>Brand Name</td><td>Savesto 24mg + 26mg Tablet</td><td>Satril 49mg + 51mg Tablet</td></tr>
<tr><td>Batch No</td><td>025FB2</td><td>5SVPD01/21</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. 0.1N HCl pH 1.2
2. Acetate buffer pH 4.5
3. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies</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:</td></tr>
</table>

Sr.no.	Shortcoming/Deficiencies
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength,so clarification is required in this regard
2.	Submit specification and detailed analytical procedure of finished product.
3.	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.

Decision: Approved. Firm shall submit following shortcomings/documents before issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**
- **Submit specification and detailed analytical procedure of finished product.**
- **Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.**

483	Name and address of manufacturer/ Applicant	**M/s High-Q Pharmaceuticals, Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi**
	Brand Name + Dosage Form + Strength	Satril 49mg +51mg Tablet
	Composition	Each Film coated tablet contains: Sacubitril…….....49mg Valsartan…….…51mg
	Diary No. Date of R & I & fee	Dy.No 3203 dated 20-12-2016 Rs.50,000/- dated 19-12-2016
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Entresto 49mg + 51mg Tablet by Novartis Pharmaceutical , USFDA Approved
	Me-too status	Savesto 49mg + 51mg Tablet by Getz Pharma
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Sacubitril + Valsartan
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.
API Lot No.	Batch no. 57319030802
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 / 75% ± 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.	1SVPD01/21	1SVPD02/21	1SVPD03/21
Batch Size	3125 Tablets	3125 Tablets	3125 Tablets
Manufacturing Date	Aug, 2021	Aug, 2021	Aug, 2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	28-10-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th meeting. • Date of inspection: 12th July, 2018 • The HPLC is 21 CFR Compliant Audit trail on the testing were available.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted
4.	• Stability study data of API from API manufacturer	Firm has submitted 3 batches stability study data of API at: • Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance & • Long Term, 24 months at Zone IV B
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License No. YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration. GMP Certificate is valid till 15-09-2026
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (Invoice No: RD2019051401-1) cleared dated 12-06-2019 specifying 2Kg. 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 submitted drug excipient compatibility studies
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 comparator product, Savesto tablet. The details are follows: Feature | Comparator Product | Product of High-Q

		<table><tr><td>Brand Name</td><td>Savesto 49mg+51mg Tablet</td><td>Satril 49mg + 51mg Tablet</td></tr><tr><td>Batch No</td><td>006FB3</td><td>1SVPD01/21</td></tr></table> Comparative dissolution studies have been performed in following mediums: 1. 0.1N HCl pH 1.2 2. Acetate buffer pH 4.5 3. Phosphate buffer pH 6.8
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.	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.	Shortcoming/Deficiencies
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength,so clarification is required in this regard
2.	Submit specification and detailed analytical procedure of finished product.
3.	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.

Decision: Approved. Firm shall submit following shortcomings/documents before issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**
- **Submit specification and detailed analytical procedure of finished product.**
- **Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.**

484.	Name and address of manufacturer/ Applicant	**M/s High-Q Pharmaceuticals, Plot No 224 & 225/1 , Sector 23, Korangi Industrial Area, Karachi**
	Brand Name + Dosage Form + Strength	Satril 97mg + 103mg Tablet
	Composition	Each Film-Coated Tablet contains: Sacubitril ……97mg Valsartan……103mg
	Diary No. Date of R & I & fee	Dy.No 3202 dated 20-12-2016 Rs.50,000/- dated 20-12-2016
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Entresto 97mg + 103mg Tablet by Novartis Pharmaceutical, USFDA Approved
	Me-too status	Savesto 97mg + 103mg by Getz Pharma
	GMP status	GMP certificate issued on 18-05-2023 on the basis of inspection conducted on 17-05-2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Sacubitril +Valsartan		
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.		
API Lot No.	Batch no. 57319030802		
Description of Pack (Container closure system)	Alu-Alu Blisters foil with Unit Carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (Months) Accelerated Time: 0, 3 & 6 (Months)		
Batch No.	2SVPD01/2021	2SVPD02/2021	2SVPD03/2021
Batch Size	2222 Tablets	2222 Tablets	2222 Tablets
Manufacturing Date	Aug-2021	Aug-2021	Aug-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	28-10-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th meeting. • Date of inspection: 12th July, 2018 • The HPLC is 21 CFR Compliant Audit trail on the testing were available.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted
4.	Stability study data of API from API manufacturer	Firm has submitted 3 batches stability study data of API at: • Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance & • Long Term, 24 months at Zone IV B
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by	Copy of Drug Manufacturing License No.

<table>
<tr><td></td><td>concerned regulatory authority of country of origin.</td><td>YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration.
GMP Certificate is valid till 15-09-2026</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 commercial invoice (Invoice No: RD2019051401-1) cleared dated 12-06-2019 specifying 2Kg. The invoice is cleared by AD (I&E) DRAP.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Firm has submitted protocols followed for conduction of stability study</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Firm has provided detailed method for analysis of FPP</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted drug excipient compatibility studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the batches</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP results of their product against comparator product, Savesto tablet. The details are follows:
<table>
<tr><td>Feature</td><td>Comparator Product</td><td>Product of High-Q</td></tr>
<tr><td>Brand Name</td><td>Savesto 97mg + 103mg Tablet</td><td>Satril 97mg + 103 mg Tablet</td></tr>
<tr><td>Batch No</td><td>013FB4</td><td>2SVPD01/21</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
4. 0.1N HCl pH 1.2
5. Acetate buffer pH 4.5
6. Phosphate buffer pH 6.8</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>Firm has submitted Documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies.</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:
<table>
<tr><td>Sr.no.</td><td>Shortcoming/Deficiencies</td></tr>
<tr><td>1.</td><td>Innovator label claim is “Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is required in this regard</td></tr>
<tr><td>2.</td><td>Submit specification and detailed analytical procedure of finished product.</td></tr>
<tr><td>3.</td><td>Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.</td></tr>
</table></td></tr>
</table>

Decision: Approved. Firm shall submit following shortcomings/documents before issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**
- **Submit specification and detailed analytical procedure of finished product.**
- **Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.**

485.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Ocaliva/Obit/Chico Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	Dy.No 43194 dated 18-12-2018 Rs.50,000/- dated 17-12-2018
	Pharmacological Group	Farnesoid X receptor agonists
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (5mg, 10mg) film coated tablets USFDA
	Me-too status	Abeticholic 5mg Tablet of M/s Dyson Research laboratories (Reg. No. 109521)
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA	
Drug	Ocaliva/Obit/Chico Tablet 5mg
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.
Manufacturer of API	M/s. Chongqing Kangle Pharmaceutical Co. Ltd. No. 4 Huazhong Road, Chongqing (Changshou) Chemical Industry Park
API Lot No.	As per invoice no. ASC-HELIX20122201 attested by DRAP batch no.ASC0004-201201 has been imported
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: TR-094 (6 months), TR-095 (6 months), TR-096 (6 months) Accelerated: 6 months
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6

<table>
<tr><td colspan="2">Batch No.</td><td>TR-094</td><td>TR-095</td><td>TR-096</td></tr>
<tr><td colspan="2">Batch Size</td><td>1,000 Tablets</td><td>1,000 Tablets</td><td>1,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>08.2021</td><td>08.2021</td><td>08.2021</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>29-09-2021</td><td>29-09-2021</td><td>29-09-2021</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">27-06-2022</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td colspan="2">Documents To Be Provided</td><td colspan="2">Status</td></tr>
<tr><td>1.</td><td colspan="2">Reference of previous approval of applications with stability study data of the firm</td><td colspan="2">Firm has referred to registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.</td></tr>
<tr><td>2.</td><td colspan="2">Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td colspan="2">Submitted</td></tr>
<tr><td>3.</td><td colspan="2">Method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td colspan="2">Submitted</td></tr>
<tr><td>4.</td><td colspan="2">Stability study data of API from API manufacturer</td><td colspan="2">Not submitted</td></tr>
<tr><td>5.</td><td colspan="2">Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">Copy of GMP certificate No. CQ20190054 dated 26/11/2019 which remain valid until 25/11/2024.</td></tr>
<tr><td>6.</td><td colspan="2">Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">The firm has provided the copy of procurement invoices of API; details are as follow.
<table>
<tr><td>API Name</td><td>Invoice No. & Date</td></tr>
<tr><td>Obeticholic Acid</td><td>ASC-HELIX20122201 22/12/2020</td></tr>
</table></td></tr>
<tr><td>7.</td><td colspan="2">Protocols followed for conduction of stability study</td><td colspan="2">Yes</td></tr>
<tr><td>8.</td><td colspan="2">Method used for analysis of FPP</td><td colspan="2">Yes</td></tr>
<tr><td>9.</td><td colspan="2">Drug-excipients compatibility studies (where applicable)</td><td colspan="2">Not Applicable</td></tr>
<tr><td>10.</td><td colspan="2">Complete batch manufacturing record of three stability batches.</td><td colspan="2">The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Ocaliva Tablet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>TR-094</td><td>1000 tablets</td><td>08-2021</td></tr>
<tr><td>TR-095</td><td>1000 tablets</td><td>08-2021</td></tr>
<tr><td>TR-096</td><td>1000 tablets</td><td>08-2021</td></tr>
</table></td></tr>
</table>

11.	Record of comparative dissolution data (where applicable)	Submitted (against the product FXR 5 Tablet 5mg of M/s .Reddy Laboratories Limited,India)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of the Evaluator

Sr.no.	Shortcoming/Deficiencies
1.	Justify for adopting the dissolution limit at 30 minutes for applied product when the innovator product recommends the acceptance criteria at 15 minutes.
2.	Stability study data of API from API manufacturer performed at zone-IV-a conditions.
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.

Decision: Approved. Firm shall submit following documents prior the issuance of Registration Letter:

- **Revised drug product specifications adopting the dissolution limit at 15 minutes as per innovator drug product/**
- **Fee for pre-registration variation i.e. Rs. 9,000/- as per SRO as per SRO1324 (I)/2024 dated 30-08-2024. Stability study data of API from API manufacturer performed at zone-IV-a conditions.**

486.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Ocaliva/Obit/Chico Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid…10mg
	Diary No. Date of R& I & fee	Dy.No 43195 dated 18-12-2018 Rs.50,000/- dated 17-12-2018
	Pharmacological Group	Farnesoid X receptor agonists
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	OCALIVA (5mg, 10mg) film coated tablets USFDA
	Me-too status	Abeticholic 10mg Tablet of M/s Dyson Research laboratories (Reg. No. 109522)
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA

Drug	Ocaliva/Obit/Chico Tablet 10mg
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.

Manufacturer of API	M/s. Chongqing Kangle Pharmaceutical Co. Ltd. No. 4 Huazhong Road, Chongqing (Changshou) Chemical Industry Park		
API Lot No.	As per invoice no. ASC-HELIX20122201 attested by DRAP batch no.ASC0004-201201 has been imported		
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: TR-091 (6 months), TR-092 (6 months), TR-093 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TR-091	TR-092	TR-093
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	08.2021	08.2021	08.2021
Date of Initiation	29-09-2021	29-09-2021	29-09-2021
No. of Batches	03		
Date of Submission	27-06-2022		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. CQ20190054 dated 26/11/2019 which remain valid until 25/11/2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has provided the copy of procurement invoices of API; details are as follow.

API Name	Invoice No. & Date
Obeticholic Acid	ASC-HELIX20122201 22/12/2020

7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Not Applicable
10.	Complete batch manufacturing record of three stability batches.	The firm has been submitted copy of Trial batch manufacturing record. Details are as under: Ocaliva Tablet Batch No. / Bach size / Mfg. Started TR-091 / 1000 tablets / 08-2021 TR-092 / 1000 tablets / 08-2021 TR-093 / 1000 tablets / 08-2021
11.	Record of comparative dissolution data (where applicable)	Submitted (against the product FXR 10 Tablet 10mg of M/s .Reddy Laboratories Limited,India)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of the Evaluator

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for adopting the dissolution limit at 30 minutes for applied product when the innovator product recommends the acceptance criteria at 15 minutes.	Firm replied that according to BCS classification, obeticholic
2.	Stability study data of API from API manufacturer performed at zone-IV-a conditions.	
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	

Decision: Approved. Firm shall submit following documents prior the issuance of Registration Letter:

- **Revised drug product specifications adopting the dissolution limit at 15 minutes as per innovator drug product/**
- **Fee for pre-registration variation i.e. Rs. 9,000/- as per SRO as per SRO1324 (I)/2024 dated 30-08-2024. Stability study data of API from API manufacturer performed at zone-IV-a conditions.**

487.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Duzall 50mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Safinamide Mesylate Eq. To Safinamide…50mg
	Diary No. Date of R& I & fee	Dy.No 4297 dated 06-02-2018 Rs.50,000 dated 02-02-2018
	Pharmacological Group	monoamine oxidase type B (MAO-B) inhibitor
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	XADAGO Tablet 50mg & 100mg SAFINAMIDE MESYLATE USFDA
	Me-too status	NA
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA			
Drug	Duzall 50mg Tablet (Safinamide Mesylate)		
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.		
Manufacturer of API	M/s. Shandong Haiyou Freda Pharmaceuticals Co. Ltd. 666 Bianhai West Road Linshu, West Industrial Zone, China		
API Lot No.	As per invoice no.S8247/2018 attested by DRAP batch no.180910 has been imported		
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: TF001 (6 months), TF002 (6 months), TF003 (6 months) Accelerated: 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TF001	TF002	TF003
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	01.2019	01.2019	01.2019
Date of Initiation	15-01-2019	15-01-2019	15-01-2019
No. of Batches	03		
Date of Submission	07-02-2023		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Not submitted</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>Copy of GMP certificate No.SD20190850 dated 24/01/2019 which remain valid until 23/01/2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has provided the copy of procurement invoices of API; details are as follow.<table><tr><td>API Name</td><td>Invoice No. & Date</td></tr><tr><td>Safinamide Mesylate</td><td>S8247/2018 24/10/2018</td></tr></table></td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not Applicable</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has been submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Duzall 50mg Tablet</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>TF001</td><td>1000 tablets</td><td>01-2019</td></tr><tr><td>TF002</td><td>1000 tablets</td><td>01-2019</td></tr><tr><td>TF003</td><td>1000 tablets</td><td>01-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Submitted (against the product innovator product Xadago Tablet 50mg of M/s. Zampon S.p.A. Via Lillo del Duca 10.20019 Bresso Italy)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Yes</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>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>Not Submitted</td></tr>
<tr><td colspan="3">Remarks of the Evaluator:<table><tr><td>Sr.no.</td><td>Shortcoming/Deficiencies</td><td>Response of the Firm</td></tr></table></td></tr>
</table>

1.	Justify for not adopting the same dissolution limit as recommended by the innovator product approved in USFDA.	Firm replied that in specification of duzall tablet control limit of dissolution was written as (NLT 80% of LC in 30 minutes). In dissolution test specification typo error occurs, instead of 80% of Q, 80% of LC was written at that time. All the stability results of dissolution also lie in 90%. Our actual limits of dissolution NLT 80% of Q within 30 minutes.
2.	Stability study data of API from API manufacturer performed at zone-IV-a conditions.	Submitted
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

488.	Name and address of manufacturer / Applicant	**M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.**
	Brand Name +Dosage Form + Strength	Duzall 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Safinamide Mesylate Eq. To Safinamide…100mg
	Diary No. Date of R& I & fee	Dy.No 4298 dated 06-02-2018 Rs.50,000 dated 02-02-2018
	Pharmacological Group	monoamine oxidase type B (MAO-B) inhibitor
	Type of Form	Form-5 D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	XADAGO Tablet 50mg & 100mg SAFINAMIDE MESYLATE USFDA
	Me-too status	NA
	GMP status	Firm submitted GMP certificate dated 25-01-2021 based on inspection dated 29th October,2020.

STABILITY STUDY DATA

Drug	Duzall 100mg Tablet (Safinamide Mesylate)
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd. Plot No. A-56, S.I.T.E., Karachi.
Manufacturer of API	M/s. Shandong Haiyou Freda Pharmaceuticals Co. Ltd. 666 Bianhai West Road Linshu, West Industrial Zone, China
API Lot No.	As per invoice no.S8247/2018 attested by DRAP batch no.180910 has been imported
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: TF001 (6 months),

	Accelerated: TF002 (6 months), TF003 (6 months) 6 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 Accelerated: 0, 3, 6		
Batch No.	TF001	TF002	TF003
Batch Size	1,000 Tablets	1,000 Tablets	1,000 Tablets
Manufacturing Date	01.2019	01.2019	01.2019
Date of Initiation	15-01-2019	15-01-2019	15-01-2019
No. of Batches	03		
Date of Submission	07-02-2023		

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 registration application approved in 312th meeting with stability data, details are as under: Zalpo/Tranz Tablet 10,20mg.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No.SD20190850 dated 24/01/2019 which remain valid until 23/01/2024.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has provided the copy of procurement invoices of API; details are as follow. API Name: Safinamide Mesylate — Invoice No. & Date: S8247/2018 24/10/2018
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	Yes
9.	Drug-excipients compatibility studies (where applicable)	Not Applicable
10.	Complete batch manufacturing record of three stability batches.	The firm has been submitted copy of Trial batch manufacturing record. Details are as under: Duzall 100mg Tablet

		<table><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>TF001</td><td>1000 tablets</td><td>01-2019</td></tr><tr><td>TF002</td><td>1000 tablets</td><td>01-2019</td></tr><tr><td>TF003</td><td>1000 tablets</td><td>01-2019</td></tr></table>
11.	Record of comparative dissolution data (where applicable)	Submitted (against the product innovator product Xadago Tablet 100mg of M/s. Zampon S.p.A. Via Lillo del Duca 10.20019 Bresso Italy)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of the Evaluator:

Sr.no.	Shortcoming/Deficiencies	Response of the Firm
1.	Justify for not adopting the same dissolution limit as recommended by the innovator product approved in USFDA.	Firm replied that in specification of duzall tablet control limit of dissolution was written as (NLT 80% of LC in 30 minutes). In dissolution test specification typo error occurs, instead of 80% of Q, 80% of LC was written at that time. All the stability results of dissolution also lie in 90%. Our actual limits of dissolution NLT 80% of Q within 30 minutes.
2.	Stability study data of API from API manufacturer performed at zone-IV-a conditions.	Submitted
3.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Record of temperature and humidity with time and date.	Submitted

Decision: Approved.

489.	Name and address of manufacturer/ Applicant	**M/s. Barrett Hodgson Pakistan Private Limited F/423, S.I.T.E., Karachi.**
	Brand Name + Dosage Form + Strength	Sacval tablet 49mg +51mg
	Composition	Each Film coated tablet contains: Sacubitril……....49mg Valsartan……..…51mg
	Diary No. Date of R & I & fee	Dy. No. 6072-A dated 14-06-2017 50,000/- dated 13-06-2017
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	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	Entresto 49mg + 51mg Tablet by Novartis Pharmaceutical , USFDA Approved
	Me-too status	Savesto 49mg + 51mg Tablet by Getz Pharma
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.

	Remarks of the Evaluator		
STABILITY STUDY DATA			
Drug	Satril (Sacubitril 49mg + Valsartan 51mg) Tablet		
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.No.6, North Airport Road Sanzao Town, Jinwan District, Zhuhai, Guangdong P.R. China.		
API Lot No.	Batch no. 57321076803		
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 / 75% ± 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.	EXP-T-1170	PLT-T-163	PLT-T-164
Batch Size	800 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	09,2022	10, 2022	10, 2022
Date of Initiation	24-10-2022	24-10-2022	24-10-2022
No. of Batches	03		
Date of Submission	27-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted
4.	Stability study data of API from API manufacturer	Firm has submitted 3 batches stability study data of API at: • Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance & • Long Term, 24 months at Zone IV B
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License No. YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration. GMP Certificate is valid till 15-09-2026
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (Invoice No: RD2019051401-1) cleared dated 05-10-2021 specifying 1.2Kg. The invoice is cleared by AD (I&E) DRAP.

<table>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Firm has submitted protocols followed for conduction of stability study</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Firm has provided detailed method for analysis of FPP</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted drug excipient compatibility studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the batches</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP results of their product against Comparator product, Uperio tablet. The details are follows:
<table>
<tr><td>Feature</td><td>Comparator Product</td><td>Tested Product</td></tr>
<tr><td>Brand Name</td><td>Uperio Tablet 49mg+51mg</td><td>Sacval 49mg + 51mg Tablet</td></tr>
<tr><td>Batch No</td><td>TLY33</td><td>EXP-T-1170</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
4. 0.1N HCl pH 1.2
5. Acetate buffer pH 4.5
6. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies</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>
</table>

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard
2.	Submit reference of previous approval of applications with stability study data of the firm.
3.	Justify for not adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.

Decision: Approved. Firm shall submit following shortcomings prior the issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**

- **Revised drug product specifications t adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.**
- **Fee for pre-registration variation as per SRO1324 (I)/2024 dated 30-08-2024.**

490.	Name and address of manufacturer/ Applicant	**M/s. Barrett Hodgson Pakistan Private Limited F/423, S.I.T.E., Karachi**.
	Brand Name + Dosage Form + Strength	Sacval 24mg + 26mg Tablet
	Composition	Each Film coated tablet contains: Sacubitril……....24mg Valsartan……..…26mg
	Diary No. Date of R & I & fee	From-5 Dy. No. 6072-A dated 14-06-2017 50,000/- dated 13-06-2017
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	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	Entresto 24mg + 26mg Tablet by Novartis Pharmaceutical , USFDA Approved
	Me-too status	Savesto 24mg + 26mg Tablet by Getz Pharma
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Satril (Sacubitril 24mg + Valsartan 26mg) Tablet		
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.No.6, North Airport Road Sanzao Town, Jinwan District, Zhuhai, Guangdong P.R. China.		
API Lot No.	Batch no. 57321076803		
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 / 75% ± 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.	EXP-T-1169	PLT-T-161	PLT-T-162
Batch Size	800 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	09,2022	10, 2022	10, 2022
Date of Initiation	24-10-2022	24-10-2022	24-10-2022
No. of Batches	03		
Date of Submission	27-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted 3 batches stability study data of API at:
Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance &
Long Term, 24 months at Zone IV B</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>Copy of Drug Manufacturing License No.
YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration.

GMP Certificate is valid till 15-09-2026</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 commercial invoice (Invoice No: RD2019051401-1) cleared dated 05-10-2021 specifying 1.2Kg. The invoice is cleared by AD (I&E) DRAP.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Firm has submitted protocols followed for conduction of stability study</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Firm has provided detailed method for analysis of FPP</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted drug excipient compatibility studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the batches</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP results of their product against Comparator product, Savesto tablet. The details are follows:
<table>
<tr><td>Feature</td><td>Comparator Product</td><td>Tested Product</td></tr>
<tr><td>Brand Name</td><td>Savesto Tablet 24mg+26mg</td><td>Sacval 24mg + 26mg Tablet</td></tr>
<tr><td>Batch No</td><td>053FB2</td><td>EXP-T-1169</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. 0.1N HCl pH 1.2
2. Acetate buffer pH 4.5
3. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
</table>

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

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard
2.	Submit reference of previous approval of applications with stability study data of the firm.
3.	Justify for not adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.

Decision: Approved. Firm shall submit following shortcomings/documents prior the issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**
- **Revised drug product specifications t adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.**
- **Fee for pre-registration variation as per SRO1324 (I)/2024 dated 30-08-2024.**

491.	Name and address of manufacturer/ Applicant	**M/s. Barrett Hodgson Pakistan Private Limited F/423, S.I.T.E., Karachi.**
	Brand Name + Dosage Form + Strength	Sacval tablet 97mg +103mg
	Composition	Each Film coated tablet contains: Sacubitril……....97mg Valsartan……..…103mg
	Diary No. Date of R & I & fee	Dy. No. 6074-A dated 14-06-2017 50,000/- dated 13-06-2017
	Pharmacological Group	Angiotensin receptor-neprilysin inhibitors (ARNi)
	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	Entresto 97mg + 103mg Tablet by Novartis Pharmaceutical , USFDA Approved
	Me-too status	Savesto 97mg + 103mg Tablet by Getz Pharma
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Satril (Sacubitril 97mg + Valsartan 103mg) Tablet
Manufacturer of API	Zhuhai Rundu Pharmaceutical Co., Ltd.No.6, North Airport Road Sanzao Town, Jinwan District, Zhuhai, Guangdong P.R. China.
API Lot No.	Batch no. 57321076803
Description of Pack	Alu-Alu blister foil with unit carton

(Container closure system)			
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 75% ± 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.	EXP-T-1171	PLT-T-165	PLT-T-166
Batch Size	800 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	09,2022	10, 2022	10, 2022
Date of Initiation	24-10-2022	24-10-2022	24-10-2022
No. of Batches	03		
Date of Submission	27-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted
4.	Stability study data of API from API manufacturer	Firm has submitted 3 batches stability study data of API at: • Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance & • Long Term, 24 months at Zone IV B
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License No. YUE 20160246 valid till 10-12-2025 issued by Guangdong Food and Drug Administration. GMP Certificate is valid till 15-09-2026
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (Invoice No: RD2019051401-1) cleared dated 05-10-2021 specifying 1.2Kg. 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 submitted drug excipient compatibility studies
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches

<table>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP results of their product against Comparator product, Uperio tablet. The details are follows:
<table>
<tr><td>Feature</td><td>Comparator Product</td><td>Tested Product</td></tr>
<tr><td>Brand Name</td><td>Uperio Tablet 97mg+103 mg</td><td>Sacval 97mg + 103mg Tablet</td></tr>
<tr><td>Batch No</td><td>TKC12</td><td>EXP-T-1171</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. 0.1N HCl pH 1.2
2. Acetate buffer pH 4.5
3. Phosphate buffer pH 6.8</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>Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies</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>
</table>

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard.
2.	Submit reference of previous approval of applications with stability study data of the firm.
3.	Justify for not adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.

Decision: Approved. Firm shall submit following shortcomings/documents prior the issuance of Registration letter:

- **Revised the label claim of applied formulation in-line with innovator product i.e. *Each film-coated tablet contains (applied strength) sacubitril and (applied strength) valsartan (as sacubitril valsartan sodium salt complex)",* along with requisite fee for pre-registration variation.**
- **Revised drug product specifications t adopting the same dissolution condition and acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.**
- **Fee for pre-registration variation as per SRO1324 (I)/2024 dated 30-08-2024.**

492.	Name and address of manufacturer/ Applicant	**M/s. Barrett Hodgson Pakistan Private Limited F/423, S.I.T.E.,Karachi.**
	Brand Name + Dosage Form + Strength	Oclozine Ophthalmic Solution 0.24%
	Composition	Each ml contains: 2.4mg Cetirizine equivalent to 2.85mg Cetirizine Hydrochloride

	Diary No. Date of R & I & fee	Dy.No 6713 dated 15-02-2019 Rs.50,000/- dated 14-02-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZERVIATE Ophthalmic Solution 0.24% , USFDA Approved
	Me-too status	NA
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Oclozine Ophthalmic Solution 0.24%		
Manufacturer of API	Karunesh Remedies, Bharuch, India		
API Lot No.	Batch no. CTZ/001/22-23		
Description of Pack (Container closure system)	LDPE Bottle		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 25% ± 5%RH Real Time: 30°C ± 2°C / 35% ± 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.	EXP-OP-303	PLT-OP-21	PLT-OP-22
Batch Size	1000 ml	1000 ml	1000 ml
Manufacturing Date	12,2022	01, 2023	01, 2023
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
No. of Batches	03		
Date of Submission	27-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer are submitted
4.	Stability study data of API from API manufacturer	Firm has submitted 3 batches stability study data of API at: • Accelerated, 6 months at 40ºC ±2ºC / 75±5% RH of drug substance & • Long Term, 60 months at Zone IV B

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No.22113667 valid till 08-11-2025 issued by Food and Drug Control Administration Gujarat State India.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance certificate (Invoice No:001/2022-23) cleared dated 02-1-2022 specifying 50Kg. 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 submitted drug excipient compatibility studies
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)	NA
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.	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.	Shortcoming/Deficiencies
1.	Justify for not performing the Bacterial Endotoxin test and Osmolality test while the batch analysis of finished product .
2.	Justify for not performing the sterility test ,Bacterial Endotoxin test and Osmolality test while conducting the stability study of finished product.

Decision: Deferred to provide justification for not performing the sterility test, Bacterial Endotoxin test and Osmolality test while conducting the batch analysis and stability study of finished product, prior the issuance of Registration Letter.

493.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.**
	Brand Name +Dosage Form + Strength	Roflubar 500mcg Tablet
	Composition	Each film coated tablet contains: Roflumilast……..500 mcg
	Diary No. Date of R& I & fee	Dy. No.1331; 27-06-2016; Rs.20,000/- (27-06-2016)
	Pharmacological Group	Inhibitors of phosphodiesterase 4
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's;Rs.600/-14's;Rs.840/-

		20's; Rs.1200/-28's; Rs.1680/- 30's; Rs.1800/- or as per DRAP's pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Omlast tablet of M/s. Genix Reg.no.100192
	GMP status	Copy of GMP Certificate valid till 05.12.2023 is submitted.
	Remarks of the Evaluator.	Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else apply on Form 5D
	Decision of 274th meeting of Registration Board: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else apply on Form 5D.	

STABILITY STUDY DATA			
Drug	Roflubar 500mcg Tablet		
Manufacturer of API	Ferrer Interquim SA. Joan Buscalla 10 E-08173 Sant Cugat Barcelona Spain		
API Lot No.	Batch no. A19005M		
Description of Pack (Container closure system)	Alu/Alu blister		
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.	EXP-T-1047	PLT-T-0129	PLT-T-0130
Batch Size	2000 Tablets	3000 Tablet	3000 Tablet
Manufacturing Date	07,2020	08, 2020	08, 2020
Date of Initiation	27-08-2020	25-09-2020	25-09-2020
No. of Batches	03		
Date of Submission	06-10-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer are submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No.NCF-II/1905/001/CAT issued dated 11/02/2019 valid for 4 years by Ministry of Health of Govt. of Catalonia Spain.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
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 submitted drug excipient compatibility studies
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)	Not submitted
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.	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.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
3.	Submit stability study data of API from API manufacturer
4.	Submit documents for the procurement of API with approval from DRAP (in case of import).
5.	Submit record of comparative dissolution data
6.	Justify for not including the content uniformity test while performing the stability study of finished product.

Decision: Deferred for the submission of following documents/shortcomings:

- **Submit requisite fee required along with stability documents.**
- **Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.**
- **Submit stability study data of API from API manufacturer.**
- **Submit documents for the procurement of API with approval from DRAP (in case of import).**
- **Submit record of comparative dissolution data.**
- **Justify for not including the content uniformity test while performing the stability study of finished product.**

494.	Name and address of manufacturer/ Applicant	**M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore**
	Brand Name + Dosage Form + Strength	CARDILOL XR 20MG CAPSULE
	Composition	Each extended-release capsule contains: Carvedilol Phosphate……...20mg
	Diary No. Date of R & I & fee	Dy.No 13424 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's and 30's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Coreg CR 20mg tablet approved by USFDA
	Me-too status	N/A
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Carvedilol Phosphate		
Manufacturer of API	Alphamed Formulations Private Limited Survey no. 225, Sampanbole village: shamirpet mandal: Medchal-Malkajgiri district Telangana, India		
API Lot No.	AF050-062A		
Description of Pack (Container closure system)	Double layered LDPE bags and HDPE container		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6, 9,12,18,24 (Months)		
Batch No.	CRA_c T1-21	CRA_c T2-21	CRA_c T3-21
Batch Size	3000 capsule	3000 capsule	3000 capsule
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	22-09-2021	22-09-2021	22-09-2021
No. of Batches	03		
Date of Submission	27-02-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 in which our product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule" through onsite panel inspection (Supplementary Agenda) of stability study data of the firm
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML no. 34/RR/AP/2008/F/R valid till 19/12/2023
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: GE2019/156 dated 9-10-2020
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	CDP against reference brand Coreg CR 20mg of M/s. Glaxo Smith Kline, Canada submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches CRA_c T1-21, CRA_c T2-21 and CRA_c T3-21 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.	Shortcoming/Deficiencies
1.	According to the innovator review literature, carvedilol phosphate extended-release hard gelatin capsules are filled with carvedilol phosphate immediate-release and controlled-release micro particles that are drug-layered and then coated with methacrylic acid copolymers. Clarify, how the applied product be similar with the reference product when you have filled only extended release pellets of carvedilol phosphate in hard gelatin capsule.

Decision: Registration Board while considered the fact that innovator formulation consists of hard gelatin capsules filled with carvedilol phosphate immediate-release and controlled-release micro particles that are drug-layered and then coated with methacrylic acid copolymers and the applied formulation is hard gelatin capsule filled with only extended release pellets (imported from M/s. Alphamed Formulations Private Limited, India) of carvedilol phosphate.Hence, Registration Board deferred the case for justification from the firm regarding the difference in applied formulation against the innovator product along with comprehensive documentation from M/s. Alphamed Formulations Private Limited, India, detailing the manufacturing process and release profile of the pellets.

495.	Name and address of manufacturer/ Applicant	**M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore**
	Brand Name + Dosage Form + Strength	LORSIN 10MG TABLET
	Composition	Each film coated tablet contains: Lorcaserin Hydrochloride……...10mg
	Diary No. Date of R & I & fee	Dy.No 11342 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Serotonin receptor agonists
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30's and 60's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Belviq 10mg tablet approved by USFDA
	Me-too status	N/A
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Deferred in 307th meeting of Registration Board

STABILITY STUDY DATA

Drug	Lorcaserin Hydrochloride		
Manufacturer of API	JIANGSU YONG'AN Pharmaceutical co., Ltd No .18, 237 Provincial Road, Economic development zone, Huai'an, Jiangsu		
API Lot No.	LCS -202007001		
Description of Pack (Container closure system)	Each Alu -Alu blister of 10 tablets packed in unit carton (3×10's)		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LOAt T2-21	LOAt T3-21	LOAt T4-21
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	08-10-2021	08-10-2021	08-10-2021
No. of Batches	03		
Date of Submission	07-09-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 in which our product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule" through onsite panel inspection (Supplementary Agenda) of stability study data of the firm
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML no. Su 20160324 valid till 06/12/2025
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: ZY20071301GW dated 29-07-2020
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	CDP against reference brand Belviq 10mg Tablet of M/s. Arena Pharmaceuticals GmbH submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches LOAt T2-2,1 LOAt T3-21 LOAt T4-21submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	submitted

Remarks of Evaluator:

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

496.	Name and address of manufacturer/ Applicant	**M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore**
	Brand Name + Dosage Form + Strength	Velsar 49/51mg Tablet
	Composition	Each Film Coated Oral Tablet Contains: Sacubitril…49mg Valsartan…51mg
	Diary No. Date of R & I & fee	Dy.No 13972 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Firm vide letter no. nil dated 19th December,2024 requested for consideration of new application on Form 5-F and withdrawal of previous submission on Form5-D.	
	Decision: Registration Board acceded the request of the firm for withdrawal of their above mentioned application and declared them as disposed off and the application of same formulation applied on Form 5F shall be considered on its turn.	

497.	Name and address of manufacturer/ Applicant	**M/s Kaizen Pharmaceuticals Pvt. Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Brand Name + Dosage Form + Strength	Razaptan Tablet 10mg
	Composition	Each Tablet Contains: Rizatriptan as Benzoate…10mg
	Diary No. Date of R & I & fee	Dy.No 8798 dated 27-02-2019 Rs.50,000/- dated 25-02-2019
	Pharmacological Group	serotonin (5-HT) 1B/1D receptor agonist (triptan)
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30's and 60's / As per SRO
	Approval status of product in Reference Regulatory Authorities	MAXALT® (rizatriptan benzoate) tablets approved by USFDA
	Me-too status	N/A
	GMP status	Firm has submitted copy of GMP inspection report dated 11-08-2020 wherein firm was GMP compliant.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Rizatriptan Benzoate		
Manufacturer of API	Glenmark Pharmaceuticals Ltd. Plot no. 3109-C G.I.D.C. Ankelshwar Gujarat India		
API Lot No.	810702750		
Description of Pack (Container closure system)	Alu -Alu blister		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1	2	2
Batch Size	1500 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	12-2017	05-2018	05-2018
Date of Initiation	29-12-2017	04-05-2018	04-05-2018
No. of Batches	03		
Date of Submission	17-11-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Refer to the inspection conducted for verification of authenticity of stability data of Rofair 500mcg Tablet.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. 2308698 and valid till 02/07/2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no:3032/SR/ROW/17-18 dated 21-06-2017
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	CDP against innovator brand Maxalt 10mg Tablet of M/s.MSD submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches 1,2,3 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.	Shortcoming/Deficiencies
1.	Justify for not adopting the USP/BP specification for the quality analysis of finished product, when the monograph of Rizatriptan Benzoate tablet is available in official pharmacoepia.
2.	Both USP and BP monograph of Rizatriptan Benzoate tablet recommends that the dissolution limit should be NLT 80% (Q) of the labeled amount of rizatriptan within 15 minutes, than justify the dissolution criteria adopted by you for the applied product.

Decision: Approved. Firm shall submit following documents/shortcomings prior the issuance of Registration Letter:

- **Justify for not adopting the USP/BP specification for the quality analysis of finished product, when the monograph of Rizatriptan Benzoate tablet is available in official pharmacopeia.**
- **Both USP and BP monograph of Rizatriptan Benzoate tablet recommends that the dissolution limit should be NLT 80% (Q) of the labeled amount of rizatriptan within 15 minutes, than justify the dissolution criteria adopted by you for the applied product.**

498.	Name and address of manufacturer/ Applicant	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Brand Name + Dosage Form + Strength	Migrip Tablet 5mg
	Composition	Each Tablet Contains: Rizatriptan Benzoate Eq. To Rizatriptan….5mg
	Diary No. Date of R & I & fee	Dy.No 21308 dated 16-11-2017 Rs.50,000 dated 16-11-2017
	Pharmacological Group	serotonin (5-HT) 1B/1D receptor agonist (triptan)
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30's and 60's / As per SRO
	Approval status of product in Reference Regulatory Authorities	MAXALT® (rizatriptan benzoate) tablets approved by USFDA
	Me-too status	N/A
	GMP status	GMP certificate issue dated 06-06-2022 based on inspection conducted on 25-03-2022
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Rizatriptan Benzoate		
Manufacturer of API	M/s. SMS Pharmaceuticals Limited, Hyderabad Telangana India		
API Lot No.	RTZ/1219032		
Description of Pack (Container closure system)	Alu-PVC Blister 10's		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-5D-RZ-22004	RD-GP-5D-RZ-22005	RD-GP-5D-RZ-22006
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
No. of Batches	03		
Date of Submission	Dec-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection of their product Dexstom 30mg and 60mg Capsule.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML available Dated 01-01-2017 valid till 31-12-2021issued by Drug Control Administration Govt. of Telangana.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no:BP/EX/19-20/193 dated 20-01-2020 attested by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	CDP against innovator brand Maxalt 5mg Tablet submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches are 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:		
Decision: Approved.		

499.	Name and address of manufacturer/ Applicant	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Brand Name + Dosage Form + Strength	Migrip Tablet 10mg
	Composition	Each Tablet Contains: Rizatriptan Benzoate Eq. To Rizatriptan….10mg
	Diary No. Date of R & I & fee	Dy.No 21308 dated 16-11-2017 Rs.50,000 dated 16-11-2017
	Pharmacological Group	serotonin (5-HT) 1B/1D receptor agonist (triptan)
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30's and 60's / As per SRO
	Approval status of product in Reference Regulatory Authorities	MAXALT® (rizatriptan benzoate) tablets approved by USFDA
	Me-too status	N/A

	GMP status	GMP certificate issue dated 06-06-2022 based on inspection conducted on 25-03-2022
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Rizatriptan Benzoate		
Manufacturer of API	M/s. SMS Pharmaceuticals Limited, Hyderabad Telangana India		
API Lot No.	RTZ/1219032		
Description of Pack (Container closure system)	Alu-PVC Blister 10's		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-GP-5D-RZ-22007	RD-GP-5D-RZ-22008	RD-GP-5D-RZ-22009
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
No. of Batches	03		
Date of Submission	Dec-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection of their product Dexstom 30mg and 60mg Capsule.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML available Dated 01-01-2017 valid till 31-12-2021issued by Drug Control Administration Govt. of Telangana.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no:BP/EX/19-20/193 dated 20-01-2020 attested by DRAP.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted

9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	CDP against innovator brand Maxalt 10mg Tablet submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches are 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:		
Decision: Approved. Firm shall select either of the pharmacopoeial monograph available for the applied formulation before issuance of registration letter along with fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.		

500.	Name and address of manufacturer / Applicant	**M/s Hiranis Pharmaceuticals (Pvt) Ltd E-145-149, North Western Industrial Zone, Port Qasim Karachi**
	Brand Name +Dosage Form + Strength	Safcort Tablet 6mg
	Composition	Each tablet contains: Deflazacort…...……. 6mg.
	Diary No. Date of R& I & fee	dated 03-04-2023,
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	Proposed Price: As per SRO.
	Approval status of product in Reference Regulator Authorities	Emflaza Tablet 6mg USFDA Approved
	Me-too status	-
	GMP status	DML by way of formulation No. 000785 dated 03-02-2019
	Remarks of the Evaluator	

STABILITY STUDY DATA	
Drug	Safcort 6mg Tablet
Manufacturer of API	M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai india
API Lot No.	APL/DFC/060008/B-22

Description of Pack (Container closure system)	White color, round, biconvex tablets, plain from both sides in Alu-PVC blister of 1x10's in 260 micro m foil and 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.	TF-260552	TF-280552	TF-270552
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	10-06.2022	10-06.2022	10-06.2022
No. of Batches	03		
Date of Submission	dated 03-04-2023.		

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 ETOXIB 120MG & ETOXIB 90MG TABLET (Etoricoxib) by following panel: 1. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women Karachi (Member of Registration Board Islamabad) 2. Dr. Saif-ur-Rehman Khattak, Director CDL, DRAP, Karachi. 3. Mr. Kirshan Das, Assistant Director, DRAP Office, Karachi
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. APL/DFC/060008/B-22) Mfg. date 01-2022) of the drug substance (Beclomethasone Dipropionate) from M/s ANUH PHARMA LTD. Mumbai, India Firm has also submitted COA from finished product manufacture 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:(APL/088/D-17, APL/094/D-17, APL/095/D-17).
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML dated 01-10-2021 in the name of M/s ANUH Pharma LTD M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai india Valid till 30.09.2026.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Clearance Certificate of Safcort of M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai india (Batch No. APL/DFC/060008/B-22) Mfg. date 01-2022)

<table>
<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><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>TF-260552</td><td>2500 Tablets</td><td>06-06.2022</td></tr>
<tr><td>TF-280552</td><td>2500 Tablets</td><td>27-05.2022</td></tr>
<tr><td>TF-270552</td><td>2500 Tablets</td><td>27-05.2022</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. Safcort Tablet (Deflazacort) 6mg Tablet against Defal tablet 6mg Batch No. 3106, Exp. date 03-2023 manufactured by Lejona
Spain 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:
Warnings and Precautions Immunosuppression and Increased Risk of Infection.
INDICATIONS AND USAGE: EMFLAZA is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older
DOSAGE AND ADMINISTRATION: • The recommended once-daily dosage is approximately 0.9 mg/kg/day administered orally • Discontinue gradually when administered for more than a few days
DOSAGE FORMS AND STRENGTHS • Tablets: 6 mg, 18 mg, 30 mg, and 36 mg (3) • Oral Suspension: 22.75 mg/mL s
Assessments Prior to First Dose of EMFLAZA
Administer all immunizations according to immunization guidelines prior to starting EMFLAZA. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting EMFLAZA</td></tr>
<tr><td colspan="3">Decision: Deferred for verification of record/receipt of Form 5-D from R&I section of Administration Division of DRAP.</td></tr>
<tr><td>501.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Hiranis Pharmaceuticals (Pvt) Ltd E-145-149, North Western Industrial Zone, Port Qasim Karachi</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Glucort P.R. Tablet 5mg</td></tr>
<tr><td></td><td>Composition</td><td>Each enteric coated tablet contains:
Beclomethasone Dipropionate …...……. 5mg.</td></tr>
</table>

	Diary No. Date of R& I & fee	28-05-2014 Dy.no. 808 R&I Rs. 1,000 / Rs. 50,000/
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	Proposed Price: As per SRO.
	Approval status of product in Reference Regulator Authorities	Clipper 5mg Tablet. Chiesi Pharma Italy
	Me-too status	-
	GMP status	DML by way of formulation No. 000785 dated 03-02-2019
	Remarks of the Evaluator	Deferred in 256th meeting of registration Board: Registration Board considered above registration applications and deferred for submission of scientifically rational laboratory scale data as per guidelines approved in 251st meeting.

STABILITY STUDY DATA			
Drug	Glucort P.R. Tablet 5mg		
Manufacturer of API	M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai India		
API Lot No.	BCD002C22		
Description of Pack (Container closure system)	White, round, biconvex, enteric coated tablets, plain from both sides in white opaque PVDC blister of 3x10's in foil and 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.	TF-230522	TF-240522	TF-250522
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	01-06.2022	01-06.2022	01-06.2022
No. of Batches	03		
Date of Submission	dated 03-04-2023.		

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 ETOXIB 120MG & ETOXIB 90MG TABLET (Etoricoxib) by following panel: 1. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women Karachi (Member of Registration Board Islamabad) 2. Dr. Saif-ur-Rehman Khattak, Director CDL, DRAP, Karachi. 3. Mr. Kirshan Das, Assistant Director, DRAP Office, Karachi

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Firm has submitted Copy of COA (Batch No. BCD 002 C22) Mfg. date 03-2022) of the drug substance (Beclomethasone Dipropionate) from M/s ANUH PHARMA LTD. Mumbai, India
Firm has also submitted COA from finished product manufacture 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:(API/164/A-15, API/164/A-16, API/025/A-17).</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 DML dated 01-10-2021 in the name of M/s ANUH Pharma LTD M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai india Valid till 30.09.2026.</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 LICENCE TO IMPORT DRUG(S) of Beclomethasone Dipropionate of M/s ANUH PHARMA LTD. Plot D-5/8 & D-5/9 T.T.C. Industrial Area M.I.D.C. Turbhe Navi Mumbai india (Batch No. BCD 002 C22) Mfg. date 03-2022)</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><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>TF-230522</td><td>2500 Tablets</td><td>26-05.2022</td></tr>
<tr><td>TF-240522</td><td>2500 Tablets</td><td>23-05.2022</td></tr>
<tr><td>TF-250522</td><td>2500 Tablets</td><td>23-05.2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>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>
</table>

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Submit record of comparative dissolution data performed against the reference/innovator/comparator product.
2.	Justify for not including the content uniformity test while performing the quality analysis of finished product.

Decision: Approved. Firm shall submit following documents/shortcomings prior the issuance of Registration Letter:

- **Record of comparative dissolution data performed against the reference/innovator/comparator product.**
- **Revised drug product specifications including the content uniformity test while performing the quality analysis of finished product.**
- Fee for pre-registration variation i.e. Rs. 9,000/- as per SRO 1324 (I)/2024 dated 30-08-2024.

502.	Name and address of manufacturer / Applicant	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Wencuval 24/26 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…24.3mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…25.7mg
	Diary No. Date of R& I & fee	Dy No. 14098: 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	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].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision of 323rd meeting of Registration Board: Deferred for following submissions: • Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

STABILITY STUDY DATA	
Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex…24.3mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…25.7mg
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province,China.
API Lot No.	RCD-LCZ696-202104211

Description of Pack (Container closure system)	1X10's 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%		
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	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	23-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
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.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	NA

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>T-01</td><td>1200 TABLETS</td><td>10-2021</td></tr>
<tr><td>T-02</td><td>1200 TABLETS</td><td>10-2021</td></tr>
<tr><td>T-03</td><td>1200 TABLETS</td><td>10-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>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>
</table>

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength,so clarification is required in this regard
3.	Submit reference of previous approval of applications with stability study data of the firm.
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
7.	Submit record of comparative dissolution data.

Decision: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- **Submit requisite fee required along with stability documents.**
- **Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard.**
- **Submit reference of previous approval of applications with stability study data of the firm.**
- **Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.**

- **Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer**
- **Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
- **Submit record of comparative dissolution data.**

503.	Name and address of manufacturer / Applicant	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Wencuval 49/51 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…48.6mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…51.4mg
	Diary No. Date of R& I & fee	Dy No. 14099: 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	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].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision of 323rd meeting: Deferred for following submissions: • Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

STABILITY STUDY DATA

Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex…48.6mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…51.4mg
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province,China.
API Lot No.	RCD-LCZ696-202104211
Description of Pack (Container closure system)	1X10's 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%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.		T-04	T-05	T-06
Batch Size		1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date		10-2021	10-2021	10-2021
Date of Initiation		27-10-2021	27-10-2021	27-10-2021
No. of Batches		03		
Date of Submission		23-12-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	Documents to Be Provided	Status		
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted		
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted		
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.		
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.		
7.	Protocols followed for conduction of stability study	Submitted.		
8.	Method used for analysis of FPP	Submitted.		
9.	Drug-excipients compatibility studies (where applicable)	NA		
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 T-01 / 1200 TABLETS / 10-2021 T-02 / 1200 TABLETS / 10-2021 T-03 / 1200 TABLETS / 10-2021		

11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength,so clarification is required in this regard
3.	Submit reference of previous approval of applications with stability study data of the firm.
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
7.	Submit record of comparative dissolution data.

Decision: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- **Submit requisite fee required along with stability documents.**
- **Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard.**
- **Submit reference of previous approval of applications with stability study data of the firm.**
- **Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.**
- **Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer**
- **Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
- **Submit record of comparative dissolution data.**

504.	Name and address of manufacturer / Applicant	**M/s Wenovo Pharmaceuticals.** **Plot # 31& 32 Punjab Small Industrial Estate Taxila**

	Brand Name +Dosage Form + Strength	Wencuval 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…97.2mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…102.8mg
	Diary No. Date of R& I & fee	Dy No. 14100: 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	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].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision of 323rd meeting of Registration Board: Deferred for following submissions: • Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

STABILITY STUDY DATA			
Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex…97.2 mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…102.8mg		
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province,China.		
API Lot No.	RCD-LCZ696-202104211		
Description of Pack (Container closure system)	1X10's 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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021

<table>
<tr><td colspan="2">No. of Batches</td><td>03</td></tr>
<tr><td colspan="2">Date of Submission</td><td>23-12-2022</td></tr>
<tr><td colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td>Documents to Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Not submitted.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Not submitted</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.</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>Not submitted</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 a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.</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>NA</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>T-01</td><td>1200 TABLETS</td><td>10-2021</td></tr>
<tr><td>T-02</td><td>1200 TABLETS</td><td>10-2021</td></tr>
<tr><td>T-03</td><td>1200 TABLETS</td><td>10-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not submitted</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
</table>

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.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard.
3.	Submit reference of previous approval of applications with stability study data of the firm.
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
7.	Submit record of comparative dissolution data.

Decision: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- **Submit requisite fee required along with stability documents.**
- **Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 strength, so clarification is required in this regard.**
- **Submit reference of previous approval of applications with stability study data of the firm.**
- **Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.**
- **Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer**
- **Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
- **Submit record of comparative dissolution data.**

Agenda of Mr. Shahrukh

509.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Canaloz 300mg tablet
	Composition	Each film Coated tablet contains: Canagliflozin hemihydrate eq to canagliflozin…. 300mg

	Diary No. Date of R& I & fee	Form-5D Dy.No 13970 dated 07-03-2019 Rs.50,000/- dated 06-03-2019 (As per main list)
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of Form	Form 5.
.	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	30's/As per SRO
	Approval status of product in Reference Regulator Authorities	INVOKANA (canagliflozin) tablets USFDA Approved with box warning.
	Me-too status	
	GMP status	Ref. No.103/2022-DRAP(AD-99202927387) dated 30-06-2022
	Remarks of the Evaluator	Not Considered Yet in any meeting

STABILITY STUDY DATA

Drug	Canaloz 300mg tablet		
Manufacturer of API	Fuxin long Rui pharmaceutical co., ltd Fluoride Industrial Park, Fumeng Country		
API Lot No.	KG-20190713-D02-KG06-01		
Description of Pack (Container closure system)	150mm Alu-PVC Foil and packed on bleach board 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, 1,2,3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	CNBt T1-21	CNBt T2-21	CNBt T3-21
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	12-06-2021	12-06-2021	12-06-2021
No. of Batches	03		
Date of Submission	19.11.22		

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.	297th meeting of the registration board held on 12-01-2021 product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule
	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA of API submitted from API ManufacturerKG-20190713-D02-KG06-01 COA of API submitted from Finished Product Manufacturer KG-20190713-D02-KG06-01

	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted
	Stability study data of API from API manufacturer	Submitted as per zone IV-A accelerated and long term stability for 3 batches
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML no. liao20150233 valid till December 20, 2022 GMP valid till August 23, 2023
	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: HN191015-01 dated October 15, 2019, 14435/2019 DRAP dated 8-11-19
	Protocols followed for conduction of stability study	Submitted
	Method used for analysis of FPP	Submitted assay by HPLC
	Drug-excipients compatibility studies (where applicable)	Firm has used SAME EXCIPIENTS AS INNOVATOR
	Complete batch manufacturing record of three stability batches.	Submitted.
	Record of comparative dissolution data (where applicable)	Comparative dissolution data with innovator Invokana Batch.No LCL5N00 is submitted in 3 mediums
	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like, Raw data sheets, chromatogram, COA, summary data sheets etc. are submitted by the firm.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Remarks of Evaluator:		
Decision: Approved. Registration letter will be issued after submission of valid copy of GMP certificate of the drug substance manufacturer (Fuxin long Rui pharmaceutical co., ltd) issued by relevant/concerned regulatory authority.		

510.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Molta Tablets 665mg
	Composition	Each XR Film Coated Tablet Contains:

		Paracetamol…665mg
	Diary No. Date of R & I & fee	Dy.No 13997 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Analgesics and antipyretics anilide Paracetamol (Acetaminophen) ATC code: N02B E01
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14, 28, 56, 98's As per SRO
	Approval status of product in Reference Regulatory Authorities	Paracetamol 665mg MR tablet (approved by TGA of Australia)
	Me-too status	Panadol Extend by GSK (097070)
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Deferred in 320th meeting for stability data

STABILITY STUDY DATA

Drug	Molta Tablets 665mg		
Manufacturer of API	Saakh Pharm (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan		
API Lot No.	18GN60008		
Description of Pack (Container closure system)	Each ALU/ PVC blister of 2×10's Tablets packed in a Unit carton.		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6, 9,12,18,24 (Months)		
Batch No.	PRA_t T2-21	PRA_t T3-21	PRA_t T4-21
Batch Size	3000 Tablets	3000 Tablets	3000 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		
Date of Submission	06-10-2022		

8DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
	Reference of previous approval of applications with stability study data of the firm.	297th meeting of the registration board held on 12-01-2021 product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule

	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted
	Stability study data of API from API manufacturer	Submitted
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted GMP no. 83/2020-DRAP (K) valid till 18-06-22
	Documents for the procurement of API with approval from DRAP (in case of import).	Material purchased locally
	Protocols followed for conduction of stability study	Submitted
	Method used for analysis of FPP	Submitted
	Drug-excipients compatibility studies (where applicable)	N/A
	Complete batch manufacturing record of three stability batches.	Submitted
	Record of comparative dissolution data (where applicable)	CDP against reference brand Panadol Extend by GSK submitted
	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	submitted

Remarks of Evaluator:

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

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

- **For adults, the highest recommended dose of Paracetamol Extend Tablet 665mg 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).**
- **Paracetamol Extend Tablet 665mg should not be used as an alternative to Panadol/ Paracetamol Tablet 500mg without prior consultation with Physician/ Pharmacist."**
- **Above-mentioned conditions will also be included in advertisement of the product and for this purpose, recommendation will be forwarded to Pharmacy Services Division, DRAP.**
- **To ensure compliance with the above-mentioned conditions, the applicant will be advised to conduct training programmes for the health care providers and submit biannual compliance reports to PE&R Division subsequent to issuance of registration.**

511.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore

	Brand Name + Dosage Form + Strength	**Glipan 25mg/5mg Tablet**
	Composition	Each tablet contains: Empagliflozin…...25mg Linagliptin……5mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 11340 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	7's, 10's; 14's; 28's; 30's, 60's, 70's, 90's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GLYXAMBI (empagliflozin; linagliptin) (10mg/5mg, 25mg/5mg) film coated tablet USFDA Approved
	Me-too status	N/A
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Deferred in 307th meeting to Submit stability studies data of three batches as per the guidelines approved in 293rd meeting of Registration Board

STABILITY STUDY DATA

Drug	**Glipan 25mg/5mg Tablet**		
Manufacturer of API	**Empagliflozin**: FUXIN LONG RUI PHARMACEUTICAL CO., LTD, FLUORIDE INDUSTRIAL PARK, FUMENG COUNTY (YI MA TU), FUXIN CITY, LIAONING PROVINCE-123000, CHINA	**Linagliptin**: FUXIN LONG RUI PHARMACEUTICAL CO., LTD, FLUORIDE INDUSTRIAL PARK, FUMENG COUNTY (YI MA TU), FUXIN CITY, LIAONING PROVINCE-123000, CHINA	
API Lot No.	E-20190310-D01-E06-03	L-20190305-D01-L09-01	
Description of Pack (Container closure system)	ALU-ALU blisters packed in unit carton.		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18 (Months)		
Batch No.	ELB_t T2-21	ELB_t T3-21	ELB_t T4-21
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	03-04-2021	03-04-2021	03-04-2021
No. of Batches	03		
Date of Submission	19-01-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Details**
1	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 in which our product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule" through onsite panel inspection (Supplementary Agenda) of stability study data of the firm
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**DML no. LIAO 20150233 valid till 20/12/2022, GMP not provided**
6	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: HN191015-01, 14435/2019-DRAP dated 08-11-2019
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	N/A
10	Complete batch manufacturing record of three stability batches.	Submitted
11	Record of comparative dissolution data (where applicable)	CDP against reference brand Glyxambi submitted
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 batches ELB_t T2-21, ELB_t T3-21, ELB_t T4-21 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:		
Decision: Approved with Innovator specifications. **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024 and submission of valid copy of GMP certificate of the drug substance manufacturer (Fuxin long Rui pharmaceutical co., ltd) issued by relevant/concerned regulatory authority.**		

512.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	**Rascod Sachet 10mg**

	Composition	Each sachet contains: Racecadotril…...10mg
	Diary No. Date of R & I & fee	No record available
	Pharmacological Group	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Hidrasec® 10mg by France Approved.
	Me-too status	"Hidrasec® 10mg" Sachet by M/s Abbott Laboratories Reg# 087082
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Firm has withdrawn application to apply on CTD
Decision: Registration Board acceded the request of the firm and decided to reject the application.		

513.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Neutrol 75mg tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 11341 dated 05-03-2019 Rs.50,000/- 4-3-2019
	Pharmacological Group	Opioid analgesic
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's and 100's, As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA (50mg, 75mg, 100mg) film coated tablets USFDA Approved
	Me-too status	Nutadol 75mg Tablets Crystolite Pharmaceuticals (Reg#097680)
	GMP status	Certificate of GMP issued to Neutro Pharma on 11.07.2019 based on inspection conducted on 28.02.2019
	Remarks of the Evaluator	Deferred for submission of stability study data in 308th meeting as per the guidelines approved in 293rd meeting of Registration Board

STABILITY STUDY DATA	
Drug	Neutrol 75mg tablet
Manufacturer of API	AMI life sciences PVT ltd., block no.82/B ECP road,, AT & post, KRAKHADI TAL-PARDA
API Lot No.	TPT/50090719
Description of Pack (Container closure system)	150mm Alu-PVC foil and packed on bleach board unit carton
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH

	Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6, 9,12,18,24 (Months)		
Batch No.	TPA_t T1-21	TPA_t T2-21	TPA_t T3-21
Batch Size	2000 TABLETS	2000 TABLETS	2000 TABLETS
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	19-07-2021	19-07-2021	19-07-2021
No. of Batches	03		
Date of Submission	Dy. No. 10866 dated 29-04-2022.		

8DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule"
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA of API submitted from API Manufacturer TPT/50090719 COA of API submitted from Finished Product Manufacturer TPT/50090719
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	Submitted
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP submitted valid until: 04-03-2023
6	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: EXP/I/19-20/0523 dated: 09/01/2020 AD ref No 1036/2020-DRAP dated 16-01-20
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	As per innovator
10	Complete batch manufacturing record of three stability batches.	Submitted
11	Record of comparative dissolution data (where applicable)	CDP studies with Tapento IR75mg Tablet B.No 004G in 3 mediums

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:		
Decision: Approved with Innovator specifications. **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024 and submission of valid copy of GMP certificate of the drug substance manufacturer (AMI life sciences PVT ltd.,) issued by relevant/concerned regulatory authority.**		

514.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	**Neutolve 15mg**
	Composition	Each tablet Contains: Tolvaptan 15mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 11343 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Vasopressin Antagonist
	Type of Form	Form-5D
	Finished product Specification	Manufacturer'Specification
	Pack size & Demanded Price	10's, 20's & 30's / As per SRO
	Approval status of product in Reference Regulatory Authorities	JYNARQUE (15mg, 30mg, 45mg, 60mg, 90mg) tablets USFDA approved
	Me-too status	
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Deferred in 307th meeting to submit stability studies data of three batches as per the guidelines approved in 293rd meeting of Registration Board

STABILITY STUDY DATA	
Drug	**Neutolve 15mg**
Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd.
API Lot No.	To191001
Description of Pack (Container closure system)	Each ALU/PVC blister of 10 Tablets packed in a unit carton.
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6, 9,12,18,24 (Months)

Batch No.	TOA_t T1-21	TOA_t T2-21	TOA_t T3-21
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	24-07-2021	24-07-2021	24-07-2021
No. of Batches	03		
Date of Submission	17-06-2022		

8DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
15.	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 in which our product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule" through onsite panel inspection (Supplementary Agenda) of stability study data of the firm
16. s	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
17.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted
18.	Stability study data of API from API manufacturer	Submitted
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP no. 22063346 valid until 29/05/2025**
20.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: KSDS201911215 16179/2019-DRAP dated 10-12-19
21.	Protocols followed for conduction of stability study	Submitted
22.	Method used for analysis of FPP	Submitted
23.	Drug-excipients compatibility studies (where applicable)	N/A
24.	Complete batch manufacturing record of three stability batches.	Submitted
25.	Record of comparative dissolution data (where applicable)	CDP against reference brand Samsca Tablet submitted
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
	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 specifications.

Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.		
515.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt.) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	**Neutolve 30mg**
	Composition	Each tablet Contains: Tolvaptan 30mg
	Diary No. Date of R & I & fee	Form-5D Dy.No 11344 dated 05-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Vasopressin Antagonist
	Type of Form	Form-5D
	Finished product Specification	Manufacturer'Specification
	Pack size & Demanded Price	10's, 20's & 30's / As per SRO
	Approval status of product in Reference Regulatory Authorities	JYNARQUE (15mg, 30mg, 45mg, 60mg, 90mg) tablets USFDA approved
	Me-too status	
	GMP status	Valid until 14-04-2025
	Remarks of the Evaluator	Deferred in 307th meeting to submit stability studies data of three batches as per the guidelines approved in 293rd meeting of Registration Board

STABILITY STUDY DATA			
Drug	**Neutolve 30mg**		
Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd.		
API Lot No.	To191001		
Description of Pack (Container closure system)	Each ALU/PVC blister of 10 Tablets packed in a unit carton.		
Stability Storage Condition	Accelerated Condition 40°C±2°C, 75% ±5 %RH Long term conditions (Real time) 30°C ± 2°C, 65% ±5 %RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6, 9,12,18,24 (Months)		
Batch No.	TOA_t T1-21	TOA_t T2-21	TOA_t T3-21
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	24-07-2021	24-07-2021	24-07-2021
No. of Batches	03		
Date of Submission	17-06-2022		

8DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Details**

1	Reference of previous approval of applications with stability study data of the firm.	Refer to the 297th meeting of the registration board held on 12-01-2021 in which our product was approved namely "Dexzol (Dexlansoprazole) 30mg & 60mg Capsule" through onsite panel inspection (Supplementary Agenda) of stability study data of the firm
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP no. 22063346 valid until 29/05/2025**
6	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no: KSDS201911215 16179/2019-DRAP dated 10-12-19
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	N/A
10	Complete batch manufacturing record of three stability batches.	Submitted
11	Record of comparative dissolution data (where applicable)	CDP against reference brand Samsca Tablet submitted
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved with Innovator specifications. **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**		

516.	Name and address of manufacturer / Applicant	M/s Pharmasol Pvt. Ltd Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Canazin 100mg Tablet.
	Composition	"Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…100mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40653 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018

	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of Form	Form 5.
.	Finished product Specifications	Inhouse Specs. Specifications.
	Pack size & Demanded Price	7"s,14"s,28"s, As per sro.
	Approval status of product in Reference Regulator Authorities	INVOKANA (canagliflozin) tablets USFDA Approved with box warning.
	Me-too status	
	GMP status	
	Remarks of the Evaluator	Deferred in M.295 for submission for stability studies

STABILITY STUDY DATA

Drug	Canazin 100mg Tablet.		
Manufacturer of API	M/s Huainan shunglong Pharmaceutical Co., Ltd., Huainan city, China.		
API Lot No.	CF20201216		
Description of Pack (Container closure system)	White colour circular biconvex tablets with REKO and break line on one face, blistered in transparent PVC having AL 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, 1,2,3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RND22172	RND22173	RND22174
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	15-10.2022	15-10.2022	15-10.2022
No. of Batches	03		
Date of Submission	Dy. No. 39312 dated 29-05-2023.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA of API submitted from API Manufacturer COA of API submitted from Finished Product Manufacturer
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	Submitted.
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin valid till 28-sep-23
6	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no CF20201216 Ref no 223/2021-Drap dated 05.01.2021
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted assay by UV
9	Drug-excipients compatibility studies (where applicable)	SAME EXCIPIENTS AS INNOVATOR
10	Complete batch manufacturing record of three stability batches.	submitted.
11	Record of comparative dissolution data (where applicable)	comparative dissolution data WITH INNOVATOR Invokana b.no 1963539075 mfg date 05-20
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 stability data sheets for three batches. Respective documents like, Raw data sheets, COA, summary data sheets etc. are submitted by the firm. Method for quantitative analysis is by UV for finish product and API method is by HPLC
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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
11.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
12.	Method used for analysis of Finished Product Assay is being performed through UV however API quantitative assay is performed through HPLC. Justification shall be submitted for not performing HPLC method of analysis which is more reliable.	
13.	GMP certificate of API manufacturer and finish product manufacturer is required.	
14.		

Decision: Registration Board, after thorough deliberation and considering the fact that the firm has applied UV spectrophotometric method for Assay test of Drug product although the HPLC method is available for the drug substance analysis hence Board, decided to reject the instant case.

517.	Name and address of manufacturer / Applicant	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Dezole 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole Release Pellets Of Dexlansoprazole Eq To Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4113 dated 30-01-2019 Rs.20,000/- dated 30-01-2019. (As per Excel sheet of PEC). Dossier of Form 5 not available.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not submitted
	Pack size & Demanded Price	Not submitted
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dextol 30mg DDR Capsule, Seraph Pharmaceutical.
	GMP status	Not submitted.
	Remarks of the Evaluator	Not Considered Yet

STABILITY STUDY DATA

Drug	Dezole 30mg Capsules		
Manufacturer of API	Not submitted		
API Lot No.	Not submitted		
Description of Pack (Container closure system)	10’s, 20’s & 30’s tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	T001	STB-T002	STB-T003
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	21-05.2021	21-05.2021	21-05.2021
No. of Batches	03		

Date of Submission	Dy. No. 14285 dated 13-06-2022.

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has not submitted Copy of COA of the drug substance (Dexlansoprazole DDR pellets) from M/s API Manufacturer Firm has also submitted COA of the drug substance with batch number DLP755 and manufacturing date May-21. (**Specification's In-house)**
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 not submitted and Finished Product Manufacturer Analytical procedures provided by the firm.
4	Stability study data of API from API manufacturer	Not submitted
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7	Protocols followed for conduction of stability study	Submitted.
8	Method used for analysis of FPP	Submitted.
9	Drug-excipients compatibility studies (where applicable)	Not submitted
10	Complete batch manufacturing record of three stability batches.	Not submitted
11	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dezole 30mg (Dexlansoprazole) capsule against dexilant capsule 30mg, in Acid media (0.1N HCl), acetate buffer pH 5.5 & Phosphate Buffer pH 7.0. 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.	Not Submitted
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from API Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	

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

518.	Name and address of manufacturer / Applicant	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Dezole 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole Release Pellets Of Dexlansoprazole Eq To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4113 dated 30-01-2019 Rs.20,000/- dated 30-01-2019. (As per Excel sheet of PEC). Dossier of Form 5 not available.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in	**DEXILANT** ® Capsule, USFDA approved.

	Reference Regulator Authorities			
	Me-too status	Dextol 60mg DDR Capsule, Seraph Pharmaceutical		
	GMP status			
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		Dezole 60mg Capsules		
Manufacturer of API		Not provided		
API Lot No.				
Description of Pack (Container closure system)		10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition		Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period		Real time: 09 months Accelerated: 06 months		
Frequency		Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.		T001	STB-T002	STB-T003
Batch Size		1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date		05-2021	05-2021	05-2021
Date of Initiation		21-05.2021	21-05.2021	21-05.2021
No. of Batches		03		
Date of Submission		Dy. No. 14286 dated 13-06-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	**Documents to Be Provided**	**Status**		
1	Reference of previous approval of applications with stability study data of the firm.	Not submitted		
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has not submitted Copy of COA of the drug substance (Dexlansoprazole DDR pellets) from M/s API Manufacturer Firm has also submitted COA of the drug substance with batch number DLP755 and manufacturing date May-21. (**Specification's In-house)**		
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 not provided and Finished Product Manufacturer analytical procedures provided by the firm.		
4	Stability study data of API from API manufacturer	Not submitted		
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		

6	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
7	Protocols followed for conduction of stability study	Submitted.
8	Method used for analysis of FPP	Submitted.
9	Drug-excipients compatibility studies (where applicable)	Not submitted
10	Complete batch manufacturing record of three stability batches.	Not submitted
11	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dezole 30mg (Dexlansoprazole) capsule against dexilant capsule 30mg, in Acid media (0.1N HCl), acetate buffer pH 5.5 & Phosphate Buffer pH 7.0. 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.	Not Submitted
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
15.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
16.	Certificate of Analysis of the drug substances from respective drug substance manufacturer shall be submitted.	
17.	Method used for analysis of drug substance/API from API Manufacturer shall be submitted.	
18.	Stability study data of API from both API manufacturer shall be submitted.	
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
20.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
21.	Drug-excipients compatibility studies (where applicable) shall be submitted.	

22.	Complete batch manufacturing record of three stability batches shall be submitted..	
23.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
24.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
25.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	

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

519.	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dexoloc 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Pellets Enteric Coated 22.5%…30mg.
	Diary No. Date of R& I & fee	Form-5 Dy.No 12874 dated 06-03-2019 Rs.20,000/- dated 05-03-2019. (As per Excel sheet of PEC). Dossier of Form 5 not available.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dextol 30mg DDR Capsule, Seraph Pharmaceutical.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dexoloc 30mg Capsule		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack. Off white color spherical shaped pallets filled in green and white hard gelatin shell		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	Trail-1	TGM-008	TGM-009
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets

Manufacturing Date	11-2021	01-2022	01-2022
Date of Initiation	01-12.2021	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39312 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	

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

520.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma (Pvt.) Ltd, Sheikhupura
	Brand Name +Dosage Form + Strength	Dexomir-60mg Capsule
	Composition	Each capsule contains: Dexlansprazole pellets 17%……60mg
.	Diary No. Date of R& I & fee	16867, 07-05-2018, 20,000/-, 27-04-2018
	Pharmacological Group	Proton pump inhibitor ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	In-house
	Pack size & Demanded Price	10’s (3’s) / Rs. 696.00
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule of Getz
	GMP status	Not submitted.

	Remarks of the Evaluator	Deferred in 283 meeting of RB for Stability study data as per 278th meeting of Registration Board are required to be submitted for applied formulation.

STABILITY STUDY DATA			
Drug	Dexomir-60mg Capsule		
Manufacturer of API	Source of pellets: M/s. Vision Pharma.		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)			
Stability Storage Condition			
Time Period			
Frequency			
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
6.	Protocols followed for conduction of stability study shall be submitted.	
7.	Method used for analysis of Finished Product shall be submitted.	
8.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
9.	Complete batch manufacturing record of three stability batches shall be submitted..	
10.	Record of comparative dissolution data shall be submitted.	
11.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

521.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma (Pvt.) Ltd, Sheikhupura
	Brand Name +Dosage Form + Strength	Dexomir-30mg Capsule
	Composition	Each capsule contains: Dexlansprazole pellets 17%……30mg
.	Diary No. Date of R& I & fee	16866, 07-05-2018, 20,000/-, 27-04-2018
	Pharmacological Group	Proton pump inhibitor ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	In-house
	Pack size & Demanded Price	10's (3's) / Rs. 696.00
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule of Getz
	GMP status	Not submitted.
	Remarks of the Evaluator	Deferred in 283 meeting of RB for Stability study data as per 278th meeting of Registration Board are required to be submitted for applied formulation.

STABILITY STUDY DATA

Drug	Dexomir-30mg Capsule		
Manufacturer of API	Source of pellets: M/s. Vision Pharma.		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)			
Stability Storage Condition			
Time Period			
Frequency			
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	

4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
6.	Protocols followed for conduction of stability study shall be submitted.	
7.	Method used for analysis of Finished Product shall be submitted.	
8.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
9.	Complete batch manufacturing record of three stability batches shall be submitted..	
10.	Record of comparative dissolution data shall be submitted.	
11.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

522.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Dexlanso 30mg Capsule
	Composition	Each capsule contains: Dexlansprazole pellets ……30mg
.	Diary No. Date of R& I & fee	No record available
	Pharmacological Group	Proton pump inhibitor ATC Code: A02BC06.
	Type of Form	Form 5.
	Finished product Specifications	In-house
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule of Getz
	GMP status	Not submitted.
	Remarks of the Evaluator	Not available in main list

STABILITY STUDY DATA

Drug	Dexomir-30mg Capsule
Manufacturer of API	
API Lot No.	**Not submitted**
Description of Pack (Container closure system)	
Stability Storage Condition	
Time Period	

Frequency			
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Stability data sheets provided only

13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches will be 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 shall be submitted.	

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

523.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Dexlanso 60mg Capsule
	Composition	Each capsule contains: Dexlansprazole pellets ……60mg
.	Diary No. Date of R& I & fee	No record available
	Pharmacological Group	Proton pump inhibitor ATC Code: A02BC06.
	Type of Form	Form 5.
	Finished product Specifications	In-house
	Pack size & Demanded Price	
	Approval status of product in	**DEXILANT** ® Capsule, USFDA approved.

	Reference Regulator Authorities	
	Me-too status	Razodex 60mg capsule of Getz
	GMP status	Not submitted.
	Remarks of the Evaluator	Not available in main list

STABILITY STUDY DATA			
Drug	Dexlanso-60mg Capsule		
Manufacturer of API			
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)			
Stability Storage Condition			
Time Period			
Frequency			
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Stability data sheets provided only
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches will be 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 shall be submitted.	

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

524.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals.Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lansodex 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Ddr Pellets Eq. To Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8284 dated 06-03-2018 Rs.20,000/- dated 06-03-2018. (As per Excel sheet of PEC). Dossier of Form 5 not available.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dextol 30mg DDR Capsule, Seraph Pharmaceutical.
	GMP status	Not submitted.
	Remarks of the Evaluator	Brand name resemblance with Lansodex of Getz.

STABILITY STUDY DATA			
Drug	Lansodex 30mg Capsule		
Manufacturer of API	M/s Vision Pharmaceutical (Pvt.) Ltd plot # 22-23, Industrial triangle, Kahuta Road, Islamabad.		
API Lot No.	(DLP-443).		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	DXL-T001	DXL-T002	DXL-T003
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	26-12.2019	27-12.2019	27-12.2019
No. of Batches	03		
Date of Submission	Dy. No. 13052 dated 28-05-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm.</td><td>Not submitted</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Firm has submitted Copy of COA (Batch No. DLP-443 Mfg. date 21-02-2019) of the drug substance (Dexlansoprazole DDR pellets 17%) from M/s Vision Pharmaceutical Pvt, Ltd. Pakistan. Specification's In-house
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>Not submitted</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>Not submitted</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>M/s Vision Pharmaceutical local purchase</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 submitted</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>DXL-T001</td><td>1200 Capsule</td><td>26-12-2019</td></tr>
<tr><td>DXL-T002</td><td>1200 Capsule</td><td>27-12-2019</td></tr>
<tr><td>DXL-T003</td><td>1200 Capsule</td><td>28-12-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted comparative dissolution of their applied formulation i.e. Lansodex 30mg (Dexlansoprazole) 30mg capsule against dexiva capsule 30mg,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>Not Submitted</td></tr>
</table>

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of the drug substances from respective drug Product manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

Decision: Approved with innovator specification's. Registration Board further decided that the registration letter will be issued after submission of following.

- **Submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Certificate of Analysis of the drug substances from respective drug Product manufacturer shall be submitted.**
- **Stability study data of API from both API manufacturers shall be submitted.**
- **Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.**

525.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals.Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lansodex 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Ddr Pellets Eq. To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8285 dated 06-03-2018 Rs.20,000/- dated 06-03-2018. (As per Excel sheet of PEC). Dossier of Form 5 not available.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dextol 60mg DDR Capsule, Seraph Pharmaceutical.
	GMP status	Not submitted.

	Remarks of the Evaluator	Brand name resemblance with Lansodex of Getz.	
STABILITY STUDY DATA			
Drug	Lansodex 60mg Capsule		
Manufacturer of API	M/s Vision Pharmaceutical (Pvt.) Ltd plot # 22-23, Industrial triangle, Kahuta Road, Islamabad.		
API Lot No.	(DLP-443).		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	DXL-T001	DXL-T002	DXL-T003
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	26-12.2019	27-12.2019	27-12.2019
No. of Batches	03		
Date of Submission	Dy. No. 13053 dated 28-05-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	**Documents to Be Provided**	**Status**	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. DLP-443 Mfg. date 21-02-2019) of the drug substance (Dexlansoprazole DDR pellets 17%) from M/s Vision Pharmaceutical Pvt, Ltd. Pakistan. **Specification's In-house** 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	Not submitted	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	M/s Vision Pharmaceutical local purchase	

<table>
<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 submitted</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>DXL-T001</td><td>1200 Capsule</td><td>26-12-2019</td></tr>
<tr><td>DXL-T002</td><td>1200 Capsule</td><td>27-12-2019</td></tr>
<tr><td>DXL-T003</td><td>1200 Capsule</td><td>28-12-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted comparative dissolution of their applied formulation i.e. Lansodex 60mg (Dexlansoprazole) 60mg capsule against dexiva capsule 60mg, 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>Not 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>Not Submitted</td></tr>
</table>

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	

10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
15.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

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

526.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Emplina 10/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin…10mg Linagliptin…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 39668 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs.
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	GLYXAMBI (USFDA Approved)
	Me-too status	
	GMP status	Not submitted.
	Remarks of the Evaluator	Decision 296th meeting: Deferred for following: Submission of application on Form-5D alongwith applicable fee. Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Emplina 10/5mg Tablets.
Manufacturer of API	
API Lot No.	
Description of Pack (Container closure system)	
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.	TEM-055	TEM-056	TEM-056
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	06-01.2022	06-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39308 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms,

	chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

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

527.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Emplina 25/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin…25mg Linagliptin…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 39669 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs.
	Type of Form	Form 5.

	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	GLYXAMBI (USFDA Approved)
	Me-too status	
	GMP status	Not submitted.
	Remarks of the Evaluator	Decision 296th meeting: Deferred for following: Submission of application on Form-5D alongwith applicable fee. Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Emplina 25/5mg Tablets.		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
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.	TEM-055	TEM-056	TEM-056
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	06-01.2022	06-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39309 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	

9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

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

528.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals(Pvt.)Ltd., 28km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	EMPILIG Tablet 10mg/5mg
	Composition	Empagliflozin……10mg Linagliptin……5mg
	Diary No. Date of R& I & fee	Dy. No.0000 dated 06,July 2022
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
.	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's 20's,28's,30's
	Approval status of product in Reference Regulator Authorities	**Glyxambi Tablet 10-5mg**
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	EMPILIG Tablet 10mg/5mg		
Manufacturer of API	**Empagliflozin** Jiangsu Yongan Pharmaceutical Co., Limited, No.18, 237 Provincial road economic development zone ,Huaian,Jiangsu china **Linagliptin** Shandong Fangming Pharmaceutical Group**,** Fangming section, huanghe road, dongming country Shandong province china		
API Lot No.	Empagliflozin……4500-202106001 Linagliptin…….2021032001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton/bottle		
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.	RD/PR21104/T1/S1	RD/PR21104/T1/S2	RD/PR21104/T1/S3
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets

Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	06-12.2021	06-12.2021	06-12.2021
No. of Batches	03		
Date of Submission	Dy. No. 19729 dated 06-07-2022.		

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.	Submitted. Stability data submitted by the firm for registration of Dasvir Tablets (Declatasvir as Dihydrochloride 60mg & 90mg) in 277th meeting
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Empagliflozin**: COA of API submitted from API Manufacturer& Finished Product Manufacturer **Linagliptin:** COA of API submitted from API Manufacturer& Finished Product Manufacturer
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	Submitted for Linagliptin . Empagliflozin not provided
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Linagliptin** :GMP certificate of API manufacturer M/s Shandong fangming pharmaceutical issued by concerned regulatory authority of country of origin valid till 17-07-24
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin**: Invoice No. **ZY21080201G/W** dated **05/08/2021**, import of **1.05Kg** (Batch No. 4500-202106001). AD attested ref no 10720 dated 16-07-21 **Linagliptin:** The firm has submitted copy of invoice No. **WEIBIN-093** dated **09-08-2021**, for import of **250g** (Batch No. 2021032001). AD attested ref no 11873/21 dated 09-08-21
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	submitted.
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against **Glyxambi Tablet 10-5mg** in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)

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 stability data sheets for three batches. Respective documents like, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
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.	GMP certificate of API manufacturer & finished product manufacturer issued by concerned regulatory authority of country of origin	Firm has submitted Letter Ref No. NMP/DRAP/EM01/2024 dated 26-12-24, and provided GMP certificate of API manufacturer Jiangsu yougan pharmaceutical co. ltd valid till 06-12-25 & finished product manufacturer valid till 07-11-25 issued by concerned regulatory authority of country of origin
2.	Stability study data of API from API manufacturer of Empagliflozin not provided	Submitted

Decision: Approved with Innovator Specification's.Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

529.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals(Pvt.)Ltd., 28km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	EMPILIG Tablet 25mg/5mg
	Composition	Empagliflozin……25mg Linagliptin……5mg
	Diary No. Date of R& I & fee	Dy. No.0000 dated 06,July 2022
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5D
.	Finished product Specifications	In-House
	Pack size & Demanded Price	10's, 14's 20's,28's,30's
	Approval status of product in Reference Regulator Authorities	**Glyxambi Tablet 25-5mg**
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	EMPILIG Tablet 25mg/5mg
Manufacturer of API	**Empagliflozin** Jiangsu Yongan Pharmaceutical Co., Limited, No.18, 237 Provincial road economic development zone ,Huaian,Jiangsu china

	Linagliptin Shandong Fangming Pharmaceutical Group**,** Fangming section, huanghe road, dongming country Shandong province china		
API Lot No.	Empagliflozin……4500-202106001 Linagliptin…….2021032001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton/bottle		
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.	RD/PR21104/T1/S1	RD/PR21104/T1/S2	RD/PR21104/T1/S3
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	06-12.2021	06-12.2021	06-12.2021
No. of Batches	03		
Date of Submission	Dy. No. 19730 dated 06-07-2022.		

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.	Submitted. Stability data submitted by the firm for registration of Dasvir Tablets (Declatasvir as Dihydrochloride 60mg & 90mg) in 277th meeting
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Empagliflozin**: COA of API submitted from API Manufacturer& Finished Product Manufacturer **Linagliptin:** COA of API submitted from API Manufacturer& Finished Product Manufacturer
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	Submitted for Linagliptin . Empagliflozin not provided
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Linagliptin** :GMP certificate of API manufacturer M/s Shandong fangming pharmaceutical issued by concerned regulatory authority of country of origin valid till 17-07-24
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin**: Invoice No. **ZY21080201G/W** dated **05/08/2021**, import of **1.05Kg** (Batch No. 4500-202106001). AD attested ref no 10720 dated 16-07-21 **Linagliptin:** The firm has submitted copy of invoice No. **WEIBIN-093** dated **09-08-2021**, for import of **250g** (Batch No. 2021032001). AD attested ref no 11873/21 dated 09-08-21

7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	submitted.
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against **Glyxambi Tablet 10-5mg** in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
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 stability data sheets for three batches. Respective documents like, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
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.	GMP certificate of API manufacturer & finished product manufacturer issued by concerned regulatory authority of country of origin	Firm has submitted Letter Ref No. NMP/DRAP/EM01/2024 dated 26-12-24, and provided GMP certificate of API manufacturer Jiangsu yougan pharmaceutical co. ltd valid till 06-12-25 & finished product manufacturer valid till 07-11-25 issued by concerned regulatory authority of country of origin
2.	Stability study data of API from API manufacturer of Empagliflozin not provided	Submitted

Decision: Approved with Innovator Specification's.

Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

530.	Name and address of manufacturer/ Applicant	High-Q Pharmaceuticals, Plot No. 224 & 225/1, sector 23, Korangi industrial area, Karachi.
	Brand Name + Dosage Form + Strength	Empaglin 10+5mg Tablet

	Composition	Each tablet contains; Empagliflozin……10mg Linagliptin……..5mg
	Diary No. Date of R & I & fee	
	Pharmacological Group	Anti-diabetic (Type 2 diabetes)
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specifications (MS)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Glyxambi 10/5mg Tablet- Boehringer ingelheim
	Me-too status	Linjardy 10/5mg Tablet-CCL Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Empaglin (Empagliflozin 10mg+ Linagliptin 5mg) Tablet		
Manufacturer of API	Empagliflozin: Fuxin Long Rui Pharmaceutical Co., Ltd Linagliptin: Venkata Narayana Active Ingredients Private Limited, India.		
API Lot No.	Empagliflozin: H-E-20210125-D04-E06-01 Linagliptin: LG0011118		
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	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	1ELPD01/21	1ELPD02/21	1ELPD03/21
Batch Size	6666 Tablets	6666 Tablets	6666 Tablets
Manufacturing Date	Dec 2021	Dec 2021	Dec 2021
Date of Initiation	10-04-2022	10-04-2022	10-04-2022
No. of Batches	03		
Date of Submission	26-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th Meeting.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA B.No 00111188 linagliptin & B.No E06-01 for empagliflozin 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	**Empagliflozin:** Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer **Linagliptin:** 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	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B 40/75- conditions for 6 months. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions for 24 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Drug Manufacturing License No.LIAO20150233 valid till 17-01-2027, Written confirmation for active substances exported to EU (LN240010) valid till 17-04-2027, 25-05-24 is submitted by the firm. **Linagliptin:**Drug Manufacturing license No. 04/NL/AP/2008/B/R Valid till 17-01-2028. GMP certificate valid till 12-01-2025, 28-10-24.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice no. HN200326-2-D cleared dated 16-04-2021 specifying 30Kg. The invoice is cleared by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial invoice no. DXP181930228 cleared dated 07-12-2018 specifying 5Kg. 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 submitted drug excipient compatibility studies
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 Glyxambi 10/5mg Tablet. Batch No 104320 1ELPD01/21 Comparative dissolution studies have been performed in following mediums: 0.1N HCl pH 1.2, Acetate buffer pH 4.5,Phosphate buffer pH 6.8
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.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved with Innovator Specification's. **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**		

531.	Name and address of manufacturer/ Applicant	High-Q Pharmaceuticals, Plot No. 224 & 225/1, sector 23, Korangi industrial area, Karachi.
	Brand Name + Dosage Form + Strength	Empaglin 25+5mg Tablet
	Composition	Each tablet contains; Empagliflozin……25mg Linagliptin……..5mg
	Diary No. Date of R & I & fee	
	Pharmacological Group	Anti-diabetic (Type 2 diabetes)
	Type of Form	Form 5-D
	Finished product Specification	Manufacturer's Specifications (MS)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Glyxambi 25/5mg Tablet- Boehringer ingelheim
	Me-too status	Linjardy 25/5mg Tablet-CCL Pharmaceuticals
	GMP status	

	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Empaglin 25+5mg Tablet		
Manufacturer of API	Empagliflozin: Fuxin Long Rui Pharmaceutical Co., Ltd Linagliptin: Venkata Narayana Active Ingredients Private Limited, India.		
API Lot No.	Empagliflozin: H-E-20210125-D04-E06-01 Linagliptin: LG0011118		
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	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	1ELPD01/21	1ELPD02/21	1ELPD03/21
Batch Size	6666 Tablets	6666 Tablets	6666 Tablets
Manufacturing Date	Dec 2021	Dec 2021	Dec 2021
Date of Initiation	10-04-2022	10-04-2022	10-04-2022
No. of Batches	03		
Date of Submission	26-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Registration Board approved Vesoft 400mg/100mg Tablets in its 284th Meeting.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA B.No 00111188 linagliptin & B.No E06-01 for empagliflozin 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	**Empagliflozin:** Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer **Linagliptin:** 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	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B 40/75- conditions for 6 months. **Linagliptin:** Firm has submitted stability study data of 3 batches of drug substance as per zone IV-B conditions for 24 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Drug Manufacturing License No.LIAO20150233 valid till 17-01-2027, Written confirmation for active substances exported to EU (LN240010) valid till 17-04-2027, 25-05-24 is submitted by the firm. **Linagliptin:**Drug Manufacturing license No. 04/NL/AP/2008/B/R Valid till 17-01-2028. GMP certificate valid till 12-01-2025, 28-10-24.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice no. HN200326-2-D cleared dated 16-04-2021 specifying 30Kg. The invoice is cleared by AD (I&E) DRAP. **Linagliptin:** Firm has submitted copy of commercial invoice no. DXP181930228 cleared dated 07-12-2018 specifying 5Kg. 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 submitted drug excipient compatibility studies
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 Glyxambi 10/5mg Tablet. Batch No | 104320 | 1ELPD01/21

		Comparative dissolution studies have been performed in following mediums: 0.1N HCl pH 1.2, Acetate buffer pH 4.5,Phosphate buffer pH 6.8
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.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved with Innovator Specification's.
Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

532.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Letrum 5mg Tablet
	Composition	Each film coated tablet contains: Linagliptin….5mg
	Diary No. Date of R& I & fee	Dy. No.1221 dated 07-07-2014 Rs. 50,000/- dated 07-07-2014
	Pharmacological Group	Dipeptidyl peptidase-4 (DPP-4) inhibitors
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Trajenta (Linagliptin) 5mg Tablets (USFDA Approved)
	Me-too status	Linvesta 5mg Tablet, Wilshire Laboratories (Private) Limited
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Letrum 5mg Tablet
Manufacturer of API	**M/s Venkata Naryana Active ingredients Pvt Ltd.**
API Lot No.	LG0011118
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%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	5LTPD01/21	5LTPD02/21	5LTPD03/21
Batch Size	5555 Tablets	5555 Tablets	5555 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	27-05.2021	27-05.2021	27-05.2021
No. of Batches	03		
Date of Submission	Dy. No. 3724 dated 09-02-2022.		

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.	Submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided B.No LG0011118 Certificate of Analysis of API from Finished Product manufacturer. Provided B.No LG0011118
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	Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer ref.no DCANLR-MFG0BD/6/2021-D12-DCANLR valid till 17-01-23.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	AD clearance Invoice no DXP181930228 dated 30-nov-18
7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	submitted.
9.	Drug-excipients compatibility studies (where applicable)	submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.

11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP studies with Trajenta 5mg tablet manufactured by B.No AB1289A
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 stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	DML of M/s Venkata Naryana Active ingredients Pvt Ltd. Valid till 17-01-28, GMP certificate valid till 12-01-24.
2.	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Submitted

Decision: Approved with Innovator Specification's.

Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

533.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals (Pvt.) Limited, 27-km, Raiwind Road, Lahore (Capsule General, Antibiotics, non-antibiotics, Cephalosporin).**
	Brand Name+ Dosage Form+ Strength	Y Nil Capsules 120mg
	Composition	Each Capsule Contains: Orlistat…120mg
	Diary No. Date of R & I & fee	Dy.No 8437 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Peripherally acting anti-obesity products
	Type of Form.	Form-5.
	Finished product Specification.	Mfg specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA approved.
	Me-too status.	Vetnor 120mg Capsule of Amarant Pharmaceuticals

	GMP status.	Panel inspection conducted on 09-07-2018 Recommended issuance of GMP.
	Remarks of Evaluator.	Submit of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision of 297th meeting of registration board	Deferred for following: Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.
	Reply submitted by the Firm	Firm has submitted Source of pellets from M/s Surge Laboratories, COA of pallets from drug substance manufacturer
	Remarks of Evaluator.	• GMP certificate of drug substance manufacturers required • Stability studies data of 3 batches from drug substance manufacturer required.
Decision: Approved with innovator specification's. Registration board further decided that the registration letter will be issued after submission of following. • **Submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.** • **GMP certificate of drug substance manufacturers required** • **Stability studies data of 3 batches from drug substance manufacturer**		
534.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals (Pvt.) Limited, 27-km, Raiwind Road, Lahore (Capsule General, Antibiotics, non-antibiotics, Cephalosporin).**
	Brand Name+ Dosage Form+ Strength	Y Nil Capsules 60mg
	Composition	Each Capsule Contains: Orlistat…60mg
	Diary No. Date of R & I & fee	Dy.No 8438 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Peripherally acting anti-obesity products
	Type of Form.	Form-5.
	Finished product Specification.	Mfg specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA approved.
	Me-too status.	Slimfit 60mg Capsule of Amarant Pharmaceuticals
	GMP status.	Panel inspection conducted on 09-07-2018 Recommended issuance of GMP.

	Remarks of Evaluator.	Submit of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision of 297th meeting of registration board	Deferred for following: Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.
	Reply submitted by the Firm	Firm has submitted Source of pellets from M/s Surge Laboratories, COA of pallets from drug substance manufacturer
	Remarks of Evaluator.	• GMP certificate of drug substance manufacturer is required • Stability studies data of 3 batches from drug substance manufacturer required.
	Decision:	
Decision: Approved with innovator specification's. Registration board further decided that the registration letter will be issued after submission of following. • **Submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.** • **GMP certificate of drug substance manufacturers required** • **Stability studies data of 3 batches from drug substance manufacturer required.**		
535.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals (Pvt.) Limited, 27-km, Raiwind Road, Lahore (Capsule General, Antibiotics, non-antibiotics, Cephalosporin).**
	Brand Name+ Dosage Form+ Strength	Tamsulid 0.8mg Capsule.
	Composition	Each Capsule Contains: Tamsulosin HCl ……0.8mg
	Diary No. Date of R & I & fee	Dy. No. 11360 dated 05-03-2019; Rs. 20,000/- dated 04-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists.
	Type of Form.	Form-5.
	Finished product Specification.	USP specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status.	Could not be confirmed
	GMP status.	GMP certificate issued on 30-10-2018 on the basis of inspection conducted on 09-07-2018.

	Remarks of Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Firm has also provided Megasin, Tamolin, Sin-A, T-lin & Lid-A Capsule as alternative brand names.
	Decision of 308th meeting of registration board	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.
	Reply submitted by the Firm	Firm has submitted COA of pallets by drug substance manufacturer, GMP certificate of supplier M/s Vision Pharmaceutical valid till 13-06-24. Stability studies data of 3 batches from drug substance manufacturer is not provided, however firm had provided stability data of finished product.
	Remarks of Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
Decision: Registration Board decided to reject the application since no evidence of RRA approval verified and firm has not provided any such evidence.		
536.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals (Pvt.) Limited, 27-km, Raiwind Road, Lahore (Capsule General, Antibiotics, non-antibiotics, Cephalosporin).**
	Brand Name+ Dosage Form+ Strength	Tamsulid 0.4mg Capsule.
	Composition	Each Capsule Contains: Tamsulosin HCl ……0.4mg

	Diary No. Date of R & I & fee	Dy. No. 11359 dated 05-03-2019; Rs. 20,000/- dated 04-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists.
	Type of Form.	Form-5.
	Finished product Specification.	USP specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	FLOMAX® 0.4 mg (tamsulosin hydrochloride, USP) Capsules, USFDA approved.
	Me-too status.	Alfamax Capsule 0.4mg, Platinum Pharmaceuticals, Reg No. 055702
	GMP status.	GMP certificate issued on 30-10-2018 on the basis of inspection conducted on 09-07-2018.
	Remarks of Evaluator.	Reference product contain pellets of Tamsulosin HCl while the applied formulation is without pellets. Label claim needs revision as per reference product with applicable fee. Source of pellets, Stability studies data of 3 batches, GMP certificate of supplier & COA of pellets along with differential fee in case of import of pellets is required. Firm has also provided Megasin, Tamolin, Sin-A, T-lin & Lid-A Capsule as alternative brand names.
	Decision of 308th meeting of registration board	Deferred for following: • Label claim needs revision as per reference product with applicable fee. • Source of pellets, Stability studies data of 3 batches, GMP certificate of supplier & COA of pellets along with differential fee in case of import of pellets.
	Reply submitted by the Firm	Firm has submitted COA of pallets by drug substance manufacturer, GMP certificate of supplier M/s Vision Pharmaceutical valid till 13-06-24. Stability studies data of 3 batches from drug substance manufacturer is not provided, however firm had provided stability data of finished product.
	Remarks of Evaluator.	• Label claim needs revision as per reference product with applicable fee. • Stability studies data of 3 batches from drug substance manufacturer required.

Decision: Approved. Registration letter will be issued after submission of

- **Revision of label claim as per innovator drug product along with with applicable fee of pre-registration as per SRO 1324 (I)/2024 dated 30-08-2024. Stability studies data of 3 batches from drug**

substance manufacturer		
537.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt. Ltd., 13th km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mycosin 125mg Tablet.
	Composition	Each film coated tablet contains: Terbinafine hydrochloride……..……. 125mg.
	Diary No. Date of R& I & fee	Dy. No. 13698 dated 07-06-2022, Fee Rs: 50,000/- dated 16.09.2017 vide deposit slip No. 0275710. (Duplicate dossier verified by R&I section.)
	Pharmacological Group	Antifungal. ATC Code: D01AE15 .
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.
	Me-too status	Diampa-M 5mg/500mg Tablets, Getz Pharma.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Mycosin 125mg Tablet.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. **Metformin HCl** (MEF/11030557): Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	White colour circular biconvex tablets with REKO and break line on one face, blistered in transparent PVC having AL 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.	Trial 04	Trial 01	Trial 02
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2021	10-2020	01-2021
Date of Initiation	01-07.2020	01-07.2020	01-07.2020
No. of Batches	03		
Date of Submission	Dy. No. 39312 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	

3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	

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

Agenda of Mr. Waqar

538.	Name and address of manufacturer / Applicant	M/s.Wenovo Pharmaceuticals. Plot # 31& 32, Punjab Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Dapawen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	2x7, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** USFDA approved.
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted.
	Remarks of the Evaluator	
STABILITY STUDY DATA		
Drug	Dapawen 10mg Tablet	

Manufacturer of API	M/s. Precise ChemiPharma Pvt Ltd. India.		
API Lot No.	120002012022		
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%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T050	T051	T052
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	30-03.2022	30-03.2022	30-03.2022
No. of Batches	03		
Date of Submission	Dy. No. 38205 dated 28/-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Precise ChemiPharma Pvt Ltd. India. Firm has also submitted COA of the drug substance with batch number 120002012022 and manufacturing date Jan-22.
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 28-09-2022. Issued by Food and Drug Administration Maharashtra. DML Valid til 31-12-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached in the name of Welmark Pharmaceuticals. (Not approved from DRAP). Firm not provided the API loan document.
7.	Protocols followed for conduction of stability study.	Not Submitted.
8.	Method used for analysis of FPP	Submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dapawen 10mg tablet (Dapagliflozin) against Dapa 10mg tablet, **Batch No. 144526, Mfg. date 02-2022 manufactured by Hilton Pharmaceuticals Pvt Ltd.** 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.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
9.	Your form application shows that you applied for **Zenwo** 10mg Tablet but all the stability data / documents is with the name of **Dapawen** 10mg Tablet, **Justifications required.**	
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	

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

539.	Name and address of manufacturer / Applicant	M/s.Wenovo Pharmaceuticals. Plot # 31& 32, Punjab Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Dapawen 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14189 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	2x7, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** USFDA approved.
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dapawen 5mg Tablet		
Manufacturer of API	M/s. Precise ChemiPharma Pvt Ltd. India.		
API Lot No.	120002012022		
Description of Pack (Container closure system)	Alu-Au Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T047	T048	T049
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	15-03.2022	15-03.2022	15-03.2022
No. of Batches	03		
Date of Submission	Dy. No. 38205 dated 28/-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Precise ChemiPharma Pvt Ltd. India. Firm has also submitted COA of the drug substance with batch number 120002012022 and manufacturing date Jan-22. (Manufacturer's **Specification)**
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 28-09-2022. Issued by Food and Drug Administration Maharashtra. DML Valid til 31-12-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached in the name of Welmark Pharmaceuticals. (Not approved from DRAP). Firm not provided the API loan document.
7.	Protocols followed for conduction of stability study.	Not Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dapawen 10mg tablet (Dapagliflozin) against Dapa 10mg tablet, **Batch No. 144526, Mfg. date 02-2022 manufactured by Hilton Pharmaceuticals Pvt Ltd.** 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.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
9.	Your form application shows that you applied for **Zenwo** 10mg Tablet but all the stability data / documents is with the name of **Dapawen** 10mg Tablet, **Justifications required.**	
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	

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

540.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Dexprazole 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) …..…30mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	Form-5 Dy.No 9753 dated 04-03-2019 Rs.20,000 dated 25-02-2019.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1x10's, 2x7's, 3x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	GMP Certificate No. 241/2019-DRAP (K), Dated, 20-09-2019.
STABILITY STUDY DATA		

Drug	Dexprazole 30mg Capsules		
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.		
API Lot No.	DP 775		
Description of Pack (Container closure system)	1x10's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	RDA-01	RDA-02	RDA-03
Batch Size	4000 capsule	4000 capsule	4000 capsule
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	20-09.2021	20-09.2021	20-09.2021
No. of Batches	03		
Date of Submission	Dy. No. 7588 dated 14-03-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Finished product manufacturer and API manufacturer provided method of analysis for API.
4.	Stability study data of API from API manufacturer	Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019, dated 31-07-19 valid for 3 years
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.

10.	Complete batch manufacturing record of three stability batches.	Submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dexprazole 30mg Capsule (Dexlansoprazole) against Razodex 30mg Capsule, Btach No. 02c15, Mfg. Date 06-2021, **manufactured by Getz Pharmaceuticals Pvt Ltd.** 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.	Firm has only submitted summary data sheets, besides this other data not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted. (instead of digital data firm submited manual data)

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
4.	Record of comparative dissolution data shall be submitted.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
7.	Submit valid GMP certificate of Semos Pharmaceuticals.	

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

541.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Dexprazole 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……60mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	Form-5 Dy.No 9752 dated 04-03-2019 Rs.20,000 dated 25-02-2019

	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1x10's, 2x7's, 3x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	GMP Certificate No. 241/2019-DRAP (K), Dated, 20-09-2019.

STABILITY STUDY DATA

Drug	Dexprazole 60mg Capsules		
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.		
API Lot No.	DP 775		
Description of Pack (Container closure system)	1x10's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	RDC-01	RDC-02	RDC-03
Batch Size	4000 capsule	4000 capsule	4000 capsule
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	16-09.2021	16-09.2021	16-09.2021
No. of Batches	03		
Date of Submission	Dy No. 9752 dated 04-03-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Finished product manufacturer and API manufacturer provided method of analysis for API.
4.	Stability study data of API from API manufacturer	Submitted.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019, dated 31-07-19 valid for 3 years
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dexprazole 60mg Capsule (Dexlansoprazole) against Razodex 60mg Capsule, Btach No. 052C48, Mfg. Date 06-2020, **manufactured by Getz Pharmaceuticals Pvt Ltd.** 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.	Firm has only submitted summary data sheets, besides this other data not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted. (instead of digital data firm submited manual data)

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
4.	Record of comparative dissolution data shall be submitted.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
7.	Submit valid GMP certificate of Semos Pharmaceuticals.	

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

542.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Noxilant 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……30mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dexxoo 30mg capsule by M/s Weatherfold Pharmaceutical Pakistan Ltd..
	GMP status	Not Submitted.

STABILITY STUDY DATA

Drug	Noxilant 30mg Capsules		
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.		
API Lot No.	DLP 775		
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	STAB-01	STAB-02	STAB-03
Batch Size			
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission	Form-5 Dy.No 39318 dated 29-12-2022 Rs.20,000 dated 25-02-2019.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019-Addl. Dir (QA & LT-I)-56, dated 22-08-22 valid for 2 years
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Noxilant 30mg Capsule (Dexlansoprazole) against Dexxoo 30mg Capsule, Btach No. 898, Mfg. Date 01-2021, **manufactured by** Weatherfold Pharmaceutical Pakistan Ltd 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.	Firm has submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Provide batch size of stability batches and provide the date of initiation of stability studies.	
7.	Submit valid GMP certificate of Nawan Laboratories.	
8.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	

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

543.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Noxilant 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……60mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Dexxoo 60mg capsule by M/s Weatherfold Pharmaceutical Pakistan Ltd..
	GMP status	Not Submitted.

STABILITY STUDY DATA

Drug	Noxilant 60mg Capsules
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.

API Lot No.	DLP 775		
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	STAB-01	STAB-02	STAB-03
Batch Size			
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission	Form-5 Dy.No 39318 dated 29-12-2022 Rs.20,000 dated 25-02-2019.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019-Addl. Dir (QA & LT-I)-56, dated 22-08-22 valid for 2 years
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A

10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Noxilant 60mg Capsule (Dexlansoprazole) against Dexxoo 60mg Capsule, Btach No. 900, Mfg. Date 01-2021, **manufactured by** Weatherfold Pharmaceutical Pakistan Ltd 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.	Firm has submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Provide batch size of stability batches and provide the date of initiation of stability studies.	
7.	Submit valid GMP certificate of Nawan Laboratories.	
8.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	

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

544.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name +Dosage Form + Strength	D-Flozin 5mg Tablet

	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Dy. No. 523/2016, dated, 23-12-2016. Fees: 50,000.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	3x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** USFDA approved.
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years).
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	D-Flozin 5mg Tablet		
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.		
API Lot No.	D87-200401		
Description of Pack (Container closure system)	3x10's, Alu-Au Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	EXP-T-1140	PLT-T-153	PLT-T-154
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	04-2022	03-2022
Date of Initiation	04.2022	04.2022	04.2022
No. of Batches	03		
Date of Submission	Dy. No. 31022 dated 01-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd. Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)**
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
4.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
5.	Complete batch manufacturing record of three stability batches shall be submitted..	
6.	Record of comparative dissolution data shall be submitted.	
7.	Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	
8.	Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point)	

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

545.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Brand Name +Dosage Form + Strength	D-Flozin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Dy. No. 522/2016, dated, 23-12-2016. Fees: 50,000.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	3x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** USFDA approved.
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years).
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	D-Flozin 10mg Tablet
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.
API Lot No.	D87-200401
Description of Pack (Container closure system)	3x10's, Alu-Au Blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	EXP-T-1141	PLT-T-155	PLT-T-156
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	04-2022	03-2022
Date of Initiation	04.2022	04.2022	04.2022
No. of Batches	03		
Date of Submission	Dy. No. 31023 dated 01-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd. Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)**
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted

11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
4.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
5.	Complete batch manufacturing record of three stability batches shall be submitted..	
6.	Record of comparative dissolution data shall be submitted.	
7.	Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	
8.	Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point)	

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

546.	Name and address of manufacturer / Applicant	**M/s. Aspin Pharma (Pvt) Ltd.** **Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Dagli 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Form 5 Dairy No. 37592 dated 13-11-2018 Rs.20,000/- dated 17-10- 2018.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals. (CDP performed with this product)**

		USFDA approved.		
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.		
	GMP status	Not Submitted		
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		Dagli 5mg Tablet		
Manufacturer of API		Fuxin Long Rui Pharmaceuticals Co. Ltd. Address : Fluoride Industrial Park, Fuxin City, Liaoning Provonce, China.		
API Lot No.		DG-20201201-D03-DG06-01		
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%		
Time Period		Real time: 06 months Accelerated: 06 months		
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.		044DS04	044DS05	044DS06
Batch Size		2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation				
No. of Batches		03		
Date of Submission		Dy. No. 21855 dated 02-08-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	**Documents to Be Provided**	**Status**		
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) Batch No. DGDZ202101 from M/s. Fuxin Long Rui Pharmaceuticals, Fuxin city, Liaoning province, China. Firm has also submitted COA of the drug substance with batch number DG-20201201-D03-DG06-01 and manufacturing date 25-12-2020. (Manufacturer's **Specification)**		
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	submitted		

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. HN21042601-H, Invoice cleared by DRAP Karachi office. Dated, 07-05-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Submit valid GMP certificate of **M/s. Aspin Pharma (Pvt) Ltd.**	
5.	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.	

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

547.	Name and address of manufacturer / Applicant	**M/s. Aspin Pharma (Pvt) Ltd.** **Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Dagli 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dairy No. 37593 dated 13-11-2018 Rs.20,000/- dated 17-10- 2018.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals. (CDP performed with this product)** USFDA approved.
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dagli 10mg Tablet		
Manufacturer of API	Fuxin Long Rui Pharmaceuticals Co. Ltd. Address : Fluoride Industrial Park, Fuxin City, iaoning Provonce, China.		
API Lot No.	DG-20201201-D03-DG06-01		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	045DS04	045DS05	045DS06
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 21856 dated 02-08-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) Batch No. DGDZ202101 from M/s. Fuxin Long Rui Pharmaceuticals, Fuxin city, Liaoning province, China. Firm has also submitted COA of the drug substance with batch number DG-20201201-D03-DG06-01 and manufacturing date 25-12-2020. (Manufacturer's **Specification)**
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	submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. HN21042601-H, Invoice cleared by DRAP Karachi office. Dated, 07-05-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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	Submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Submit valid GMP certificate of **M/s. Aspin Pharma (Pvt) Ltd.**	
5.	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.	

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

548.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38599 dated 23-11-2018 Rs.20,000/- dated 23-11-2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals.**
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo 5mg Tablets
Manufacturer of API	**Not submitted**
API Lot No.	**Not submitted**
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%
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TD-013	TD-014	TD-015
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06-01-2022	06-01-2022	06-01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 39302 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms,

	chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s Navegal Laboratories.	

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

549.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38598 dated 23-11-2018 Rs.20,000/- dated 23-11-2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.

	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.**
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo 10mg Tablets		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**Not submitted**		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	TD-016	TD-017	TD-018
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 39303 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	

12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s Navegal Laboratories.	

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

550.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad
	Brand Name +Dosage Form + Strength	Dapxin 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 32163 dated 26-09-2018 Rs.20,000/- dated 26-09-2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals.**
	Me-too status	Dapa 5mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dapxin 5mg Tablets		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation			
No. of Batches	03		

Date of Submission	Dy. No. 39319 dated 29-12-2022.	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Hicon submitted COA OF Finished product, API COA is not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s Hicon Pharmaceuticals.	

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

551.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad
	Brand Name +Dosage Form + Strength	Dapxin 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 32164 dated 26-09-2018 Rs.20,000/- dated 26-09-2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.**
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	
STABILITY STUDY DATA		

Drug	Dapxin 10mg Tablets		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 39319 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Hicon submitted COA OF Finished product, API COA is not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.

10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are required by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s Hicon Pharmaceuticals.	

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

552.	Name and address of manufacturer / Applicant	**M/s. Pharmasol Pvt Ltd.** **Plot No. 549, Sundar Industrial Estate, Raiwind**

		Road Lahore.
	Brand Name +Dosage Form + Strength	Dapoglin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Dy.No 40657 dated 06-12-2018 Rs.20,000/- Dated 06-12- 2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	1x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** **(CDP also performed on this product).**
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dapoglin 10mg Tablet		
Manufacturer of API	M/s. Huainan Shunlong Pharmaceuticals Co. Ltd. Address : Hunainan Economic and Technological Development Zone, China.		
API Lot No.	20201101		
Description of Pack (Container closure system)	2x10'S, Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	MR-T1	MR-T3	MR-T3
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	07-2021	07-2021	07-2021
No. of Batches	03		
Date of Submission	Dy. No. 21856 dated 02-08-2022.		

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.	submitted

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) Batch No. 20201101 from M/s. Huainan Shunlong Pharmaceuticals Co. Ltd Firm has also submitted COA of the drug substance with batch number 20201101 and manufacturing date. (Manufacturer's **Specification)**
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	submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Anhui Food and Drug Administration, Anhui Pharmaceutical And Proffessional Association, Huainan , China. (Not acceptable to DRAP), Firm also submitted Form-3, and Form 07 of the API manufacturer. (Acceptable)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. 20201101, Invoice cleared by DRAP Lahore office. Dated, 05-01-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 6 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Submit valid GMP certificate of **M/s. Pharmasol Pvt Ltd.**	
4.	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data).	

Decision: Approved with Innovator specifications.

- **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024 and submission of valid copy of GMP certificate of the drug substance manufacturer *(M/s. Huainan Shunlong Pharmaceuticals Co. Ltd, China)* issued by relevant/concerned regulatory authority along with valid copy GMP certificate of M/s. Pharmasol Pvt Ltd.**

553.	Name and address of manufacturer / Applicant	**M/s Winlet Pharmaceuticals Pvt Ltd.** **30-km, Lahore Sargodha Road, Sargodha.**
	Brand Name +Dosage Form + Strength	Dapazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 15780 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	3x10's, MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.** USFDA approved.
	Me-too status	Dapa 10mg tablet, **by** Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dapazin 10mg Tablet
Manufacturer of API	Fuxin Long Rui Pharmaceuticals Co. Ltd. Address : Fluoride Industrial Park, Fuxin City, Liaoning Provonce, China.
API Lot No.	DG-20200516-D01-DG06-07
Description of Pack (Container closure system)	3x10's, Alu-Au Blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH

	Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	11-01.2022	11-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 19917 dated 07-07-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) from API manufacturer. Firm has also submitted COA of the drug substance. (Manufacturer's **Specification)**
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone. (Not acceptable to DRAP). Firm also submitted the DML of the API manufacturer.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement letter attached, Cleared by DRAP office Lahore. Letter Ref. No. 2258/2021/DRAP-AD-VIII (I&E). Dated, 10-02-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	submitted

10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
4.	Submit valid GMP certificate of **M/s Winlet Pharmaceuticals Pvt Ltd.**	

Decision: Approved with Innovator specifications.

- **Registration letter will be issued after submission of 9000/- fee for change in specifications as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024 and submission of stability study data of API from API manufacturer *(M/s. Fuxin Long Rui Pharmaceuticals Co. Ltd, China)* along withvalid copy GMP certificate of M/s. Winlet Pharmaceuticals Pvt Ltd.**

554.	Name and address of manufacturer / Applicant	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lanso 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) …..…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14802 dated 07-03-2019 Rs.20,000/- dated 28-02-2019
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.

	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Last inspection report dated 31-01-2022.

STABILITY STUDY DATA			
Drug	Lanso 30mg Capsules		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	STAB-01	STAB-02	STAB-03
Batch Size			
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Not Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheet only. No other data as per the checklist approved by the Board in 293rd meeting is submitted. (COA, Chromatograms etc not provided)
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of M/s Winthrox Laboratories Pvt Ltd.	
7.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
9.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	

11.	Record of comparative dissolution data shall be submitted.	

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

555.	Name and address of manufacturer / Applicant	**M/s. Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Zelanso 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole …… 30mg
	Diary No. Date of R& I & fee	Dy No. 15995: 07-03-2019 PKR 20,000/-: 07-03-201
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019.

STABILITY STUDY DATA			
Drug	Zelanso 30mg Capsules		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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	3000 Capsule	3000 Capsule	3000 Capsule
Manufacturing Date	05-10-2022	05-10-2022	05-10-2022
Date of Initiation	05-10-2022	05-10-2022	05-10-2022
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Not Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data summary sheet and chromatograms only. No other data as per the checklist approved by the Board in 293rd meeting is submitted. (COA not provided, submitted documents are also non attested)
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	

2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s. Zeta Pharmaceuticals.**	
7.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
9.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. (Again advised to Submit attested copies).	
11.	Record of comparative dissolution data shall be submitted.	
12.	Revise your label claim as per the reference product along with submission of requisite fee.	

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

556.	Name and address of manufacturer / Applicant	**M/s. Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Zelanso 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole …… 60mg
	Diary No. Date of R& I & fee	Dy No. 15996: 07-03-2019 PKR 20,000/-: 07-03-2019.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019.

STABILITY STUDY DATA	
Drug	Zelanso 60mg Capsules
Manufacturer of API	
API Lot No.	

Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
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	3000 Capsule	3000 Capsule	3000 Capsule
Manufacturing Date	05-10-2022	05-10-2022	05-10-2022
Date of Initiation	05-10-2022	05-10-2022	05-10-2022
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Not Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.

11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data summary sheet and chromatograms only. No other data as per the checklist approved by the Board in 293rd meeting is submitted. (COA not provided, submitted documents are also non attested)
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s. Zeta Pharmaceuticals.**	
7.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
9.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. (Again advised to Submit attested copies).	
11.	Record of comparative dissolution data shall be submitted.	
12.	Revise your label claim as per the reference product along with submission of requisite fee.	

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

557.	Name and address of manufacturer / Applicant	**M/s. Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi. KPK.**
	Brand Name +Dosage Form + Strength	Dexlansip 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole …… 30mg

	Diary No. Date of R& I & fee	Dy.No 13513 dated 07-03-2019 Rs.20,000/- dated 07-03-2019.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Not submitted.

STABILITY STUDY DATA

Drug	Dexlansip 30mg Capsules		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 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		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted

4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Not Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s. Hisun Pharmaceutical Industries.**	
7.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	

8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
9.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. (advised to Submit attested copies).	
11.	Record of comparative dissolution data shall be submitted.	
12.	Revise your label claim as per the reference product along with submission of requisite fee.	

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

558.	Name and address of manufacturer / Applicant	**M/s. Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi. KPK.**
	Brand Name +Dosage Form + Strength	Dexlansip 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole …… 60mg
	Diary No. Date of R& I & fee	Dy.No 13514 dated 07-03-2019 Rs.20,000/- dated 07-03-2019.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Not submitted.

STABILITY STUDY DATA

Drug	Dexlansip 60mg Capsules		
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	2x7's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 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		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Not Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s. Hisun Pharmaceutical Industries.**	
7.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
9.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. (advised to Submit attested copies).	
11.	Record of comparative dissolution data shall be submitted.	
12.	Revise your label claim as per the reference product along with submission of requisite fee.	

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

559.	Name and address of manufacturer / Applicant	**M/s. Life Pharmaceutical Company.** **24-III, Industrial Estate, Multan, Pakstan.**
	Brand Name +Dosage Form + Strength	Danzo 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……30mg
	Diary No. Date of R& I & fee	Dy.No.1035 R&I date 24-02-2016 , Rs.20,000/- dated 24-02-2016.
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	15's, and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.

	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Not submitted.

STABILITY STUDY DATA			
Drug	Danzo 30mg Capsules		
Manufacturer of API	M/s Vision Pharmceuticals, (Pvt. Ltd.) Islamabad.		
API Lot No.	DLP738		
Description of Pack (Container closure system)	1x10's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TB-DX30-01	TB-DX30-02	TB-DX30-03
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	07-08-2021	07-08-2021	07-08-2021
No. of Batches	03		
Date of Submission	17-03-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.

9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted. (But its manualy filled, instead of digital data logger record).

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Your firm submitted manualy pen filled data instead of Digital Data logger. You are again advised to submit the digital data logger record.	
5.	Submit valid GMP certificate of M/s. Life Pharmaceutical Company.	
6.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
8.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	

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

560.	Name and address of manufacturer / Applicant	**M/s. Life Pharmaceutical Company.** **24-III, Industrial Estate, Multan, Pakstan.**
	Brand Name +Dosage Form + Strength	Danzo 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) …..…60mg
	Diary No. Date of R& I & fee	Dy.No.1034 R&I date 23-02-2016 , Rs.20,000/- dated 24-02-2016.

	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	15's, and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.
	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Not submitted.

STABILITY STUDY DATA

Drug	Danzo 60mg Capsules		
Manufacturer of API			
API Lot No.	DLP738 / 5843		
Description of Pack (Container closure system)	1x10's Capsule in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	TB-DX60-01	TB-DX60-02	TB-DX60-03
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	08-08-2021	08-08-2021	08-08-2021
No. of Batches	03		
Date of Submission	17-03-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted. (But its manualy filled, instead of digital data logger record).

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). Your firm submitted manualy pen filled data instead of Digital Data logger. You are again advised to submit the digital data logger record.	
5.	Submit valid GMP certificate of **M/s. Life Pharmaceutical Company.**	
6.	Provide Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	

8.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	

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

561.	Name and address of manufacturer / Applicant	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Brand Name +Dosage Form + Strength	Britam 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Brivaracetam…25mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 41219 dated 07-12-2018 Rs.50,000/- dated 06-12-2018
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Cubriva 25mg Tablet by M/s Genix Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted

STABILITY STUDY DATA

Drug	Britam 25mg Tablet		
Manufacturer of API	**Not provided**		
API Lot No.	Not provided		
Description of Pack (Container closure system)	2x14's Tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	NPD-PR21-11-T1-S1	NPD-PR21-11-T1-S2	
Batch Size	5000	5000	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	25-02-2022	25-02-2022	
No. of Batches	02		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has **submitted** stability data summary sheet COA and chromatograms of 02 Batched (having batch size of 5000 Tablets).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	**Observation**	**Reply by the firm**

1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s Wilshire Laboratories Pvt Ltd.**	
7.	Provide Method used for analysis of API from API Manufacturer.	
8	Provide Certificate of analysis of API from API manufacturer.	
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
10.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

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

562.	Name and address of manufacturer / Applicant	**M/s Wilshire Laboratories Pvt Ltd.** **124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Brand Name +Dosage Form + Strength	Britam 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Brivaracetam…10mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 41217 dated 07-12-2018 Rs.50,000/- dated 06-12-2018
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Cubriva 10mg Tablet by M/s Genix Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted

STABILITY STUDY DATA

Drug	Britam 10mg Tablet
Manufacturer of API	**Not provided**
API Lot No.	Not provided

Description of Pack (Container closure system)	2x14's Tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	NPD-PR21-11-T1-S1	NPD-PR21-11-T1-S2	
Batch Size	5000	5000	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	25-02-2022	25-02-2022	
No. of Batches	02		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.

11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has **submitted** stability data summary sheet COA and chromatograms of 02 Batched (having batch size of 5000 Tablets).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s Wilshire Laboratories Pvt Ltd.**	
7.	Provide Method used for analysis of API from API Manufacturer.	
8.	Provide Certificate of analysis of API from API manufacturer.	
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
10.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

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

563.	Name and address of manufacturer / Applicant	**M/s Wilshire Laboratories Pvt Ltd.** **124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Brand Name +Dosage Form + Strength	Britam 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Brivaracetam…50mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 41219 dated 07-12-2018 Rs.50,000/- dated 06-12-2018
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.

	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Cubriva 50mg Tablet by M/s Genix Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted

STABILITY STUDY DATA

Drug	Britam 50mg Tablet		
Manufacturer of API	**Not provided**		
API Lot No.	Not provided		
Description of Pack (Container closure system)	2x14's Tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	NPD-PR21-012T2-S1	NPD-PR21-012T2-S2	
Batch Size	5000	5000	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	09-02-2022	09-02-2022	
No. of Batches	02		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has **submitted** stability data summary sheet COA and chromatograms of 02 Batched (having batch size of 5000 Tablets).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s Wilshire Laboratories Pvt Ltd.**	
7.	Provide Method used for analysis of API from API Manufacturer.	
8.	Provide Certificate of analysis of API from API manufacturer.	
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
10.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

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

564.	Name and address of manufacturer / Applicant	**M/s Wilshire Laboratories Pvt Ltd.** **124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Brand Name +Dosage Form + Strength	Britam 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Brivaracetam…75mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 41220 dated 07-12-2018 Rs.50,000/- dated 06-12-2018
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Cubriva 75mg Tablet by M/s Genix Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted

STABILITY STUDY DATA

Drug	Britam 75mg Tablet		
Manufacturer of API	**Not provided**		
API Lot No.	Not provided		
Description of Pack (Container closure system)	2x14's Tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	NPD-PR21-13-T1-S1	NPD-PR21-13-T1-S2	
Batch Size	5000	5000	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	28-02-2022	28-02-2022	
No. of Batches	02		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has **submitted** stability data summary sheet COA and chromatograms of 02 Batched (having batch size of 5000 Tablets).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	

2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s Wilshire Laboratories Pvt Ltd.**	
7.	Provide Method used for analysis of API from API Manufacturer.	
8.	Provide Certificate of analysis of API from API manufacturer.	
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
10.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

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

565.	Name and address of manufacturer / Applicant	**M/s Wilshire Laboratories Pvt Ltd.** **124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**
	Brand Name +Dosage Form + Strength	Britam 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Brivaracetam…100mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 41221 dated 07-12-2018 Rs.50,000/- dated 06-12-2018
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Cubriva 100mg Tablet by M/s Genix Pharmaceuticals Pvt Ltd.
	GMP status	Not submitted

STABILITY STUDY DATA	
Drug	Britam 100mg Tablet
Manufacturer of API	**Not provided**
API Lot No.	Not provided
Description of Pack (Container closure system)	2x14's Tablets in Alu-Alu blister pack.
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH

	Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	NPD/PR21-014/T4-S1	NPD/PR21-014/T4-S2	
Batch Size	5000	5000	
Manufacturing Date	02-2022	02-2022	
Date of Initiation	07-02-2022	07-02-2022	
No. of Batches	02		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from Finished Product manufacturer. Provided. COA from API Manufacturer is not provided.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Not Submitted
4.	Stability study data of API from API manufacturer	Not Submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Not Submitted.

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has **submitted** stability data summary sheet COA and chromatograms of 02 Batched (having batch size of 5000 Tablets).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted.	
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
6.	Submit valid GMP certificate of **M/s Wilshire Laboratories Pvt Ltd.**	
7.	Provide Method used for analysis of API from API Manufacturer.	
8.	Provide Certificate of analysis of API from API manufacturer.	
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
10.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	
11.	Record of comparative dissolution data shall be submitted.	

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

566.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad
	Brand Name +Dosage Form + Strength	Empxin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 12172 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Blood glucose Lowering drugs / Antidiabetic
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in	Jardiance tablets (USFDA Approved)

	Reference Regulator Authorities	
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Empxin 10mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation			
No. of Batches	03		
Date of Submission	29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Hicon submitted COA OF Finished product, API COA is not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches, Other data is also submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

14.	Submit valid GMP certificate of M/s Hicon Pharmaceuticals.	

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

567.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad
	Brand Name +Dosage Form + Strength	Empxin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 12172 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Blood glucose Lowering drugs / Antidiabetic
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Empxin 10mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation			
No. of Batches	03		
Date of Submission	29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	**Documents to Be Provided**	**Status**

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Hicon submitted COA OF Finished product, API COA is not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches, Other data is also submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not 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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s Hicon Pharmaceuticals.	

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

Case No. 01: Registration of Baricitinib 2mg and 4mg Tablets.

M/s. CCL has submitted a letter while referring Baricitinib containing drug products (Barib 2mg & 4mg Tablet) approved in the name of their firm stated as under:

> The honorable Lahore High Court, Lahore through order dated 02-05-2024 passed F.A.O No. 22656 of 2024, suspended operation of Order by the learned Intellectual Property Tribunal, Lahore, in the following words:
>
> **C.M. No. 2/2024**
>
> 6. Notice for the above-said dated. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/DRAP shall remain suspended.

Case was referred to Legal Affair's Division for status of case and their opinion. Accordingly, opinion of said division is as under:

i. The background of the matter is that registration of drugs containing Baricitnib including that of CCL Pharma Pvt. Ltd. were approved in various meeting of the Registration Board. Subsequently, before the Drug Registration Certificates could be issued, Suits were filed by Incyte Holding Corporation/ Eli Lilly Pakistan Pvt. Ltd. before the learned Intellectual Property Tribunal, Lahore. The Suits contended that Drug Registration Certificates should not be issued by placing reliance on the concept of Patent-Linkage. Ad-Interim Injunctions were issued against various firms whose registration of generic/ me-too of Baricitnib containing drugs had been approved by the Registration Board including CCL Pharma Pvt. Ltd. Learned Tribunal restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications.
   Ad-Interim Injunction was granted by the learned Intellectual Property Tribunal against CCL Pharma. Pvt. Ltd. through Order dated 03-03-2023. The Application for Interim Relief under Order 39 Rule 1 and 2 C.P.C. was decided through Order dated 03-04-2024 .

ii. Being aggrieved, DRAP filed appeal against the order dated 03.04.2024 in Lahore High Court, Lahore bearing FAO No. 22656 of 2024 in which interim relief was given by the High Court through Order dated 02-05-2024 . Relevant excerpt thereof is as under:
   "**C.M. No. 2/ 2024**
   6. Notice for the above-said date. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/ DRAP shall remain suspended."
   Subsequently, the said FAO was decided in favor of DRAP through Judgment dated 27-05-2024 (Certified copy is attached). Under the Doctrine of Merger, the Interim Order dated 02-05-2024 merged into the Final Judgment dated 27-05-2024. The Final Judgment dated 27-05-2024 set aside the Interim Injunction/ Stay Order granted by the learned Intellectual Property Tribunal, Lahore to the extent of CCL Pharmaceutical Pvt. Ltd., in the following words:
   "(ii). The interim injunction granted by the learned Tribunal, to the extent of DRAP for restraining DRAP to proceed with pending application of respondent No. 4 may be vacated;"

iii. After the grant of the above mentioned final relief by the Honorable Court, both CCL Pharma Pvt. Ltd. is free to seek Drug Registration from DRAP and further DRAP is also free to process and grant Drug Registration to CCL Pharma Pvt. Ltd. In other words, DRAP is free to perform its functions to the extent of application by CCL Pharma Pvt. Ltd.
   After Order by the Honorable Lahore High Court, Lahore dated 02-05-2024 and Final Judgment by the Honorable Court dated 27-05-2024, there is no legal impediment to the issuance of Drug Registration Certificates for drugs containing Baricitnib of CCL Pharma Pvt. Ltd. It must be emphasized that as the Honorable Court has specifically directed DRAP to proceed with CCL Pharmaceutical Pvt. Ltd.'s pending application for registration, therefore, it is a legal responsibility of the relevant persons/Board to abide by the Order and not delay the issuance of Drug Registration Certificate. Please note that any further unnecessary delay might tantamount to Contempt of Court.

iv. Furthermore, the Registration Board in its 297th Meeting held on 12th to 15th of January, 2021, held that barring the cases where interim injunction is granted by the Honorable Court, the drug registration shall not be stopped. The decision is reproduced as under:
"After detailed deliberations, Registration Board decided that grant of marketing authorization/ registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court."
As the restraining order by the learned Tribunal has been completely set aside by the Honorable High Court through Judgment dated 27-05-2024 **only to the extent of CCL Pharma Pvt. Ltd.** therefore, as per decision of the 297th Meeting of the Registration Board, there is no legal impediment in the grant of Drug Registration to CCL pharma. **It is again clarified that any delay in complying with the aforementioned direction of the Honorable Court is contemptuous in nature and therefore, the competent authority should promptly issue CCL Pharma Pvt. Ltd.'s Drug Registration Certificate as long as the Company meets all requirements under the drug laws.**

v. As discussed in detail above, the Honorable High Court through Judgment dated 27-05-2024 has granted relief only to the extent of CCL Pharma Pvt. Ltd. Therefore, it is a relief which is 'in personam' granted to the extent of parties to the case i.e. CCL Pharma. This concept has been defined by the Honorable High Court in judgment reported as **2014 PLC (CS) 288** in the following words:
"It differs from a judgment in personam as this judgment is in form as well as substance between the parties claiming the right, and that it is so inter parties appears by the record itself."

vi. Furthermore, since the Judgment dated 27-05-2024 does not lay down a Principle of Law, therefore, it is a judgment 'in personam' which only benefits the party to the lis i.e. CCL Pharma Pvt. Ltd.
It is pertinent to mention here that Learned Tribunal has restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications. Therefore, unless and until the Honorable High Court sets aside the learned Tribunal's both aforementioned directions to the extent of DRAP completely in relation to all other companies, DRAP cannot issue Drug Registration Certificate to other companies. Any violation of learned Tribunal's Order would be contemptuous as noted by the Honorable High Court in judgment reported as PLD 1975 Lahore 126 in the following words:
"5… When an injunction order has been issued, it must be obeyed; and the only remedy of the aggrieved party is to come up in appeal to a superior Court to have the order vacated. So long as the order stands and its operation has not been suspended by another Court or by the Court which passed the order, it will not be tolerated that any person should disobey that order."

vii. In the light of above facts and legal position, the Judgment dated 27-05-2024 by Lahore High court is 'in personam', therefore, its benefit can only be granted to CCL Pharma Pvt. Ltd. and Drug Registration Certificate can only be issued to it. The registration letters regarding the product containing namely Baricitinib cannot be granted to the other companies against whom the Incytee Holdings and ELi Lilly filed suit in Intellectual Property Tribunal, Lahore due to the operative stay orders.

It is pertinent to mention here that it is also mentioned in Hon'ble High Court Order dated 27.05.2024 that

" 4 (iii) ''the above, however, shall not be construed as permitting respondent No. 4 to advertise, market or deal with Baricitinib in any manners and the injunctive order to the extent of respondent No. 4 may be examined in appeal No. 22665 of 2024 filed by respondent No. 4."

Proceeding of 343rd Meeting:

Registration Board was appraised that during meeting of the Board, on behalf of i. Incyte Holdings Corporation ii. Eli Lilly and company and iii. Eli Lilly Pakistan (Pvt) Ltd., Mr. Hassan Irfan Khan Advocate has sent a reference stating that CCL has submitted a letter, willfully and purposely misrepresenting the actual facts and legal position with regard to litigation by their clients against CCL for infringement of patents relating to baricitinib.

Copy of above reference has been handed over to Law expert of M/o Law & Justice, Islamabad for review and discussion in forthcoming meeting of the Board.

Decision of 343rd Meeting:

Registration Board, in-order to complete review of the case in light of reference submitted by Mr. Hassan Irfan and Lahore High Court deferred the case for further deliberation.

Proceedings of 344th meeting

Registration Board deliberated the matter in detail. There are other companies including M/s CCL pharma who also filed the applications for registration of the same molecule before Board. However, M/s Incytee Holdings and M/s Eli lilly filed suits before Intellectual Property Tribunal, Lahore against all said companies/firm & DRAP and obtained ad-interim injunctions. As stated above, The Lahore High Court, Lahore while vacating ad-interim order against DRAP, directed DRAP to proceed with pending application of respondent No. 4 i.e M.s CCL Pharma. It is pertinent to mention here that the ad-interim injunction orders against other companies are not vacated so far by the IPT, Lahore or Lahore High Court, Lahore till date.

Decision:

In view of the above, the Registration Board decided to proceed with the pending Regsitration Letter of M/s CCL Pharma regarding Baricitinib with additional condition of registration that 'the registration letter shall not be construed as permitting M/s CCL Pharmaceuticals to advertise, market or deal with Baricitinib in any manners till final adjudication of FAO No. 22665 of 2024 filed by the Company."

Moreover, The Board also directed PE&R Division to place all pending applications of Baricitinib of all companies/firms in next meeting. Further, the Board also directed Deputy Director (Legal Affairs) of DRAP to give a comprehensive presentation in next meeting on latest status of court orders by IPT, Lahore or Lahore high court.

Case No.2 Registration of Drug M/s. Pharmawise Labs; Lahore.

Registration Board in its 228th meeting approved the following products of M/s. Pharmawise Labs, Lahore and the firm has informed that they have not yet got registration letter:

Sr. No.	Name of Drug(s)	Demanded Pack Size/Price	Decision	Remarks
1.	Simiwise Suspension Each 5ml contains: Simethicone……25mg	120ml As per SRO	**M-228** Approved subject to Installation of HVAC system in section.	Status of formulation in RRA not confirmed and firm has submitted request for standardization of formulation as per RRA, MHRA as **Each 5ml contains:** **Aluminium Hydroxide…220mg** **Magnesium Hydroxide…200mg** **Simethicone…….25mg**

Firm has submitted following documents:

i. Photocopy of fee challan of Rs.8000/- and Rs.12000/-
ii. Fee of Rs.37000/- vide challan No. 39351347086, for above mentioned standardization.
iii. GMP certificate issued based upon evaluation conducted on 18-10-2022.
iv. Section approval of Syrup (General) Section.
v. Inspection report dated 21-03-2023 confirming that firm has installed HVAC system in their manufacturing facility.

Decision: Registration Board accede to request of the firm and decided to approved product as per following details:
Simiwise Suspension
Each 5ml contains:
Aluminium Hydroxide…220mg
Magnesium Hydroxide…200mg
Simethicone…….25mg
Registration baord further decided that registration letter shall be issued after verification of fee as per decision of 285th meeting of the Board.

RRR Section

Case No.01 M/s. Uni-Tiech Pharmaceuticals Pvt Limited, Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi

The below mentioned products was discussed in 336th meeting of Registration Board and the Registration board was decided as under:

Decision in 336th meeting of Registration Board:
Registration Board directed the firm to apply afresh for registration of above products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Snaglin 500mg Dry Powder Injection
	Composition	Each vial contains Cefazolin as sodium…..500mg
	Dairy No. date of R &I fee	9163 dated 02.09.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s
	GMP Status	GMP inspection report dated 11.06.2024 and GMP GMP indicating the compliance good.
	Remark of the Renewal section	**Decision 336th meeting**: **Registration Board directed the firm to apply afresh for registration of above products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024** Registration of Snaglin 500mg Dry Powder Injection (047472) applied afresh as per direction of Registration Board in 336th meeting due to non-submission of renewal application.
	Decision: Approved	

Case No.02 M/s. Crown Pharmaceuticals, Plot No.286, industrial Triangle Kahuta Road, Islamabad

1.	Brand Name + Dosage Form and Strength	Crobal 500mcg tablet (Reg No 032308)
	Composition	Each film coated tablet contains: Mecobalamin …….500mcg
	Dairy No. date of R &I fee	13284 dated 13.12.2024 Rs.37000/-
	Type of form	Fom-5

	Finished product specifications	JP Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection for renewal of DML was conducted on 14.05.2024
	Remark of the Renewal section	Registration of Crob al 500mcg tablet (032308) applied afresh due to non-submission of renewal application. **Formulation approved in RRA (PMDA) is in Sugar coated form hence formulation to be standardized in line with RRA along with prescribed fee.**
	Decision: Approved **Firm will submit fee (as per SRO) for standardization of formulation in line with RRA.**	
2.	Brand Name + Dosage Form and Strength	Fasier 50mg Tablet
	Composition	Each tablet contains: Clomifene citrate …..50mg
	Dairy No. date of R &I fee	13284 dated 13.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection for renewal of DML was conducted on 14.05.2024
	Remark of the Renewal section	Registration of Fasier 50mg Tablet (024829) applied afresh due to non-submission of renewal application.
	Decision: Approved	
3.	Brand Name + Dosage Form and Strength	Crole 50mg tablet
	Composition	Each tablet contains: Levosulpiride……..50mg
	Dairy No. date of R &I fee	Dy No.13284 dated 13.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection for renewal of DML was conducted on 14.05.2024
	Remark of the Renewal section	Registration of Crole 50mg tablet (060138) applied afresh due to non-submission of renewal application.
	Decision: Approved	
4.	Brand Name + Dosage Form and Strength	Cazicin 250mg tablet
	Composition	Each tablet contains: Azithromycin as dihydrate …….250mg
	Dairy No. date of R &I fee	Dy No.13284 dated 13.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection for renewal of DML was conducted on 14.05.2024
	Remark of the Renewal section	Registration of Cazicin 250mg tablet (028798) applied afresh due to non-submission of renewal application.
	Decision: Approved	

Case No.03 M/s. SPL Pharmaceuticals (Pvt) Ltd., Plot No.4, Phase-III Hattar Industrial Estate, Hattar

1.	Brand Name + Dosage Form and Strength	Roxim 20mg capsule
	Composition	Each capsule contains: Piroxicam Beta-cyclodextrin eq. to Piroxicam…….20mg
	Dairy No. date of R &I fee	12893 dated 02.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per SRO,2x10's
	GMP Status	DML renewal inspection report dated 09th October 2023. Capsule General section is mentioned.
	Remark of the Renewal section	Registration of Roxim 20mg capsule (073351) applied afresh due to non-submission of renewal application within valid period of time 06.09.2022 **Piroxicam (as Beta-cyclodextrin) 20mg capsule is not found in any RRA**
	Decision: Deferred for approval status of applied formulation /dosage form in RRA.	
2.	Brand Name + Dosage Form and Strength	Polyfol 100mg Capsule
	Composition	Each capsule contains Iron polymaltose complex eq. to Elemental iron……100mg Folic Acid……..550mcg
	Dairy No. date of R &I fee	12893 dated 02.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per SRO,3x10's
	GMP Status	DML renewal inspection report dated 09th October 2023. Capsule General section is mentioned.
	Remark of the Renewal section	Registration of Polyfol 100mg Capsule (073352) applied afresh due to non-submission of renewal application within valid period of time 06.09.2022
	Decision: Approved	
3.	Brand Name + Dosage Form and Strength	Q-Flox 250mg Tablet
	Composition	Each tablet contains Ciprofloxacin (as HCl)…….250mg
	Dairy No. date of R &I fee	12893 dated 02.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per SRO, 2x10's
	GMP Status	DML renewal inspection report dated 09th October 2023. Tablet General section is mentioned.
	Remark of the Renewal section	Registration of Q-Flox 250mg Tablet (073353) applied afresh due to non-submission of renewal application within valid period of time 06.09.2022 **Applied formulation is available in USP. Firm is required to apply for change of specification along with prescribed fee.**

		Moreover, formulation approved in RRA is in film coated form hence formulation to be standardized in line with RRA along with prescribed fee.
	Decision: Approved **Firm will submit fee (as per SRO) for standardization of formulation in line with RRA and change of finished product specification.**	
4.	Brand Name + Dosage Form and Strength	Volfox 250mg tablet
	Composition	Each tablet contains Levofloxacin Hemihydrate eq. to Levofloxacin…….250mg
	Dairy No. date of R &I fee	12893 dated 02.12.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per SRO,2x10's
	GMP Status	DML renewal inspection report dated 09th October 2023. Tablet General section is mentioned.
	Remark of the Renewal section	Registration of Volfox 250mg tablet (073354) applied afresh due to non-submission of renewal application within valid period of time 06.09.2022 **Applied formulation is available in USP. Firm is required to apply for change of specification along with prescribed fee.** **Moreover, formulation approved in RRA is in film coated form hence formulation to be standardized in line with RRA along with prescribed fee.**
	Decision: Approved **Firm will submit fee (as per SRO) for standardization of formulation in line with RRA and change of finished product specification**	

Case No.04 M/s. Benson Pharmaceuticals, Plot No.3 Main Road, national Industrial Zone, RCCI, Rawat Rawalpindi

1.	Brand Name + Dosage Form and Strength	Benpime 1gm Injection
	Composition	Each vial contains: Cefepime (as HCl with L-arginine)…….1gm
	Dairy No. date of R &I fee	7658 dated 29.07.2024 Rs.75000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO,1s
	GMP Status	GMP certificate issued on 24th November, 2022
	Remark of the Renewal section	Registration of Benpime 1gm Injection (060428) applied afresh due to non-submission of renewal for the year.
	Remarks: Last contract extension permission vide letter No.F.8-5/2015-Reg-III (M-250) dated 28th August, 2015 valid till 30.06.2020 manufacture by **M/s. Shawan Pharmaceuticals, Islamabad**	
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Benpime 500mg Injection
	Composition	Each vial contains: Cefepime (as HCl with L-arginine)…….500mg

	Dairy No. date of R &I fee	7651 dated 29.07.2024 Rs.75000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s
	GMP Status	GMP certificate issued on 24th November, 2022
	Remark of the Renewal section	Registration of Benpime 500mg Injection (060429) applied afresh due to non-submission of renewal for the year.
	Remarks: Last contract extension permission vide letter No.F.8-5/2015-Reg-III (M-250) dated 28th August, 2015 valid till 30.06.2020 manufacture by M/s. Shawan Pharmaceuticals, Islamabad	
	Decision: Approved	

Case No. 05 M/s. Arreta Pharmaceuticals (Pvt) Ltd, Plot No.13, Street no. n-5, RCCI, Industrial Estate, Rawalpindi

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	088433	Nside Tablet 100mg Each film coated tablet contains: Nimesulide……100mg (As per innovator's Specifications)	12.03.2018 In the name of M/s Tayyab laboratories Change of title 14.01.2019	Dy No.10357 Rs.30, 000/- Dated 18.04.2023 Due date : 11.03.2023 Application received after due date within 60 days.	Renewal is granted w.e.f 12.03.2023 to 11.03.2028. **Formulation approved in RRA (AIFA Italy) is in uncoated form hence it need to be standardized in line with RRA along with fee.**

Remarks:
Firm has submitted differential fee as renewal applications submitted after due date but within sixty days as per SRO.1005/(i)/2017. Now the firm has requested for regularization for above mentioned product.

Case No. 06 M/s. Samara Stores 17, Qamar Market, Unit 07 Latifabad Hyderabad Pakistan

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Remarks
1.	034513	Amoxystin Water Soluble Powder Each gm Contains: Amoxycillin Trihydrate…200mg Colistin (as Sulphate)…800,000 IU	27/11/2004	Slip No. 5955551612 Dated: 05.11.2024 Rs.300, 000/- Dy No 13088 Dated 09.12.2024	Renewal is granted w.e.f 27.11.2024 to 26.11.2029 **Letter will be issued**

		Manufactured by: M/s The Arab Pesticides & veterinary Drugs Mfg Co Jordan)		Last renewal dated 26.08.2019	**after verification of CoPP from exporting country**

Remarks:

Firm has submitted renewal applications after due date but within 60 days , fee has been submitted as per SRO.1005/(I)/2017.

Case No. 07 M/s. Oval Pharmaceuticals 112/11, Quaid-e-Azam Industrial Estate Township, Lahore

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	049923	Reofen Suspension Each 5ml Contains Ibuprofen…100mg (BP specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	Renewal is granted 17.07.2023 to 16.07.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
2.	049924	Silvone Cream 50gm Each Tube Contains Silver Sulphadiazine…1%w/w (USP specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	Renewal is granted 17.07.2023 to 16.07.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
3.	049928	Moncaine Gel 15gm Each gm Contains Lidocaine HCl…2%w/w (USP specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/-	Renewal is granted 17.07.2023 to 16.07.2028

				Dated 09.12.2024	**Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
4.	049929	Xettol Antiseptic Solution Contains Chloroxylenol Solution…50%v/v (BP specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	Renewal is granted 17.07.2023 to 16.07.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
5.	049930	Iodine CMS Ointment Each Tube Contains Polymyxin Iodine…4%w/w Methyl Salicylate…5%w/w (BP specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	**Deferred for approval status of applied formulation in RRA.**
6.	049931	Polymalt-III Syrup Each 5ml Contains Iron (as Hydroxide Polymaltose)…50mg (oval's specification)	17-07-2008	Dy No.23032 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	Renewal is granted 17.07.2023 to 16.07.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
7.	049925	Septodine Antiseptic Solution	17-07-2008	Dy No.23032 Rs.30000/-	Renewal is granted

		Each 100ml Contains Povidone Iodine…10gm (USP specification)		19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	17.07.2023 to 16.07.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status**
8.	009884	GENTIAN VIOLET 0.5% LOT Contains GENTIAN VIOLET 0.5%, W/V	19/09/1988	Dy No.23031 Rs.30000/- 19.09.2023 & Dy No.13089 Rs.15000/- Dated 09.12.2024	Renewal is granted 19.09.2023 to 18.09.2028 **Letter will be issued after confirmation of section approval/manufacturing facility and updated DML status** Fee to be submitted for grant of finished product specification. As applied formulation is available in USP

Remarks:

Renewal applications was submitted after sixty days but within one year hence firm has submitted differential fee as per SRO.1005/(I)/2017. Now the firm has requested for regularization for above mentioned product.

Case No. 08 M/s. Jaens Pharmaceuticals (Pvt) Ltd. 25-km Lahore Sheikhupura Road, Sheikhupura

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Remarks/ Decision

1.	097639	Jeronum 1gm injection (IV) Each vial contains: Meropenem (as Trihydrate)……1gm (USP Specifications) **Manufactured by:** **M/s. Nichloas Pharmaceuticals, Islamabad**	22.08.2019	Tracking ID#QG4-92T-WGG6 Rs.372000/- Dated 20.12.2024	**Renewal is granted 22.08.2024 to 21.08.2029**
2.	097640	Jeronum 500mg injection (IV) Each vial contains: Meropenem (as Trihydrate)……500mg (USP Specifications) **Manufactured by:** **M/s. Nichloas Pharmaceuticals Islamabad**	22.08.2019	Tracking ID#73R-64Q-GZG2 Rs.372000/- Dated 20.12.2024	**Renewal is granted 22.08.2024 to 21.08.2029**
Remarks: Renewal applications was submitted after sixty days but within one year hence firm has submitted differential fee as per SRO.1005/(I)/2017. Now the firm has requested for regularization for above mentioned product.					

ItemNo. III Division of Quality Assurance & Laboratory Testing

CASE No. 01: 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, 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	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Result of CDL
Tempramine Suspension (Paracetamol 120mg/5ml, Chlorpheniramine maleate 1mg/5ml)	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-	5TR131	11- 2020	11- 2022	-do-
-do-	-do-	5TR052	05- 2020	05- 2022	-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

Decisions and Proceedings of 326th Meeting of Registration Board

Case was discussed in 326th Meeting of the Registration Board held on 14th - 16th March 2023. The Board after considering the facts of the case and after thorough deliberations decided:

1. *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.*
2. *Submission of RCA and CAPA by the firm.*
3. *Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*

Decisions and Proceedings of 164th Meeting of Appellate Board

Firm's appeal was discussed in 164th sitting of The Drugs Appellate Board, appeal was dismissed and decision of DRB was enforced in Appellate Board decision.

1. *For the foregoing reasons and discussions, the Appellate Board has decided that it is sufficiently proven beyond doubt that the Appellant manufactured 'sub-standard' Tempramine Syrup which endangered public health which is an offence under Section 23(1)(a)(v) of the Drugs Act, 1976. The Board noted with dismay that the Appellant has done nothing to improve the safety, quality and efficacy of Tempramine Syrup, which is also prescribed to minor and infants, thus endangering public health.*
2. *Taking guidance from Order by the Honorable Supreme Court dated 11-02-2023 passed in Civil Petition No. 2279/2022 the Appellant cannot be allowed to undertake manufacturing of Tempramine Syrup till the time that all defects leading to the Tempramine Syrup being 'sub-standard' are found, addressed and removed;*
3. *Consequent to the above, the Appellate Board holds that the Impugned Order has been found to be well reasoned, speaking, passed through application of mind, free from any jurisdictional error, misreading or non-reading of law or evidence and passed in a fair, unbiased and neutral manner by affording all due process rights to the Appellant. Therefore, for the reasons as provided above, the Appeal is dismissed. The following Order by the Registration Board shall be enforced in its letter and spirit in the larger public interest.*
4. *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.*
5. *Submission of RCA and CAPA by the firm.*
6. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT."

Honorable High Court Order

M/s Woodward Pakistan Pvt. Ltd. thereafter challenged it before the Honorable High Court in C.P. No. D-2506 of 2024. The Honorable Court through Order dated 22-05-2024 directed for its CAPA to be verified. The relevant excerpts are reproduced as under:

"In the meanwhile, respondents are directed to form panel and decide the application of the petitioner, seeking Corrective & Preventive Action, available at page 139, preferably, within a period of two weeks from the date of receipt of this order."

Panel of Inspection

A Panel for Inspection was created vide letter number F. 03-18/ 2023-QC(326-RB) dated 15-07-2024 comprising of following members:

1. Mr. Syed Hakim Masood, area FID, DRAP, Karachi
2. Dr. Saif ur Rehman Khattak, Director, CDL, Karachi
3. Dr. Awais Ahmad Juno, Assistant Director, CDL, Karachi.

Recommendations by Panel of Inspection

Consequently, inspection was conducted by panel on 23rd July 2024, and following conclusion and recommendations were given by panel:

Conclusion

1. *The comprehensive RCA/CAPA dated 03rd June 2024 was proper and satisfactory.*
2. *The improvement and formulation of tempramine suspension and necessary arrangements to manufacture the subject product in future as per standard quality parameters are also effective.*

Recommendations

1. *The firm, if allowed by Honorable Sindh High Court to manufacture the product must strictly observe the current good manufacturing practices (cGMP) in future.*

2. *Three validation batches must also be manufactured and studied for stability studies (accelerated and real time) on concurrent basis to establish long term stability of the revised formulation.*

Decision of Honorable High Court

The case was fixed for arguments on 24-09-2024 when the Honorable Court remanded the matter back to the Registration Board for decision on the Inspection Report. Relevant excerpt is reproduced as under:

"It is then requested by both counsel i.e. learned counsel for Petitioner and learned counsel for DRAP, that it may now be placed before the Registration Board for its further affect so that the Petitioner may be able to manage production, marketing and sale of their products."

Proceedings and Decision of 340th Meeting of Registration Board.

Panel inspection report and decision of Honorable High Court were presented before Registration Board. The Board, after considering the facts of the case and thorough deliberations, decided as follows:

1. ***Resumption of registration of Tempramine Suspension, Registration Number* 011432.**
2. ***Firm will conduct stability studies (accelerated and real time) up to assigned shelf life as per zone IV-A and will submit data in case of out of specification results.***
3. ***Additional Director, Karachi will nominate an officer for sampling of product, for test and analysis, from first three commercial batches of product and sale of product is allowed only after standard test and analysis report from CDL, Karachi.***

Updated Status of Case

Mr. Hakim Masood, FID, Karachi submitted vide letter No. SHM-166-168/2024-FID-IV (K) dated 17th December 2024, that as per direction of Additional Director. DRAP, Karachi he visited the premises of M/s W. Woodward Pakistan (Pvt) Ltd. situated at plot No. F-275. S.I.T.E, Karachi on 01-12-2024 and draw the samples from the first three commercial batches of Tempramin Suspension on prescribed Form-3. The Sealed samples were sent to the Federal Government Analyst, CDL, Karachi on prescribed Form-4. The Federal Government Analyst issued following test reports:

S. No.	Product Name	Batch No.	Mfg. Date	Exp. Date	CDL Report
1	Tempramine Suspension	9TR040	NOV 24	NOV 26	No. KQ- l2-24- 000169 dated l3th December 2024 **Standard Quality**
2	-do-	9TR041	NOV 24	NOV 26	No. KQ- l2-24- 000170 dated l3th December 2024 **Standard Quality**
3	-do-	9TR042	NOV 24	NOV 26	No. KQ- l2-24- 000172 dated l3th December 2024 **Standard Quality**

The Case is placed before the Board in the light of decision of 344th meeting of Registration Board.

Decision of 344th meeting of Registration Board

QA & LT Division presented the case before the Registration Board. The Board after threadbare deliberation decided to allow the sale of the product Tempramine Suspension.

The Board deliberated on the necessity of delegating power to streamline the handling of such matters.

After deliberation, the Board decided to delegate the following function / power to the Director of Quality Assurance & Laboratory Testing (QA&LT).

Functions / Powers	Functions / Powers Delegated to
Grant of permission of sale of product after fulfillment of compliance to decisions of Registration Board and standard report by CDL, Karachi.	Director Quality Assurance and Laboratory Testing

ItemNo. IV Division of Biological Evaluation & Research

Category	Import / Local	Type of application	Number
Human	Imported	New Biological Entities (NBEs)	11
		Deferred cases of previous meetings of the Registration Board (other than export)	02
		Biosimilar Products (Hard dossiers)	08
	Locally manufactured	Export cases	07
Veterinary	Imported	Veterinary Biological Products	39
	Locally manufactured	Veterinary Biological Products	01
Human	Imported	Post Registration Variation Case	01
		Total	**69**

Agenda Item No. 1. Registration Applications of New Biological Entities (NBEs)

S.No	Biological Entity	Brand name	Applicant
1.	Vaccine	Arexvy Vaccine Injection	GSK Pakistan Limited
2.	Vaccine	Abrysvo Powder & Solvent for Solution for Injection	Pfizer Pakistan Limited
3.	Vaccine	Prevenar 20 suspension for injection in pre-filled syringe	Pfizer Pakistan Limited
4.	(TPA) Tenecteplase	Metalyse Powder for solution for injection	Martin Dow Marker Limited
5.	Insulin Icodec	Awiqli® FlexTouch® 700U/mL, 1 ml pre-filled pen Solution for injection	Novo Nordisk Pharma (Pvt.) Ltd.
6.	Insulin Icodec	Awiqli® FlexTouch® 700U/mL, 1.5 ml pre-filled pen Solution for injection	Novo Nordisk Pharma (Pvt.) Ltd.
7.	Insulin Icodec	Awiqli® FlexTouch® 700U/mL, 3ml pre-filled pen Solution for injection	Novo Nordisk Pharma (Pvt.) Ltd.
8.	Monoclonal Antibody Avelumab	Bavencio 20mg/ml concentrate for solution for infusion	Martin Dow Specialties (Private) Limited
9.	Monoclonal Antibody Toripalimab	Tuoyi 240mg/6ml Vial	AJM Pharma Pvt Ltd
10.	Monoclonal Antibody Trinbelimab	Anti-D	OBS AGP (Private) Limited
11.	CTST	CTST	HealthBee Projects Private Limited

1.	**Name, address of Applicant / Importer**	**M/s GlaxoSmithKline Pakistan Limited,** **F-268, S.I.T.E., Karachi.**
	Details of Drug Sale License of importer	**License No: 063** **Address:** M/s GlaxoSmithKline Pakistan Limited F-268, S.I.T.E., Karachi **Address of Godown:** M/s Connect Logistics (Pvt.), Ltd, Plot No.73, B,C,D-K-28 Phase II Trans Liyari Quarters, Hawksbay Road, Karachi. **Validity: 03-10-2029** **Status:** Drug License by way of wholesale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	**Marketing Authorization Holder and Batch Release Site:** GlaxoSmithKline Biologicals SA Rue de I'Institut 89,1330 Rixensart, Belgium
	Name, address of manufacturer(s)	**Manufacturer of the Bulk finished product, primary packaging, secondary packaging** GlaxoSmithKline Biologicals SA Avenue Fleming, 20, 1300,Wavre, Belgium
	Name of exporting country	Belgium.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Legalized eCOPP** No. of Certificate:01/24/002086 Request:99582 Dated: 20 February 2024. Issued by EMA confirming Free sale and GMP. Electronic COPP has been verified at the following link: Authenticity verification for electronic certificates | European Medicines Agency (EMA) **Certificate Number** 01/24/002086 **Request Number** 99582 **Importing Country** PAKISTAN **Medicinal Product** Arexvy Powder and suspension for suspension for injection **Issued On** 20/02/2024 **Signed By** Alberto Ganan Jimenez **Signature validity** Signed and all signatures are valid.
	Details of letter of authorization / sole agency agreement	**Original Letter of authorization** **dated: 13th Feb 2024**  We hereby confirm that : Product license holder i.e., **GlaxoSmithKline Biologicals SA**, abbreviated GSK Biologicals SA or SmithKline Beecham Biologicals SA, a company organized and existing under the laws of Belgium, whose registered office is located at rue de l'Institut 89, 1330 Rixensart, Belgium, duly registered with the Central Database for Enterprises under enterprise number VAT BE 0440 872 918 (RPM Brabant wallon), authorizes **GlaxoSmithKline Pakistan Limited**, with registered offices at The Sykes Building, 35 Dockyard Road, West Wharf, Karachi, 74000, Pakistan, as their local authorized distributor for the following product in local market of 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	Tracking ID:L4T-P4X-JWMU Application Number:3686 December 25, 2024
Details of fee submitted	**Deposit Slip no**. 583397365565 **PKR** 300,000: **Dated** 15-11-2024
The proposed proprietary name / brand name	**Arexvy Vaccine**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**After reconstitution, one dose (0.5 mL) contains:** RSVPreF3[1] antigen[2],[3] - 120 micrograms; [1]Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3; [2]RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology; [3]adjuvanted with $AS01_E$ containing: plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) - 25 micrograms 3-O-desacyl-4'- monophosphoryl lipid A (MPL) from *Salmonella minnesota* - 25 micrograms
Dosage form of applied drug	Intramuscular injection
Pharmacotherapeutic Group of (API)	Not yet Assigned as per SMPC.
Reference to Finished product specifications	Innovator's specifications
Proposed pack size	Powder for 1 dose in a vial (type I glass) with stopper (butyl rubber). • Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber)
Proposed unit price	To be confirmed later
Shelf life	3 Years
Storage conditions	Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package in order to protect from light.
The status in reference regulatory authorities	The product is registered by USFDA,EMA.
For generic drugs (me-too status)	N/A

<table>
<tr><td>Module-II (Quality Overall Summary)</td><td>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.</td></tr>
<tr><td>Name, address of drug substance manufacturer</td><td>GlaxoSmithKline Biologicals SA
Parc de la Noire Epine Avenue Fleming, 20 1300 Wavre Belgium</td></tr>
<tr><td>Module-III Drug Substance:</td><td>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.</td></tr>
<tr><td>Stability Studies of Drug Substance
(Conditions & duration of Stability studies)</td><td>Based on the above, the Company proposes a shelf-life of 36 months at -45°C (≤-35°C) for RSVPreF3 purified bulk stored in HDPE bottles 1000 mL closed by polypropylene screw cap. The shelf-life is calculated as from the manufacturing date.</td></tr>
<tr><td>Module-III Drug Product:</td><td>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.</td></tr>
<tr><td>Analytical method validation/verification of product</td><td>Firm has submitted that the data from the PPQ batches demonstrate that the FDC drug product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and that the in-process tests are suitable to monitor the manufacturing process.</td></tr>
<tr><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product.</td></tr>
<tr><td>Container closure system of the drug product</td><td><table>
<tr><td>Material of construction</td><td>Coloured polypropylene top fixed on a natural aluminium varnished cap</td></tr>
<tr><td>Functionality</td><td>Secure the stopper to the vial</td></tr>
<tr><td>Contact with the product</td><td>The vial flip-off caps are not in contact with the product</td></tr>
<tr><td>Sterilisation</td><td>The vial flip-off caps are not sterilised</td></tr>
</table></td></tr>
<tr><td>Stability study data of drug product, shelf life and storage conditions</td><td>Long-term real time stability studies were conducted on the eight drug product lots upon 36-months storage at +5°C ± 3°C for lots DRSVA029A, DRSVA033A, DRSVA034B, DRSVA035A and DRSVA035B and after 24-months storage at +5°C ± 3°C for lots DRSVA039A, DRSVA040A and DRSVA041A. The results of this long-term real time stability study show that the stability data met the acceptance criteria in place for process 2.3 lots and the criteria proposed for commercial lots. These observations were confirmed by the results of statistical analyses which show that there are no statistically significant trends for the pH, RSVPreF3 In vitro relative potency and RSVPreF3 Trimer (batches DRSVA029A, DRSVA033A,</td></tr>
</table>

	DRSVA034B, DRSVA035A, DRSVA035B, DRSVA040A and DRSVA041A). A significant trend was observed for water content, showing an increase of 0.013 % per month. The increase is commonly observed for lyophilized products and is likely due to the progressive release of residual water from the vials stopper. In addition, a statistically significant trend was observed for RSVPreF3 Trimer only for batch DRSVA039A, which showed a decrease of -0.024% per month. Nevertheless, the shelf-life estimation applying the proposed specification limits of 95% supports an estimated shelf-life of 73 months, fully supporting the proposed shelf-life of 36 months for the commercial product. In conclusion, **these results support the use of RSVPreF3 final container lot of the commercial product up to 36 months after storage at +5°C ± 3°C**
Non-Clinical Studies	**DISCUSSION AND CONCLUSIONS** In the repeated dose toxicity studies in rabbits, administration of RSVPreF3/AS01B was well tolerated for 3 administrations once every 2 weeks as an IM injection of 120 µg or 240 µg RSVPreF3/dose. It was associated with local injection site inflammation, a transient mild systemic inflammatory response and changes in draining lymph nodes that were fully or partially reversed after the 4-week recovery period. All findings are consistent with the expected effect of a vaccine. No adverse findings were identified as any changes were of limited severity, did not impact the animal's health and well-being, and demonstrated complete or partial recovery. A safety margin to the intended clinical dose up to a factor 33.3 was calculated on a BW basis. The nonclinical safety of RSVPreF3/AS01E with regards to reproductive and developmental toxicity has been assessed in a GLP pre, peri and post-natal development study conducted in rabbits. There were no noteworthy findings in this study. The intramuscular administration of RSVPreF3/AS01E at 120 µg PreF3/dose was well tolerated and demonstrated no effects on female fertility, embryo-fetal, pre- and post-natal development. In summary, results from toxicity studies indicate that RSVPreF3/AS01 was generally well tolerated in a preclinical species and showed effects as expected from the stimulation of the immune response, provides a summary of key information of performed toxicity studies.
Clinical Studies	A Phase 3, open-label, randomized, controlled,multi-country study to evaluate the immune response,safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine in adults aged 60 years and above

Remarks of Evaluator

Overview

Arexvy is a vaccine used to protect adults 60 years of age and older against lower respiratory tract disease (LRTD, diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV). It can also be used in adults from 50 to 59 years old who are at increased risk for RSV disease. Arexvy contains a version of a protein found on the surface of the virus called RSVPreF3.

S #.	DRAP Questions	GSK Response	Evaluator Assessment
1	Submit Valid DSL	DSL is valid, copy is enclosed Annexure 01	Valid DSL has been provided by the applicant.

2	Provide name of exporting country	GlaxoSmithKline Biologicals SA Rue de I'Institut 89, B-1330 Rixensart, Belgium	Belgium is the exporting country.
3	The COPP does not provide any information about QC of the finished medicinal product	The QC Site of Finished Product is: GlaxoSmithKline Biologicals SA Parc de la Noire Epine Avenue Fleming, 20 1300 Wavre Belgium The details may be seen in Annexure 02	The applicant has now submitted the QC Site of Finished Product is: GlaxoSmithKline Biologicals SA Avenue Fleming, 20, 1300 Wavre Belgium. Therefore, requisite fee is required for correction in typographical error.
4	The manufacturing site mentioned on Form 5 F is different than COPP	In earlier submitted form MAH and batch release site was mentioned i.e. GlaxoSmithKline Biologicals SA Rue de I'Institut 89, B-1330 Rixensart, Belgium And the manufacturing site is: GlaxoSmithKline Biologicals SA Parc de la Noire Epine 20, Avenue Fleming, 1300, Wavre, Belgium Updated Form 5 F is also attached - Annexure 03	The applicant has now submitted the MAH and batch release site mentioned is GlaxoSmithKline Biologicals SA Rue de I'Institut 89, B-1330 Rixensart, Belgium And the manufacturing site is: GlaxoSmithKline Biologicals SA Avenue Fleming, 20, 1300, Wavre, Belgium Updated Form 5 F is also attached - Annexure 03. Therefore, requisite fee is required for correction in typographical error.
5	The LOA is between M/s GSK, 35 Dockyard instead of DSL holder. Clarification is required	GlaxoSmithKline Pakistan Ltd. hereby affirm as under: 1. GlaxoSmithKline Pakistan Ltd (GSK) is registered under its Head/ Corporate Office located at 35 Dockyard Road, West Wharf, Karachi, 74000 Pakistan with the Securities Exchange of Pakistan (SECP). Therefore, all agreements/contracts entered by GSK refer to the registered address. 2. GSK has three manufacturing sites located at: a. F/268, S.I.T.E., Karachi (DML No. 000233) b. Plot 5, Sector 21, Korangi Industrial Area, Karachi (DML No. 000248) c. 35-Dockyard Road, West Wharf, Road, Karachi (DML No. 000017) The above three sites have been duly registered as manufacturing sites and have their separate registrations with the Drug Regulatory Authority of Pakistan. The division of manufacturing of products is allocated amongst the three sites therefore, the Drug Manufacturing Licenses of products refer to the Site it is	GlaxoSmithKline Pakistan Ltd (GSK) is registered under its Head/ Corporate Office located at 35 Dockyard Road, West Wharf, Karachi, 74000 Pakistan with the Securities Exchange of Pakistan (SECP). Therefore, all agreements/contracts entered by GSK refer to the registered address.

		manufactured at and not the SECP registered address.	
6	Submit hard copy of COPP and LOA	CoPP and LOA copies are enclosed and original will be submitted to DRAP in person **Annexure 05**	Submitted by the Applicant.
7	Module 2 does not contain clinical overview and summary	Clinical overview and the summary data is enclosed **Annexure 06**	Clinical overview and the summary data has been provided.
8	Submit complete data for Module 4	Complete Module 4 (Non-Clinical Data) is enclosed including: Pharmacology Pharmacokinetic Toxicology **Annexure 07**	Complete data for Module 4 has been provided by the firm.

Decision of 344th Meeting: The Registration Board approved the formulation with shelf life of 36 months to be stored at 2 °C – 8 °C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of requisite fee for correction in manufacturing / QC site of Finished Product that is: GlaxoSmithKline Biologicals SA Avenue Fleming, 20, 1300 Wavre Belgium.

2.	**Name, address of Applicant / Importer**	**Pfizer Pakistan Limited** 12-Dockyard Road West Wharf Karachi
	Details of Drug Sale License of importer	**License No**: 035 **Address:** 12-Dockyard Road West Wharf Karachi **Address of Godown:** 12-Dockyard Road West Wharf Karachi **Validity:** Valid **Status:** Drug License by Way of Wholesale No. Renewal: License valid till 19-07-2028.
	Name and address of marketing authorization holder (abroad)	Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium
	Name, address of manufacturer(s)	**<u>Manufacturing of all steps of the finished medicinal product + Manufacturing of solvent</u>** Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium.
	Name of exporting	Belgium.

country	
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**eCOPP** Certificate No. 01/24/005213 Request: 100951 Dated: 15-05-2024 Issued by European Medicine Agency (EMA) The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. The eCOPP has been verified electronically at the following link: Authenticity verification for electronic certificates | European Medicines Agency (EMA) **Certificate Number** 01/24/005213 **Request Number** 100951 **Importing Country** PAKISTAN **Medicinal Product** Abrysvo Powder and solvent for solution for injection **Issued On** 15/05/2024 **Signed By** Alberto Ganan Jimenez **Signature validity** Signed and all signatures are valid.
Details of letter of authorization / sole agency agreement	**Original Letter of Authorization** Dated: 15th April 2024 **Letter of Authorization** The undersigned company Pfizer Europe MA EEIG having a principal place of business at Boulevard de la plaine 17, 1050 Bruxelles, Belgium as the MA holder in the country of origin hereby authorizes Pfizer Pakistan Limited, located at B-2, S.I.T.E., Karachi Pakistan to be responsible for all matters pertaining to the registration of the below mentioned product in Pakistan. **Product Description** / **Generic Name** Abrysvo, Powder and solvent for solution for injection Intramuscular Injection RSV subgroup A stabilised prefusion F protein RSV subgroup B stabilised prefusion F protein 120 mcg/0.5 mL (60 mcg of each prefusion protein antigen per dose)
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
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	**eApp. Tracking ID:** Y26-375-HNRS **Submission Date:** 09-11-2024
Details of fee submitted	PKR 75,000/-: (deposit slip no. 2423190231) dated, 04-10-2024 PKR 225,000/-: (deposit slip no. 7624691214) dated, 30-10-2024 Total Amount: 300,000/-
The proposed proprietary name / brand name	**Abrysvo Powder and Solvent for Solution for Injection** **Respiratory syncytial virus vaccine (bivalent, recombinant)**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	After reconstitution, one dose (0.5 mL) contains: RSV subgroup A stabilised prefusion F antigen[1,2] 60 micrograms RSV subgroup B stabilised prefusion F antigen[1,2] 60 micrograms (RSV antigens) [1]glycoprotein F stabilised in the prefusion conformation [2]produced in Chinese Hamster Ovary cells by recombinant DNA technology.
Pharmaceutical form of applied drug	Powder and solvent for solution for injection
Pharmacotherapeutic Group of (API)	Vaccines, other viral vaccines; ATC code: J07BX05
Reference to Finished product specifications	Innovator's Specs
Shelf Life	24 months As per submitted data.
Storage Condition	2-8°C
Proposed Pack size	Pack containing 1 vial of powder (antigens), 1 pre-filled syringe of solvent, 1 vial adaptor with 1 needle (1 dose pack). Pack containing 5 vials of powder (antigens), 5 pre-filled syringes of solvent, 5 vial adaptors with 5 needles (5 dose pack).
Proposed unit price	Will be provided at the time of Price Fixation
The status in reference regulatory authorities	EMA Approved.
For generic drugs (me-too status)	Not Applicable
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guideline including information related to Drug Substance and Drug Product. 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. Firm has also summarized information related to Process Parameters and in-Process Test of Drug Product.
Name, address of drug substance manufacturer	**Wyeth BioPharma** Division of Wyeth Pharmaceuticals LLC. One Burtt Road, Andover, MA 01810, USA.

Module-III Drug Substance:	**General information** 847A and 847B antigens are trimeric, recombinant glycoprotein ectodomain antigens from RSV produced in Chinese Hamster Ovary (CHO) cells. The sequence used for the 847A AS is derived from the Ontario RSV strain while the 847B sequence has been derived from the Buenos Aires RSV strain. **Manufacture, characterization and process controls** The active substances are manufactured in Wyeth BioPharma, Andover MA, USA. This is also the site of AS testing, master cell bank (MCB) storage and working cell bank (WCB) manufacture and AS storage for both 847A and 847B. MCBs for both are also stored in Pfizer Ireland Pharmaceuticals, Dublin, Ireland and additional WCB storage takes place at Pfizer Inc., 875 Chesterfield, MO, USA. The 847A and 847B manufacturing processes are highly similar with the only differences between both processes being a different maximum cell age at End of Production, mass challenge during ultrafiltration (UF)/ diafiltration (DF)1, load concentration during anion-exchange (AEX) chromatography and maximum time allowed for freezing post final filtration. The 847A and 847B AS manufacturing process follows a standard method for recombinant protein production. **A single 847A or 847B AS batch is manufactured from individual production fed-batch bioreactors to produce commercial scale material at approximately 12,000 L**. **Characterization** 847A and 847B can exist in two conformations, prefusion and post-fusion conformations. **Specification** The proposed specifications for **847A AS** are listed in Table 2 below. They include appropriate specifications for identity, potency, purity and physicochemical attributes (clarity; colouration; pH; 090177e19e1d904c\Final\Final On: 24-Jul-2023 16:18 (GMT) CHMP assessment report EMA/CHMP/290323/2023 Page 27/167 protein concentration, identity; relative prefusion content (potency); trimer; high molecular mass species; low molecular mass species; purity; residual HCP; bioburden and endotoxin). The proposed specifications for **847B AS** are listed in Table 3 below. They include appropriate specifications for identity, potency, purity and physicochemical attributes (clarity; colouration; pH; protein concentration, identity; relative prefusion content (potency); trimer; high molecular mass species; low molecular mass species; purity; residual HCP; bioburden and endotoxin).
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	A shelf life for both 847A and 847B AS of 24 months when stored at -40°C ± 10°C in EVA bags, is accepted.
RSVpreF Vaccine	
Module-III Drug Product:	Firm has submitted data of drug product of RSV including its description, composition, pharmaceutical development, manufacture, batch formula, 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 of materials, container closure system and stability studies.

	Analytical method validation/verification of product	Validation studies performed for non-compendial, endotoxin, and sterility methods for DP batch release and stability are provided.
	Container closure system of the drug product	<table><tr><th>Component</th><th>Description</th></tr><tr><td>Vial</td><td>2 mL Type I borosilicate glass vial, 13 mm finish OR 2 mL aluminosilicate glass vial, 13 mm finish</td></tr><tr><td>Vial Stopper</td><td>13 mm vial stopper composed of 4432/50 elastomer (synthetic chlorobutyl rubber)</td></tr><tr><td>Vial Seal</td><td>13 mm aluminum vial seal with tamper-evident polypropylene flip off cap</td></tr></table>
	Stability study data of drug product, shelf life and storage conditions	Results from stability studies on drug product stored at the long-term condition of 5 ± 3°C are presented for 11 primary lots and 4 supportive lots in Section 3.2.P.8.3 Long-Term. 090177e1a0e240f6\Approved\Approved On: 06-Jun-2024 16:26 (GMT) RSVpreF Vaccine (Pfizer) 3.2.P.8.1 Stability Summary and Conclusion PFIZER Currently there are 36 months of data available for 7 primary stability lots and 24 months of data available for process validation lots at 5 ± 3°C. There is also up to 48 months of data available for one of the supportive stability lots and 36 months for the other supportive lot. All data remained within the protocol acceptance criteria as well as the commercial stability acceptance criteria.
	Sterile Water for Injection	
	Module-III Drug Product:	Firm has submitted data of sterile water for injection including its description, composition, pharmaceutical development, manufacture, batch formula, 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 of materials, container closure system and stability studies.
	Analytical method validation/verification of product	The validation studies for endotoxin, sterility, and dye ingress methods performed for sterile water diluent are provided.
	Container closure system of the drug product	<table><tr><th>Component</th><th>Description</th></tr><tr><td>Syringe</td><td>1 mL BD Hypak Type I Borosilicate glass with plastic rigid tip cap (PRTC®) Luer lock connection. Syringe tip cap composed of gray West 7025/65 elastomer. Syringe barrel coated with Liveo 360 Medical fluid [a].</td></tr><tr><td></td><td>1 mL Schott Type I Borosilicate glass with syriQ® rigid cap Luer lock connection. Syringe tip cap composed of gray West 7025/65 elastomer. Syringe barrel coated wi Liveo 360 Medical fluid [a].</td></tr><tr><td>Plunger Stopper</td><td>1-3 mL stopper composed of gray West 4432/50 elastomer. Stopper is coated with Liveo 360 Medical fluid [a].</td></tr></table> a. The polydimethylsiloxane used in the production of the silicone emulsion used complies to the followir monographs: USP/NF Dimethicone, Ph.Eur. Dimeticone, Yakuki 327 Silicone Oil for Medical Device Lubricant (I) and INCI Dimethicone.
	Stability study data of drug product, shelf life and storage conditions	Currently there are 36 months of data available for 4 primary stability lots, 24 months of data available for 1 additional primary stability lot and 24 months of data available for the process validation lots at 5 ± 3°C. All data remain within the acceptance criteria in place at the time of testing as well as the commercial stability acceptance criteria.
	Non-Clinical Studies	RSVpreF were tested in a repeat-dose toxicity study in rats and in a combined fertility and pre- and postnatal developmental toxicity study in pregnant and lactating rabbits. In both studies, the vaccine formulations, with or without Al(OH)3, were administered IM (120 µg each of 847A and 847B, total of 240 µg antigens) at 2x the selected clinical dose (total of 120 µg antigens).

		Repeat-dose administrations of RSVpreF (1 dose every 3 or 2 weeks) for a total of 3 doses to Wistar Han rats were tolerated without evidence of systemic toxicity and produced a functional antibody response and anticipated local inflammatory reaction. Nonadverse immune responses and/or inflammatory reactions were evident at the injection sites and draining lymph nodes, and clinical pathology changes, when present, were consistent with immune stimulation or inflammation at the injection sites. These findings were interpreted to be nonadverse because of limited severity, lack of systemic findings, and absence of clinical signs. All findings were typical of those observed with administration of other vaccines, including aluminum-containing vaccines. In a fertility, reproductive, and developmental study in NZW rabbits, following administration of RSVpreF with or without Al(OH)3 twice premating and twice during gestation (for a total of 4 doses), there were no indications of maternal systemic toxicity or effects on mating performance or fertility in female rabbits or on embryo-fetal or postnatal survival, growth, or development in the F1 offspring.
	Clinical Studies	**Respiratory Syncytial Virus Bivalent Stabilized Prefusion F Subunit Vaccine (RSVpreF) For Maternal Immunization** • A Phase 3, randomized, doubleblinded, placebo-controlled trial to evaluate the efficacy and safety of a respiratory syncytial virus (RSV) prefusion F subunit vaccine in infants born to women vaccinated during pregnancy. • A Phase 2b, randomized, placebo controlled, observer-blinded trial to evaluate the safety, tolerability, and immunogenicity of a respiratory syncytial virus (RSV) vaccine in pregnant women 18 through 49 years of age and their infants. • A Phase 3, randomized, doubleblind, placebo-controlled study to evaluate the safety, tolerability, and immunogenicity of 3 lots of respiratory syncytial virus (RSV) prefusion F subunit vaccine in healthy adults. • \A Phase 2b, placebo-controlled, randomized, observer-blind study to evaluate the safety, tolerability, and immunogenicity of a respiratory syncytial virus (RSV) vaccine when administered concomitantly with tetanus, diphtheria, and acellular pertussis vaccine (Tdap) in healthy nonpregnant women 18 through 49 years of age. • A Phase 1/2, placebo-controlled, randomized, observer-blind, dosefinding, first-in-human study to describe the safety, tolerability, and immunogenicity of a respiratory syncytial virus (RSV) vaccine in healthy adults **Respiratory Syncytial Virus Bivalent Stabilized Prefusion F Subunit Vaccine (RSVpreF) For Older Adult Immunization** • A Phase 3 study to evaluate the efficacy, immunogenicity, and safety of respiratory syncytial virus (RSV) prefusion F subunit vaccine in adults. • A Phase 3, randomized, doubleblind, placebo-controlled study to evaluate the safety, tolerability, and immunogenicity of respiratory syncytial virus prefusion F subunit vaccine when coadministered with seasonal inactivated influenza vaccine in adults ≥65 years of age. • A Phase 1/2, placebo-controlled, randomized, observer-blind, dosefinding, first-in-human study to describe the safety, tolerability, and immunogenicity of a respiratory syncytial virus (RSV) vaccine in healthy adults.

		• A Phase 1/2, placebo-controlled, randomized, observer-blind, dosefinding, first-in-human study to describe the safety, tolerability, and immunogenicity of an adjuvanted respiratory syncytial virus (RSV) vaccine in healthy older adults. • Phase 2a, randomized, doubleblind, placebo-controlled study to evaluate the safety, jmmunogenicity and efficacy of a respiratory syncytial virus vaccine (RSVpreF) in a virus challenge model in healthy adults. • A Phase 2b, placebo-controlled, randomized, observer-blind study to evaluate the safety, tolerability, and immunogenicity of a respiratory syncytial virus (RSV) vaccine when administered concomitantly with tetanus, diphtheria, and acellular pertussis vaccine (Tdap) in healthy nonpregnant women 18 through 49 years of age. • Phase 3, randomized, doubleblind, placebo-controlled study to evaluate the safety, tolerability, and immunogenicity of 3 lots of respiratory syncytial virus (RSV) prefusion F subunit vaccine in healthy adults

Remarks of Evaluator

Overview

Abrysvo is a vaccine for protecting against lower respiratory tract disease (LRTD; diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV) in adults 60 years of age and older.

It is also for use in mothers during pregnancy to protect their infants against LRTD from birth through 6 months of age.

Abrysvo contains versions of two proteins found on the surface of the virus called RSV subgroup A stabilised prefusion F and RSV subgroup B stabilised prefusion F.

Shortcomings	**Applicant Response**	**Evaluator Remarks**
Hard copies of COPP , original/notarized valid LOA and valid DSL	We will submit the original, legalized and valid COPP, original/notarized valid LOA and valid DSL within two days. In fact, we submitted our application on eAPP so could not submit hard copies.	Applicant has provided hard copies of COPP , original LOA and valid DSL.
Place drug substance part before drug product part for Module 2.	We have attached the relevant file after correction.	Drug substance part has been placed before drug product part.
Submit complete Module 5.	Module 5 is attached with our initial application. But we will also provide USB (Within 2 days) containing complete dossier including M5.	Module 5 has been attached.
Submit stability data of drug substance and drug product of commercial batches till claimed shelf life.	We have attached the relevant file.	Stability data of 24 months have been provided.

In section 3.2.P.3.1 there are two testing sites mentioned i.e. Pfizer, Belgium and Pfizer, Ireland. Clarification is required.	Yes two sites are mentioned at 3.2.P.3.1. Apparently, Pfizer Puurs is the major site for all the activities including testing as mentioned in relevant section. But Pfizer Grange Castle, Ireland is also an additional site for testing. We have attached Table 3.2.P.5.3-1. where you can see all the activities related to testing being done at both sites.	**<u>Manufacturing of all steps of the finished medicinal product + Manufacturing of solvent</u>** Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium.

Decision of 344th Meeting: The Registration Board approved the formulation with shelf life of 24 months to be stored at 2 °C – 8 °C **as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of clarification for difference in address of importer mentioned on Letter of authorization located at B2 S.I.T.E Karachi and DSL located at 12-Dockyard Road West Wharf Karachi.**

3.	**Name, address of Applicant / Importer**	**M/s Pfizer Pakistan Limited** 12-Dockyard Road West Wharf, Karachi
	Details of Drug Sale License of importer	**License No**: 035 **Address:** 12-Dockyard Road West Wharf Karachi **Address of Go down:** 12-Dockyard Road West Wharf Karachi **Validity:** Valid **Status:** Drug License by Way of Wholesale No. Renewal: License valid till 19-07-2028.
	Name and address of marketing authorization holder (abroad)	M/s Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium
	Name, address of manufacturer(s)	**Manufacturing the bulk finished product and primary packaging of the dosage form** Pfizer Ireland Pharmaceuticals Grange Castle Business Park Clondalkin, Dublin 22, Ireland **Secondary Packaging & Batch Release by:** Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs-Sint-Amands Belgium
	Name of exporting country	Belgium
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**<u>eCOPP</u>** Certificate No: 01/24/009564 Request:102793 Dated 30-08-2024 Certifying Authority: European Medicine Agency (EMA) The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. The eCOPP has been verified electronically at the following link:

		Authenticity verification for electronic certificates | European Medicines Agency (EMA) **Certificate Number** 01/24/009564 **Request Number** 102793 **Importing Country** PAKISTAN **Medicinal Product** Prevenar 20 Suspension for injection **Issued On** 30/08/2024 **Signed By** Alberto Ganan Jimenez **Signature validity** Signed and all signatures are valid.
	Details of letter of authorization / sole agency agreement	**Original Letter of Authorization** **Dated: 15th April 2024** **Letter of Authorization** The undersigned company Pfizer Europe MA EEIG having a principal place of business at Boulevard d a plaine 17, 1050 Bruxelles, Belgium, as the MA holder in the country of origin hereby authorizes Pfize akistan Limited, located at B-2. S.I.T.E., Karachi Pakistan to be responsible for all matters pertaining t he regulation of these products in Pakistan. The following table shows the details for this product i akistan. **Product Description** / **Generic Name** Prevenar 20 Sterile Liquid Suspension in a Pre-filled Syringe / 20-valent Pneumococcal Conjugate (20vPnC) Vaccine Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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	**eApp. Tracking ID:** 335-NYP-6EHZ **Submission Date:** 11-11-2024
	Details of fee submitted	PKR 75,000/-: (deposit slip no. 05847147684) dated, 04-10-2024 PKR 225,000/-: (deposit slip no. 4025142975) dated, 30-10-2024 Total Amount: 300,000/-
	The proposed	**Prevenar 20 suspension for injection in pre-filled syringe**

	proprietary name / brand name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One dose (0.5 mL) contains: Pneumococcal polysaccharide serotype 1[1,2] 2.2 µg Pneumococcal polysaccharide serotype 3[1,2] 2.2 µg Pneumococcal polysaccharide serotype 4[1,2] 2.2 µg Pneumococcal polysaccharide serotype 5[1,2] 2.2 µg Pneumococcal polysaccharide serotype 6A[1,2] 2.2 µg Pneumococcal polysaccharide serotype 6B[1,2] 4.4 µg Pneumococcal polysaccharide serotype 7F[1,2] 2.2 µg Pneumococcal polysaccharide serotype 8[1,2] 2.2 µg Pneumococcal polysaccharide serotype 9V[1,2] 2.2 µg Pneumococcal polysaccharide serotype 10A[1,2] 2.2 µg Pneumococcal polysaccharide serotype 11A[1,2] 2.2 µg Pneumococcal polysaccharide serotype 12F[1,2] 2.2 µg Pneumococcal polysaccharide serotype 14[1,2] 2.2 µg Pneumococcal polysaccharide serotype 15B[1,2] 2.2 µg Pneumococcal polysaccharide serotype 18C[1,2] 2.2 µg Pneumococcal polysaccharide serotype 19A[1,2] 2.2 µg Pneumococcal polysaccharide serotype 19F[1,2] 2.2 µg Pneumococcal polysaccharide serotype 22F[1,2] 2.2 µg Pneumococcal polysaccharide serotype 23F[1,2] 2.2 µg Pneumococcal polysaccharide serotype 33F[1,2] 2.2 µg [1]Conjugated to CRM_{197} carrier protein (approximately 51 µg per dose) [2]Adsorbed on aluminium phosphate (0.125 mg aluminium per dose)
	Pharmaceutical form of applied drug	Pre-filled Syringe
	Pharmacotherapeutic Group of (API)	Vaccines, pneumococcal vaccines; ATC code: J07AL02
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	1 pre-filled syringe + 1 needle 10 pre-filled syringes + 10 needles
	Proposed unit price	Will be provided at the time of Price Fixation
	Shelf life	18 months. As per submitted stability data of commercial batches.
	Storage Condition	2-8˚C
	The status in reference regulatory authorities	EMA Approved.
	For generic drugs (me-too status)	Not Applicable.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guideline including information related to Drug Substance and Drug Product. 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.

<table>
<tr><td></td><td>Name, address of drug substance manufacturer Pneumococcal Polysaccharides

Manufacturing Sites for Pneumococcal Saccharide-CRM197 Conjugates</td><td>
Table 3.2.S.2.1-1. Pneumococcal Polysaccharide Manufacturing Sites
<table>
<tr><th rowspan="2">Site</th><th colspan="13">Pneumococcal Polysaccharide</th></tr>
<tr><th>1</th><th>3</th><th>4</th><th>5</th><th>6A</th><th>6B</th><th>7F</th><th>9V</th><th>14</th><th>18C</th><th>19A</th><th>19F</th><th>23F</th></tr>
<tr><td>Andover, MA, United States</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td></td><td>8</td><td>10A</td><td>11A</td><td>12F</td><td>15B</td><td>22F</td><td>33F</td></tr>
<tr><td>Sanford, NC, United States</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
</table>
Table 3.2.S.2.1-3. Pneumococcal Saccharide - CRM₁₉₇ Conjugate Manufacturing Sites
<table>
<tr><th rowspan="2">Site</th><th colspan="13">Pneumococcal Saccharide-CRM₁₉₇ Conjugate</th></tr>
<tr><th>1</th><th>3</th><th>4</th><th>5</th><th>6A</th><th>6B</th><th>7F</th><th>9V</th><th>14</th><th>18C</th><th>19A</th><th>19F</th><th>23F</th></tr>
<tr><td>Grange Castle Suite 1, Ireland</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X[a]</td><td>X</td><td></td><td></td><td>X[a]</td><td></td><td>X</td><td></td></tr>
<tr><td>Grange Castle Suite 2, Ireland</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td></td><td>X</td><td></td><td>X</td></tr>
<tr><td></td><td>8</td><td>10A</td><td>11A</td><td>12F</td><td>15B</td><td>22F</td><td>33F</td></tr>
<tr><td>Sanford, NC United States</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
</table>
a. Activated saccharides processed in Manufacturing Suite 1 may be shell frozen and lyophilized using equipment in Manufacturing Suite 2.
</td></tr>
<tr><td></td><td>Name, address of drug substance manufacturer CRM197</td><td>CRM197 derived from fermentation with casamino acid-yeast extract based medium (CRM197 (CY process)) is used to manufacture conjugates of serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and CRM197 derived from fermentation with defined medium (CRM197 (DM process)) is used to manufacture conjugates of serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F.
<table>
<tr><th>Site</th><th>Responsibilities</th></tr>
<tr><td>Wyeth Pharmaceutical Division of Wyeth Holdings LLC
4300 Oak Park
Sanford, NC 27330
United States</td><td>Cell bank manufacturing, testing and storage

Manufacture of CRM₁₉₇

Testing of CRM₁₉₇</td></tr>
<tr><td>Pfizer Inc.
875 Chesterfield Parkway West
Chesterfield, MO 63017
United States</td><td>Cell bank storage</td></tr>
</table>
Abbreviations: CRM₁₉₇ = diphtheria cross reactive material</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>Firm has submitted detailed drug substance data of CRM-CY, CRM-DS and all 20 serotypes related to general information (nomenclature, structure, general properties), Manufacturer, description of manufacturing process and controls, critical steps, process validation, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, batch formula, 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 of materials, container closure system and stability studies.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product. The validation studies for the following analytical procedures are documented in this section: aluminum concentration, total protein concentration and aluminum-</td></tr>
</table>

		bound protein, container closure integrity, identity (saccharide/CRM197), percent polysorbate 80, endotoxin, sterility, and total and bound antigenicity (SDS)
	Container closure system of the drug product	Syringe 1 mL Becton, Dickinson and Company Hypak Type I borosilicate glass with Plastic Rigid Tip Cap (PRTC) tip cap assembly that includes a Luer lock adapter, a rigid cap, and a tip cap. Syringe barrel is coated with silicone oil lubricant, compliant with Ph. Eur. 3.1.8. Tip cap is composed of gray West Pharmaceuticals (West) 7025/65 elastomer (synthetic isoprene/bromobutyl blend rubber). 1 mL Schott Pharmaceuticals Type I borosilicate glass with syriQ Rigid Cap (SRC) tip cap assembly that includes a Luer lock adapter, a rigid cap, and a tip cap. Syringe barrel is coated with silicone oil lubricant, compliant with Ph. Eur. 3.1.8. Tip cap is composed of gray West 7025/65 elastomer (synthetic isoprene/bromobutyl blend rubber).Plunger Stopper 1-3 mL plunger stopper composed of gray West 4432/50 elastomer (chlorobutyl rubber). Plunger stopper is coated with silicone oil lubricant, compliant with Ph. Eur. 3.1.8
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study. The data presented provide rationale and justification for the 20vPnC vaccine shelf life claim of 24 months when stored at the recommended temperature of 2-8 C. Expiration dating is from the date of manufacture of the filled syringes, defined as the date filling is initiated, to1 month less than the established expiration dating. The shelf life for drug product is based on 24 months of real time stability data from the primary stability lots generated at the long term condition of 5(+-)3C in the horizontal orientation. The 24 months of accumulated data available for the primary stability lots demonstrate that the quality attributes remain in conformance with the commercial stability acceptance criteria throughout the shelf life. Data accumulated from the 15 supportive lots stored at 5(+-)3 C further demonstrate that quality attributes remain in conformance with the commercial stability acceptance criteria throughout the claimed shelf life.
	Non Clinical Studies	**Pharmacology** ✓ VR-VTR-10620 - Immunogenicity of Streptococcus pneumoniae 20vPnC Vaccine in Rabbits (HT12-0009) ✓ VR-VTR-10621 - Immunogenicity of Streptococcus pneumoniae Serotype 8, 10A, 11A, 12F, 15B, 22F and 33F Conjugates in Mice ✓ VR-VTR-10555 - Evaluation of Cross-Functional Opsonophagocytic Immune ✓ Responses within Serotype 15 of Streptococcus pneumonia VR-VTR-10666 Immunogenicity of Seven New Streptococcus pneumoniae Conjugates in 20vPnC in Rats ✓ VR-VTR-10674 Immunogenicity of Streptococcus pneumoniae Serotype 33F Conjugates in Mice ✓ VR-VTR-10660 - Incidence of 4-keto-N-acetyl-quinovosamine in Streptococcus pneumoniae serotype 12F strains and Impact on Immunogenicity **Toxicology** **Repeat-Dose Toxicity** 12GR385 - 59-Day Intramuscular Toxicity Study of PF-06549581 and PF06482077 in Rabbits with a 30-Day Recovery Period Study 12GR385

	Clinical Studies	**Reports of Efficacy and Safety Studies (Adult IPD and Pneumonia)** **Reports of Controlled Clinical Studies Pertinent to the Claimed Indication** • B7471002-A Phase 2, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine in Adults 60 Through 64 Years of Age. • B7471004 - A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine (20VPNC) When Coadministered With Seasonal Inactivated Influenza Vaccine (SIIV) in Adults ≥65 Years of Age. • B7471006 - A Phase 3, Randomized, Open-Label Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine in Adults >= 65 Years of Age Without Prior Pneumococcal Vaccination. • B7471008 - A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of 3 Lots of a 20-Valen Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults 18 Through 49 Years of Age. • B7471026 - A Phase 3, Randomized, Double-Blind Trial to Describe the Safety and Immunogenicity of 20-valent Pneumococcal Conjugate Vaccine When Coadministered With a Booster Dose of BNT162b2 in Adults 65 Years of Age and Older **Reports of Efficacy and Safety Studies (Pediatric IPD and Pneumonia)** • **Reports of Controlled Clinical Studies Pertinent to the Claimed Indication** B7471003 - Phase 2, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine in Healthy Infants • B7471011 - Phase 3, randomized, double-blind, trial of safety and no inferior immunogenicity of a 4-dose series (2, 4, 6, and 12-15 months of age) • B7471012 - A Phase 3, Randomized, Double-Blind Trial To Evaluate The Safety And Immunogenicity Of A 20-Valent Pneumococcal Conjugate Vaccine Given As A Series Of 2 Infant Doses And 1 Toddler Dose In Healthy Infants • 7471013 - Phase 3, randomized, double-blind, trial of safety of a 4-dose series (2, 4, 6, and 12-15 months of age) • Study Reports of Uncontrolled Clinical Studies B7471014 - Phase 3, single-dose, open-label trial of safety and immunogenicity in children 15 months to <18 years of age.

Remarks of Evaluator

Shortcoming	Applicant Response	Evaluator Assessment
Clarification is required for submission of two COPPs.	We attached two CoPPs because we applied two pack sizes mentioned below. Pack Size: 1 pre-filled syringe + 1 needle 10 pre-filled syringes + 10 needles	There is no obligation on submission of separate COPP for each pack size.

There is variation between packaging site mentioned on Form 5 F and COPP.	Following sites mentioned on Form 5F and CoPP which are same. 1) Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland responsible for manufacturing the bulk finished product and primary packaging of the dosage form (Activity mentioned as b, f on CoPP) 2) Pfizer Manufacturing Belgium NV, Rijksweg 12 2870 Puurs-Sint-Amands Belgium, responsible for batch release of the finished medicinal product in the EU and secondary packaging of the product (Activity mentioned as e, g on CoPP)	**Manufacturing the bulk finished product and primary packaging of the dosage form** Pfizer Ireland Pharmaceuticals Grange Castle Business Park Clondalkin, Dublin 22, Ireland **Secondary Packaging & Batch Release by:** Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs-Sint-Amands Belgium
Revised Form 5 F providing details of concentration.	Revised Form 5F submitted.	Applicant has provided the revised Form 5 F.
Bookmark each S part separately and submit stability data of commercial batches.	File is attached for your reference	Each S part has been submitted separately and stability data of commercial batches have been attached.
Submit stability data of drug product of commercial batches.	File is attached for your reference	Stability data of 18 months for commercial batches have been attached.
Submit Module 5.	Already submitted and we will provide electronic form of dossier in USB within two days.	Submitted by the applicant.

Decision of 344th Meeting: The Registration Board approved the formulation with shelf life of 18 months to be stored at 2-8˚C as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022. Registration letter will be issued on submission of clarification for difference in address of importer mentioned on Letter of authorization located at B2 S.I.T.E Karachi and DSL located at 12-Dockyard Road West Wharf Karachi.

4.	**Name, address ofApplicant / Importer**	M/s **Martin Dow Marker Ltd.** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.
	Details of Drug Sale License of importer	License No: 0188 **Address:** 7th Floor, Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **Validity**: 07/12/2026
	Name and address of marketing authorization holder (abroad)	M/s Boehringer Ingelheim International GmbH Address: Binger Strasse 173 55216 Ingelheim am Rhein, Germany

	Name, address of manufacturer(s)	Name: M/s Boehringer Ingelheim Pharma GmbH & Co. KG Address: Birkendorfer Strasse 65, 88397 Biberach/ Riss, Germany
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. 01/24/009168), Request No.102638, dated 19-08-2024, issued by European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands. The CoPP specifiesthat the product is licensed for sale in the country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization/ sole agency agreement	Firm has submitted legalized Letter of Authorization from M**/s** Boehringer Ingelheim International GmbH, Binger Strasse 173 55216 Ingelheim am Rhein Germany, dated 07-08-2024.
	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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date ofsubmission	Tracking. No.: L75-785-3EQ6 R&I dated: 07-11-2024 **(Receipt of E-app)**
	Details of fee submitted	Rs: 300,000 Dated: 06-11-2024 Deposit Slip No. 6352223984
	The proposed proprietaryname / brand name	**Metalyse Powder for Solution for Injection**
	Strength /concentrationof drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Tenecteplase……5000 Units (25 mg)
	Dosage form of applieddrug	Powder for solution for injection
	PharmacotherapeuticGroup of (API)	Thrombolytic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	2–8 °C
	The status in referenceregulatory authorities	Metalyse Powder for solution for injection (EMC)

	For generic drugs (me-too status)	-
	Module-II (QualityOverall Summary)	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, referencestandard, 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	Name: Boehringer Ingelheim Pharma GmbH & Co. KG Address: Birkendorfer Strasse 65 88397 Biberach an der Riss Germany.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physicalform, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and itsvalidation, batch analysis, container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches as; **Long term stability data** (-20°C ± 5°C) at 0,6,12 and 24 months. **Accelerated stability study** (+5°C ± 3°C) at 0,1,2 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/ verification of product	Method validation was carried out for water content, Identification by RP-HPLC, High performance size exclusion chromatography, Single-chain, Capillary gel electrophoresis reduced, Imaged capillary isoelectric focusing, Clot lysis, Arginine, Polysorbate 90, Protein concentration by UV-scan, Bacterial Endotoxin, Sterility & Protein concentration by UVscan
	Container closure system of thedrug pro	The container closure system consists of primary packaging materials and secondary packaging materials. The primary container is a colourless type I borosilicate glass vial. The closure consists of two components: The 20 mm grey coated lyophilisation bromobutyl rubber stopper and a crimp cap made with aluminium crimp cap with dark blue plastic button. The Glass vial & plunger stopper complying with Ph. Eur. and USP edition.
	Stability study data ofdrug product, shelf storage conditions	Firm has submitted stability study data of 3 batches at real time andaccelerated conditions. The real time stability data provided is conducted at (+30°C ± 2°C/ 75%RH ± 5%) at 0,3,6,9,12,18,24,30 and 36 months. The accelerated stability data provided is of 03 batches and is conducted at (+40°C ± 2°C/ 75%RH ± 5%) at 12 months.
	Module-IV (Non-Clinical)	Firm has submitted: • Fibrinolytic activity of Tenecteplase carried out in rabbit, dog, and rat plasma Efficacy of tenecteplase in a rabbit arteriovenous shunt model of thrombolysis.
	Module-V (Clinical)	Firm has submitted, • A pilot dose-escalation safety study of tenecteplase in AIS. • Phase IIB/III trial of tenecteplase in AIS: results of a prematurely terminated randomised clinical trial. • Alteplase vs. tenecteplase for thrombolysis after ischaemic stroke (ATTEST): a Phase II, randomised, open-label, blinded endpoint study.

	Remarks of Evaluator	Application fulfils the requirement of CTD Dossier.
	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin, Registration Board approved the product in compliance of current Import Policy for finished drugs.	

5.	**Name, address of Applicant / Importer**	**M/s Novo Nordisk Pharma (Private) Limited,** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi- 75600 Pakistan
	Details of Drug Sale License of importer	**License No: 636** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi. **Address of go-down:** 208/1, Sector 23, KIA, Karachi **Validity:** 08.04.2028 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark.
	Name, address of manufacturer(s)	**Primary Packaging and Secondary Packaging:** Novo Nordisk A/S Brennum Park 1 DK-3400 Hillerød Denmark **Batch Release:** M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark
	Name of exporting country	Denmark
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP No. (01/24/010576), Request No.103243 dated 17/09/2024, issued by the European Medicine Agency. The CoPP specifies free sale status of the product in EU with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted attested and legalized letter of product specific authorization from Corporate Vice President of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark authorizes "M/s Novo Nordisk Pharma (Private) Limited" to import, distribute & sale the product. The letter was issued on 03-July-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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Tracking ID: 13V-AWM-RBYA, dated 19-11-2024
	Details of fee submitted	Rs. 300,000/ Deposit Slip No. 097782187871 Dated: 31/Oct/2024
	The proposed proprietary name / brand name	**Awiqli® FlexTouch® 700U/mL, 1ml pre-filled pen** **Solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains: 700 units of insulin icodec* in 1 mL solution 1 mL solution contains 700 units of insulin icodec* (equivalent to 26.8 mg insulin icodec). *produced in Saccharomyces cerevisiae by recombinant DNA technology.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, insulins and analogues for injection, long acting, ATC Code: A10AE07.
	Reference to Finished product specifications	In House Specifications
	Proposed Pack size	1 pre-filled pen with 9 disposable NovoFine Plus needles.
	Proposed unit price	As per SRO 228(I) 2024
	Shelf Life	30 Months
	Storage Conditions	Store in a refrigerator (2 °C - 8 °C).
	The status in reference regulatory authorities	The product is registered in EMA
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterisation of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.

	Name, address of drug substance manufacturer	Address	Activity
		Novo Nordisk A/S Hallas Allé 1 DK-4400 Kalundborg Denmark	Manufacture of drug substance: Fermentation, recovery and purification Storage of Master Cell Bank and Working Cell Banks
		Novo Nordisk A/S Novo Allé 1 DK-2880 Bagsværd Denmark	Manufacture of Working Cell Banks Storage of Master Cell Bank and Working Cell Banks
	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 process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: 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 for the primary stability studies and the PV study stored at -20°C ± 5°C are within the acceptance criteria for all tested parameters and show no change over time. All batches have comparable stability profiles. The data for each test parameter in the stability studies stored at accelerated conditions at +5°C ± 3°C for 12 months show no change over time. All batches have comparable stability profiles. All studies show that batches from the primary stability study have comparable stability profile to the batches from the PV stability study supporting a shelf life for insulin icodec of 30 months when stored at -20°C ± 5°C. Batch Number: (LU20011, LU20012 and LU20013)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.	
	Analytical method validation/verification of product	Firm has submitted analytical methods as per In House Specs. The methods are Validated as per SOP's. The Analytical methods are as follows: • Macroscopy • Identity of insulin icodec • Identity B of insulin icodec • Content of insulin icodec • pH • High molecular weight proteins • Hydrophilic impurities • Hydrophilic related substances • Hydrophobic related substances • Hydrophobic impurities • Zinc total • Bacterial endotoxins • Sterility • Identity of metacresol • Identity of phenol	

		• Metacresol • Phenol • Particulate matter ≥10 µm ≥25 µm • Dose accuracy • Extractable volume
	Container closure system of the drug product	The cartridge system 1 ml consists of the following components: 1. A cartridge 1 ml made of type 1 glass, colourless. 2. A rubber plunger made of chlorobutyl rubber. 3. A laminate rubber disc (primary packaging) inserted in an aluminium cap (secondary packaging). The rubber disc is made of laminated bromobutyl and isoprene rubber. The bromobutyl rubber is in direct contact with the drug product.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. Three primary stability batches of each variant of insulin icodec drug product are tested in stability for up to 36 months at long-term storage condition (5°C ± 3°C), and up to 6 months and 3 months at accelerated storage conditions (25°C ± 2°C) and (30°C ± 2°C), respectively. Based on the conducted stability studies for the three variants of insulin icodec drug product, the proposed shelf life and storage for the drug-device combination product of 30 months at 2 – 8°C including an in-use period of 12 weeks at or below 30°C is justified. Batch Number: LLDG010A, LLDG011A, LLDG012A
	Module-IV	The Firm has submitted following non-clinical studies: **1. Overview of Pharmacology Studies** • Primary pharmacology • Secondary Pharmacology • Safety Pharmacology • Pharmacokinetic drug interaction **2. Overview of Pharmacokinetic Studies** • Absorption • Distribution • Metabolism and excretion • Pharmacokinetic drug interaction • Other Pharmacokinetic studies **3. Overview of Toxicology Studies** • Single Dose Toxicity • Repeat Dose Toxicity • Genotoxicity • Carcinogenicity • Reproductive and Development Toxicity • Fertility and early embryonic development • Embryo-fetal development • Prenatal and postnatal development, including maternal function • Studies in Juvenile Animals • Impurities • Local Tolerance

		• Other Toxicity studies
	Module-V	The Firm has submitted following clinical studies: • Randomised, double-blind, double dummy, active-controlled. Single centre, multiple-dose, dose escalation • Single-centre, single dose, open label, parallel group • Randomised, 2-period crossover, single-centre, open-label, multiple dose • Randomised, single-centre, open label, 2-period crossover, multiple dose • Randomised, single-centre, open label, 2-period cross-over, multiple dose • Single-centre, open-label, one period, multiple-dose 2-centre, single-dose, open-label, parallel-group • Single-centre, open-label, single group, multiple-dose • Randomised, single-centre, open label, 3-period cross-over • Randomised, double-blind, double dummy, active-controlled, parallel group, stratified, multicenter, multinational, treat-to-target • Multinational, multi centre, randomised, open label, active controlled, parallel-group • Randomised, multinational, multi centre, open label, active controlled, parallel-group • Randomised, open label, parallel group, active-controlled, multi centre, multinational, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, stratified, double blinded, double dummy, active controlled, parallel-group, multi centre, multiregional, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, open label, parallel group, active-controlled, multi centre, multi-national • Randomised, multi-centre, multinational, open-label, active controlled, parallel-group, treat-to-target • A Trial Investigating the Pharmacokinetic Properties of insulin icodec after Administration in Different Injection Regions in Subjects with Type 2 Diabetes • In vitro binding to mouse, rat, rabbit, dog and human plasma proteins • In vitro binding of NNC 0148-0000-0287 to human serum albumin • Binding Affinity for Human Serum Albumin • Comparative Study of Binding Affinities for Human, Rat, Rabbit, Canine and Porcine Serum Albumins • Metabolism in mouse, rat, rabbit, dog and human hepatocytes, a cross-species comparison • In Vitro Metabolism with Human Insulin Degrading Enzyme • Metabolite Analysis of Human Serum from Male Subjects with Type 2 Diabetes Following Multiple Subcutaneous Dosing of insulin 287 – Samples from Trial NN1436-4314 • A Meta-Analysis of Data from NN1436-4383, NN1436-4478, NN1436-4479, NN1436-4480, and NN1436-4625 Integrated summary of immunogenicity
	Remarks of Evaluator	Application fulfils the requirement of CTD Dossier.

	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.

6.	**Name, address of Applicant / Importer**	**M/s Novo Nordisk Pharma (Private) Limited,** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi- 75600 Pakistan
	Details of Drug Sale License of importer	**License No: 636** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi. **Address of go-down:** 208/1, Sector 23, KIA, Karachi **Validity:** 08.04.2028 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark.
	Name, address of manufacturer(s)	**Primary Packaging and Secondary Packaging:** Novo Nordisk A/S Brennum Park 1 DK-3400 Hillerød Denmark **Batch Release** M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark
	Name of exporting country	Denmark
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP No. (01/24/010576) Request No.103243 dated 17/09/2024, issued by the European Medicine Agency. The CoPP specifies free sale status of the product in EU with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted attested and legalized letter of product specific authorization from Senior Vice President (Submission and Life Cycle Management) of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark authorizes "M/s Novo Nordisk Pharma (Private) Limited" to import, distribute & sale the product. The letter was issued on 03-July-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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Tracking no. J2Q-GGT-X1UJ Dated: 19-11-2024
	Details of fee submitted	Rs. 300,000/ Deposit Slip No. 53878567 Dated: 31/Oct/2024
	The proposed proprietary name / brand name	**Awiqli® FlexTouch® 700U/mL, 1.5 ml pre-filled pen** **Solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains: Each pre-filled pen contains 1050 units of insulin icodec* in 1.5 mL solution. 1 mL solution contains 700 units of insulin icodec* (equivalent to 26.8 mg insulin icodec). **produced in Saccharomyces cerevisiae by recombinant DNA technology.*
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, insulins and analogues for injection, long acting, ATC Code: A10AE07.
	Reference to Finished product specifications	In House Specifications
	Proposed Pack size	1 pre-filled pen with 13 disposable NovoFine Plus needles
	Proposed unit price	As per SRO 228(I) 2024
	Shelf Life	30 Months
	Storage Conditions	Store in a refrigerator (2 °C - 8 °C).
	The status in reference regulatory authorities	The product is registered in EMA
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterisation of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.

	Name, address of drug substance manufacturer	Address	Activity
		Novo Nordisk A/S Hallas Allé 1 DK-4400 Kalundborg Denmark	Manufacture of drug substance: Fermentation, recovery and purification Storage of Master Cell Bank and Working Cell Banks
		Novo Nordisk A/S Novo Allé 1 DK-2880 Bagsværd Denmark	Manufacture of Working Cell Banks Storage of Master Cell Bank and Working Cell Banks
	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 process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: 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 for the primary stability studies and the PV study stored at -20°C ± 5°C are within the acceptance criteria for all tested parameters and show no change over time. All batches have comparable stability profiles. The data for each test parameter in the stability studies stored at accelerated conditions at +5°C ± 3°C for 12 months show no change over time. All batches have comparable stability profiles. All studies show that batches from the primary stability study have comparable stability profile to the batches from the PV stability study supporting a shelf life for insulin icodec of 30 months when stored at -20°C ± 5°C. Batch Number: (LU20011, LU20012 and LU20013)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.	
	Analytical method validation/verification of product	Firm has submitted analytical methods as per In House Specs. The methods are Validated as per SOP's. The Analytical methods are as follows: • Macroscopy • Identity of insulin icodec • Identity B of insulin icodec • Content of insulin icodec • pH • High molecular weight proteins • Hydrophilic impurities • Hydrophilic related substances • Hydrophobic related substances • Hydrophobic impurities • Zinc total • Bacterial endotoxins • Sterility • Identity of metacresol	

		• Identity of phenol • Metacresol • Phenol • Particulate matter ≥10 µm ≥25 µm • Dose accuracy • Extractable volume
	Container closure system of the drug product	The cartridge system 1.5 ml consists of the following components: 1. A cartridge 1.5 ml made of type 1 glass, colourless. 2. A rubber plunger made of chlorobutyl rubber. 3. A laminate rubber disc (primary packaging) inserted in an aluminium cap (secondary packaging). The rubber disc is made of laminated bromobutyl and isoprene rubber. The bromobutyl rubber is in direct contact with the drug product.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. Three primary stability batches of each variant of insulin icodec drug product are tested in stability for up to 36 months at long-term storage condition (5°C ± 3°C), and up to 6 months and 3 months at accelerated storage conditions (25°C ± 2°C) and (30°C ± 2°C), respectively. Based on the conducted stability studies for the three variants of insulin icodec drug product, the proposed shelf life and storage for the drug-device combination product of 30 months at 2 – 8°C including an in-use period of 12 weeks at or below 30°C is justified Batch Number: KW59Y70, KW59Y71 and KW59Y74
	Module-IV	The Firm has submitted following non-clinical studies: **1. Overview of Pharmacology Studies** • Primary pharmacology • Secondary Pharmacology • Safety Pharmacology • Pharmacokinetic drug interaction **2. Overview of Pharmacokinetic Studies** • Absorption • Distribution • Metabolism and excretion • Pharmacokinetic drug interaction • Other Pharmacokinetic studies **3. Overview of Toxicology Studies** • Single Dose Toxicity • Repeat Dose Toxicity • Genotoxicity • Carcinogenicity • Reproductive and Development Toxicity • Fertility and early embryonic development • Embryo-fetal development • Prenatal and postnatal development, including maternal function • Studies in Juvenile Animals • Impurities • Local Tolerance • Other Toxicity studies

	Module-V	The Firm has submitted following clinical studies: • Randomised, double-blind, double dummy, active-controlled. Single centre, multiple-dose, dose escalation • Single-centre, single dose, open label, parallel group • Randomised, 2-period crossover, single-centre, open-label, multiple dose • Randomised, single-centre, open label, 2-period crossover, multiple dose • Randomised, single-centre, open label, 2-period cross-over, multiple dose • Single-centre, open-label, one period, multiple-dose 2-centre, single-dose, open-label, parallel-group • Single-centre, open-label, single group, multiple-dose Randomised, single-centre, open label, 3-period cross-over • Randomised, double-blind, double dummy, active-controlled, parallel group, stratified, multicenter, multinational, treat-to-target • Multinational, multi centre, randomised, open label, active controlled, parallel-group • Randomised, multinational, multi centre, open label, active controlled, parallel-group • Randomised, open label, parallel group, active-controlled, multi centre, multinational, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, stratified, double blinded, double dummy, active controlled, parallel-group, multi centre, multiregional, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, open label, parallel group, active-controlled, multi centre, multi-national • Randomised, multi-centre, multinational, open-label, active controlled, parallel-group, treat-to-target • A Trial Investigating the Pharmacokinetic Properties of insulin icodec after Administration in Different Injection Regions in Subjects with Type 2 Diabetes • In vitro binding to mouse, rat, rabbit, dog and human plasma proteins • In vitro binding of NNC 0148-0000-0287 to human serum albumin • Binding Affinity for Human Serum Albumin • Comparative Study of Binding Affinities for Human, Rat, Rabbit, Canine and Porcine Serum Albumins • Metabolism in mouse, rat, rabbit, dog and human hepatocytes, a cross-species comparison • In Vitro Metabolism with Human Insulin Degrading Enzyme • Metabolite Analysis of Human Serum from Male Subjects with Type 2 Diabetes Following Multiple Subcutaneous Dosing of insulin 287 – Samples from Trial NN1436-4314 • A Meta-Analysis of Data from NN1436-4383, NN1436-4478, NN1436-4479, NN1436-4480, and NN1436-4625 Integrated summary of immunogenicity
	Remarks of Evaluator	Application fulfils the requirement of CTD Dossier.

	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.

7.	**Name, address of Applicant / Importer**	**M/s Novo Nordisk Pharma (Private) Limited,** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi- 75600 Pakistan
	Details of Drug Sale License of importer	**License No: 636** **Address:** 113, Shahrah-e-Iran, Clifton, Karachi. **Address of go-down:** 208/1, Sector 23, KIA, Karachi **Validity:** 08.04.2028 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark.
	Name, address of manufacturer(s)	**Primary Packaging and Secondary Packaging:** Novo Nordisk A/S Brennum Park 1 DK-3400 Hillerød Denmark **Batch Release:** M/s Novo Nordisk A/S, Novo Allé 1, DK-2880 Bagsværd, Denmark
	Name of exporting country	Denmark
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted CoPP No. (01/24/010576) Request No.103243 dated 17/09/2024, issued by the European Medicine Agency. The CoPP specifies free sale status of the product in EU with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted attested and legalized letter of product specific authorization from Senior Vice President (Submission and Life Cycle Management) of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark authorizes "M/s Novo Nordisk Pharma (Private) Limited" to be their wholly owned subsidiary and sole importer in Pakistan and to import, distribute & sale the product. The letter was issued on 03-July-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 ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Tracking No. QQ7-WTQ-98XJ Dated 19-11- 2024
	Details of fee submitted	Rs. 300,000/ Deposit Slip No. 74926425548 Dated: 31/Oct/2024
	The proposed proprietary name / brand name	**Awiqli® FlexTouch® 700U/mL, 3ml pre-filled pen** **Solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains: 2100 units of insulin icodec* in 3 mL solution 1 mL solution contains 700 units of insulin icodec* (equivalent to 26.8 mg insulin icodec). **produced in Saccharomyces cerevisiae by recombinant DNA technology.*
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, insulins and analogues for injection, long acting, ATC Code: A10AE07.
	Reference to Finished product specifications	In House Specifications
	Proposed Pack size	1 pre-filled pen with 13 disposable NovoFine Plus needles
	Proposed unit price	As per SRO 228(I) 2024
	Shelf Life	30 Months
	Storage Conditions	Store in a refrigerator (2 °C - 8 °C).
	The status in reference regulatory authorities	The product is registered in EMA
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubilities, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterisation of impurities and justification of specification, reference

		standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.	
	Name, address of drug substance manufacturer	Address	Activity
		Novo Nordisk A/S Hallas Allé 1 DK-4400 Kalundborg Denmark	Manufacture of drug substance: Fermentation, recovery and purification Storage of Master Cell Bank and Working Cell Banks
		Novo Nordisk A/S Novo Allé 1 DK-2880 Bagsværd Denmark	Manufacture of Working Cell Banks Storage of Master Cell Bank and Working Cell Banks
	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 process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: 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 for the primary stability studies and the PV study stored at -20°C ± 5°C are within the acceptance criteria for all tested parameters and show no change over time. All batches have comparable stability profiles. The data for each test parameter in the stability studies stored at accelerated conditions at +5°C ± 3°C for 12 months show no change over time. All batches have comparable stability profiles. All studies show that batches from the primary stability study have comparable stability profile to the batches from the PV stability study supporting a shelf life for insulin icodec of 30 months when stored at -20°C ± 5°C. Batch Number: (LU20011, LU20012 and LU20013)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.	
	Analytical method validation/verification of product	Firm has submitted analytical methods as per In House Specs. The methods are Validated as per SOP's. The Analytical methods are as follows: • Macroscopy • Identity of insulin icodec • Identity B of insulin icodec • Content of insulin icodec • pH • High molecular weight proteins • Hydrophilic impurities • Hydrophilic related substances • Hydrophobic related substances • Hydrophobic impurities	

		• Zinc total • Bacterial endotoxins • Sterility • Identity of metacresol • Identity of phenol • Metacresol • Phenol • Particulate matter ≥10 µm ≥25 µm • Dose accuracy • Extractable volume
	Container closure system of the drug product	The cartridge system 3 ml consists of the following components: 1. A cartridge 3 ml made of type 1 glass, colourless. 2. A rubber plunger made of chlorobutyl rubber. 3. A laminate rubber disc (primary packaging) inserted in an aluminium cap (secondary packaging). The rubber disc is made of laminated bromobutyl and isoprene rubber. The bromobutyl rubber is in direct contact with the drug product.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. Three primary stability batches of each variant of insulin icodec drug product are tested in stability for up to 36 months at long-term storage condition (5°C ± 3°C), and up to 6 months and 3 months at accelerated storage conditions (25°C ± 2°C) and (30°C ± 2°C), respectively. Based on the conducted stability studies for the three variants of insulin icodec drug product, the proposed shelf life and storage for the drug-device combination product of 30 months at 2 – 8°C including an in-use period of 12 weeks at or below 30°C is justified. Batch Number: KW59F35, KW59F36 and KW59E02
	Module-IV	The Firm has submitted following non-clinical studies: **1. Overview of Pharmacology Studies** • Primary pharmacology • Secondary Pharmacology • Safety Pharmacology • Pharmacokinetic drug interaction **2. Overview of Pharmacokinetic Studies** • Absorption • Distribution • Metabolism and excretion • Pharmacokinetic drug interaction • Other Pharmacokinetic studies **3. Overview of Toxicology Studies** • Single Dose Toxicity • Repeat Dose Toxicity • Genotoxicity • Carcinogenicity • Reproductive and Development Toxicity • Fertility and early embryonic development • Embryo-fetal development

		• Prenatal and postnatal development, including maternal function • Studies in Juvenile Animals • Impurities • Local Toleranc • Other Toxicity studies
	Module-V	The Firm has submitted following clinical studies: • Randomised, double-blind, double dummy, active-controlled. Single centre, multiple-dose, dose escalation • Single-centre, single dose, open label, parallel group • Randomised, 2-period crossover, single-centre, open-label, multiple dose • Randomised, single-centre, open label, 2-period crossover, multiple dose • Randomised, single-centre, open label, 2-period cross-over, multiple dose • Single-centre, open-label, one period, multiple-dose • 2-centre, single-dose, open-label, parallel-group • Single-centre, open-label, single group, multiple-dose • Randomised, single-centre, open label, 3-period cross-over • Randomised, double-blind, double dummy, active-controlled, parallel group, stratified, multicenter, multinational, treat-to-target • Multinational, multi centre, randomised, open label, active controlled, parallel-group • Randomised, multinational, multi centre, open label, active controlled, parallel-group • Randomised, open label, parallel group, active-controlled, multi centre, multinational, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, stratified, double blinded, double dummy, active controlled, parallel-group, multi centre, multiregional, treat-to-target • Randomised, open label, active controlled, parallel group, multi centre, multinational, treat-to-target • Randomised, open label, parallel group, active-controlled, multi centre, multi-national • Randomised, multi-centre, multinational, open-label, active controlled, parallel-group, treat-to-target • A Trial Investigating the Pharmacokinetic Properties of insulin icodec after Administration in Different Injection Regions in Subjects with Type 2 Diabetes • In vitro binding to mouse, rat, rabbit, dog and human plasma proteins • In vitro binding of NNC 0148-0000-0287 to human serum albumin • Binding Affinity for Human Serum Albumin • Comparative Study of Binding Affinities for Human, Rat, Rabbit, Canine and Porcine Serum Albumins • Metabolism in mouse, rat, rabbit, dog and human hepatocytes, a cross-species comparison • In Vitro Metabolism with Human Insulin Degrading Enzyme • Metabolite Analysis of Human Serum from Male Subjects with Type 2 Diabetes Following Multiple Subcutaneous Dosing of insulin 287 – Samples from Trial NN1436-4314

		• A Meta-Analysis of Data from NN1436-4383, NN1436-4478, NN1436-4479, NN1436-4480, and NN1436-4625 Integrated summary of immunogenicity
	Remarks of Evaluator	Application fulfils the requirement of CTD Dossier.
	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.	

8.	**Name, address ofApplicant / Importer**	**M/s Martin Dow Specialties (Private) Limited.** Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.
	Details of Drug Sale License of importer	License No: 0186 **Address:** 7th Floor, Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi **Validity**: 07/12/2026
	Name and address of marketing authorization holder (abroad)	M/s **Merck Europe BV** Address: Gustav Mahlerplein 102, 1082, MA Amsterdam, The Netherlands
	Name, address of manufacturer(s)	Name: Merck Serono SA Address: Succursale d'Aubonne Zone Industrielle de l'Ouriettaz 1170 Aubonne Switzerland
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP Certificate No: 01/24/005804, Request No.101200, from European Medicines Agency (EMA) located at Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netharlands. The COPP specifiesthat the product is licensed for sale in the country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization/ sole agency agreement	Firm has submitted legalized Letter of Authorization Certificate from Merck Europe B.V, Gustav Mahlerplein 102, 1082, MA Amsterdam, The Netherlands, dated 06-06-2024.
	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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date ofsubmission	Application Tracking ID.: RM1-TZB-UD6E Through E-app dated: 08-11-2024
	Details of fee submitted	Rs: 300,000/- Dated: 06-11-2024 Deposit Slip No. 0817185751
	The proposed proprietaryname / brand name	**Bavencio 20 mg/mL concentrate for solution for infusion**
	Strength /concentrationof drug of Active Pharmaceutical ingredient (API) per unit	Concentrate for solution for infusion Each mL of concentrate contains Avelumab …….20mg One vial of 10 mL contains 200 mg of Avelumab
	Dosage form of applieddrug	Concentrate for solution for infusion
	PharmacotherapeuticGroup of (API)	Monoclonal antibodies
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's (10ml Vial)
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	2°C - 8°C
	The status in referenceregulatory authorities	Bavencio 20 mg/mL concentrate for solution for infusion – European Medicine Agency (EMA) – CoPP has been provided.
	For generic drugs (me-too status)	-
	Module-II (QualityOverall Summary)	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non- clinical and clinical overviews and summaries.
	Name, address of Drug substance manufacturer	M/s **MERCK SERONO SA** Address: Succursale d'Aubonne Zone Industrielle de l'Ouriettaz 1170 Aubonne Switzerland
	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, container closure system.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches as; **Long term stability data** (+5°C ± 3°C) at 0,3,6,9,12, 18, 24 & 36 months. **Accelerated stability study** (+25°C ± 2°C, 60% ± 5%) at 0,3 & 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.
	Analytical method validation/ verification of product	For validation of the analytical procedures for identity by SE-HPLC, identity by iCE, charge variants by iCE, protein content by optical density, biological activity by blockade bioassay, HMW species by SE-HPLC, LMW species by non-reduced CE-SDS, electrophoretic purity by reduced CE-SDS, deamidation by IEX-HPLC, and oxidation by peptide mapping/RP-UPLC.
	Container closure system of thedrug proc	The primary container consists of a 16 mL nominal capacity colorless type I borosilicate glass vial (Ph.Eur., USP and JP, current version). The Closure consists of two components: A grey halobutyl rubber stopper, fluoro resin laminated (Ph.Eur. and USP, current version) & An aluminium seal fitted with a removable plastic cap
	Stability study data ofdrug product, shelf storage conditions	Firm has submitted stability study data of 3 batches at real time and accelerated conditions. The real time stability data provided is conducted at (+5°C ± 3°C) at 0, 1, 2, 3, 6, 9, 12, 18 & 24 36, 48 & 60 months. The accelerated stability data provided is of 03 batches and is conducted at (+25°C ± 2°C/ 60%RH ± 5%) at 0, 1, 3 & 6 months.
	Module-IV (Non-Clinical)	Firm has submitted: • Nonclinical studies that have been conducted in order to characterize the in vitro and in vivo pharmacological activity of avelumab. • Pharmacokinetic studies evaluated in mice and cynomolgus monkeys. • Toxicological profile of avelumab evaluated in mice, rats and cynomolgus monkeys.
	Module-V (Clinical)	Firm has submitted: • Clinical Safety data of avelumab for the treatment of patients with metastatic Merkel cell carcinoma (mMCC) in a treatment-naïve Stage IV population. • Data supporting the use of avelumab as maintenance treatment for patients with locally advanced or metastatic urothelial carcinoma (aUC) who have completed first-line platinum-based induction chemotherapy (gemcitabine + cisplatin or gemcitabine + carboplatin) without evidence of disease progression.
	Remarks of Evaluator	Application fulfils the requirement of CTD Dossier.
	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.	

9.	**Name, address of Applicant / Importer**	M/s **AJM Pharma (Pvt.) Ltd, Karachi** Postal Address: 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan.

Details of Drug Sale License of importer	Drug License by Way of Whole Sale License No: 262 Office Address: 1st Floor Shafi Cour Civil Line Merether Road Validity: 22-02-2028 Godown Address: Ground floor, Plot no. 44 Sector 27, Korangi Industrial Area, Karachi
Name of Marketing Authorization holder (abroad):	M/s Coherus Biosciences, Inc. 333 Twin Dolphin Drive, Suite 600, Redwood City, CA 94065, USA
Name, address of manufacturer(s)	M/s Suzhou Union Biopharm Co., Ltd. 999 Longqiao Rd Wujiang Economic and Technological Development Zone Suzhou, Jiangsu, 215200, China
Name of exporting country	China
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Valid Apostille COPP Certificate Number: TY65-VMM4 Certifying Authority: United States Food and Drug Administration, Address: 10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America Validity: November 06, 2026
Details of letter of authorization / sole agency agreement	The firm has provided notarized letter of authorization issued by M/s TopAlliance Biosciences, Inc , 9430 Key West Ave, Suite 125, Rockville, MD 20850, USA, dated: 20th November 2024, with a validity of 05 years.
Status of the applicant	- Manufacturer ☒ Importer - Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) - Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale - Export sale - Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import - Buk import and local repackaging - Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form -5F Tracking ID: G41-UQT-WHGX Dated: 2024-11-22
Details of fee submitted	Rs: 75,000/- & 225,000/- (Differential fee) Dated: 21/11/2024 & 2024/12/04 Deposit Slip No. 44071791 & 09141089650 Total fee : 300,000/-
The proposed proprietary name / brand name	TUOYI 240mg/6ml Vial
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 6ml solution vial contains: Toripalimab…… 240mg

	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Toripalimab is an anti-PD-1 monoclonal antibody **Proposed indications**: Nasopharyngeal carcinoma
	Reference to Finished product specifications	Manufacturer Specifications.
	Proposed Pack size	Pack size : 1's
	Proposed unit price	As per current SRO.
	Shelf Life	36 Months
	Storage Conditions	Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light.
	The status in reference regulatory authorities	Reference List Drug : Toripalimab 240mg/6ml Vial Manufacturer Name: **Suzhou Union Biopharm** Brand Name: LOQTORZ Strength: 240 mg/6 mL (Vial) Dosage Form: Liquid for single injection Pack Size: 1's Registration Number: BLA 761240
		USFDA Approved Product.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, Biological Characteristics, Mechanism of Action of Toripalimab, Manufacturer and Testing Facility Information, description of manufacturing process and controls, Process Flow Diagram – Upstream Manufacturing, List of In-Process Controls, characterization, specifications analytical procedures and its validation, batch analysis reports and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Suzhou Union Biopharm Co., Ltd. 999 Longqiao Rd Wujiang Economic and Technological Development Zone Suzhou, Jiangsu, 215200, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data of Toripalimab related to general properties, Biological Activity, Description of Manufacturing Process and Process Controls, Specifications for Raw Materials Used in Upstream, Downstream manufacturing, Controls of Raw Materials and Reagents of Non-Biological Origin, List of In-Process Controls, Major Equipment, Control of Source and Starting Materials of Biological Origin , physical form, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and its specifications, integrity , absorption, Extractable and Leachable Study , stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	According to the stability study results of the drug substance on both long-term Stability Study (≤ -40°C) for 36 months and accelerated Stability Study (5 ± 3°C) for 12 months' stability studies conducted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture details , manufacturing process and process control, process validation protocols reports , control of excipients, control of drug product, specifications, analytical procedures & its validation of analytical procedures, batch analysis reports , justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the following analytical method validation reports. 1. Visible Particles 2. Subvisible particles are analyzed according to USP <787>. 3. The sterility test is performed using the membrane filtration method following USP <71>. 4. Osmolality of the DP samples is tested in following USP<785>. 5. Extractable Volume USP<698>. 6. Polysorbate 80 Content 7. Container closure integrity testing (CCIT) of the DP samples is performed according to < USP 1207> using the vacuum decay method <ASTMF2338-09>. 8. Endotoxin test 9. Bioburden
	Container closure system of the drug product	The Primary Container Closure System Used for Toripalimab DP of Type I neutral borosilicate glass injection vial, Injection chlorobutyl Flurotec 4110/40 rubber stopper & Aluminum-plastic seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of multiple batches The accelerated stability study data is conducted at 5℃ ±3℃ for 36months. The real time stability study data is conducted at 25 ± 2°C, 60 ± 5% RH for 12 months Batch No.: 20161212, 20180101, 20180102.
	Module-IV Non-Clinical study:	The firm has submitted the Pharmacological, toxicological studies performed in animals and in-vitro studies.
	Module-V Clinical Studies:	Firm has submitted Phase I, Phase II and Phase III Clinical Studies, establishing the safety, efficacy and dose tolerability of the drug at clinical level.
	Remarks of Evaluator: Application fulfils the requirement of CTD Dossier.	
	Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.	

10.	**Name, address of Applicant / Importer**	M/s **OBS AGP (Private) Limited.** Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
	Details of Drug Sale License of importer	**License No: 024** **Address:** OBS AGP PRIVATE LIMITED **Address of Godown:** PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter **Valid Upto:** 27-03-2028
	Name and address of marketing authorization holder (abroad)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name, address of manufacturer(s)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name of exporting country	INDIA
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.COPP/CERT/KD/132878/2023/11/48285/232480) dated 12-12-2023 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. **The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29 March, 2025.** **GMP:** Firm has submitted original, legalized copy of GMP certificate(NEW-WHO-GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051Maharashtra state India.
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s OBS AGP Limited 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.: 01-02-2024
	Details of fee submitted	PKR 300,000/-: 01-02-2024
	The proposed proprietary name / brand name	**Anti D 300 mcg PFS**
	Strength / concentration of drug of Active	**Anti D 300 mcg PFS**

	Pharmaceutical ingredient (API) per unit	Each Prefilled Syringe contains: Trinbelimab (purified liquids bulk) ..... 300 mcg
	Pharmaceutical form of applied drug	Liquid Injection.
	Pharmacotherapeutic Group of (API)	Immunoglobulin
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	1's
	Proposed unit price	
	The status in reference regulatory authorities	Not available
	For generic drugs (me-too status)	-
	Module-II (Quality Overall Summary)	QOS as per WHO QOS-PD template and 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 submitted by the company are subject to verification.
	Name, address of drug substance manufacturer	**Bharat Serums & Vaccines Ltd.** Plot No. K-27, K-27 Part and K-27 /1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) , Thane 421506, Maharashtra State, India
	Module-III Drug Substance:	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 submitted by the company are subject to verification
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	stability study data of 3 batches of API (BB5620001, BB5621001, BB5621002) conducted at accelerated conditions 5°C ± 3°C for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C for 18 months submitted by the company are subject to verification
	Module-III Drug Product:	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 submitted by the company are subject to verification
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparison with innovators formulation and bioequivalence studies Of Rhophylac 300 micrograms / 2 ml, solution for injection in prefilled syringe , CSL Behring UK Limited submitted by the company are subject to verification
	Analytical method validation/verification of product	analytical method validation studies for the applied product submitted by the company are subject to verification
	Container closure system of the drug product	One Tray contains Clear, colourless USP Type I Glass vial and one ampoule of diluent.

	Stability study data of drug product, shelf life and storage conditions	stability study data of 3 batches (B25922001, B25922002, B25922003) The accelerated stability study data is conducted at 25˚C ± 2˚C / 60% ± 5%RH for 6 months.The real time stability study data of 09 months is conducted at 5˚C ± 3˚C submitted by the company are subject to verification

Evaluator remarks:

Applicant has wrongly claimed Rhophylac 300 micrograms / 2 ml, solution for injection in prefilled syringe, CSL Behring UK Limited as its reference product, Rhophylac 300 micrograms / 2 ml which is plasma derived product that contains **Rho(D) immune globulin** (also known as anti-D immunoglobulin / antibodies against the **RhD antigen** which is found on the surface of red blood cells). It is used to prevent or treat Rh immunization, a condition that can occur during pregnancy when an Rh-negative mother is carrying an Rh-positive fetus. Rhophylac works by preventing the mother's immune system from developing antibodies against Rh-positive red blood cells, which could be harmful in future pregnancies.

- Anti-D immunoglobulin works by **binding to Rh-positive red blood cells** that have entered the Rh-negative individual's circulation. This prevents the mother's immune system from recognizing the Rh-positive cells as foreign and creating antibodies against them.
- It essentially **masks** the Rh-positive red blood cells and **prevents immune activation** that would normally lead to the production of Rh antibodies.

The applicant did not provide any evidence of the status in reference regulatory authorities of Trinbelimab.

Decision: Deferred for provision of evidence of the status of Trinbelimab and its approved indications in reference regulatory authorities for subsequent evaluation.

11.	**Name, address of Applicant / Importer**	M/s **HealthBee Projects Private Limited** **Address:** Office E-02, 3rd Floor, Jasim Arcade, Plot No. 64-65, Lane-1, Square Commercial, Phase VII, Bahria Town, Islamabad
	Details of Drug Sale License of importer	**License No: 01-374-0176-065437D** **Address:** Ground Floor, Momi Plaza, Plot no 43, Business Square Phase 7, Bahria Town, District Rawalpindi **Address of Godown:** Ground Floor, Momi Plaza, Plot no 43, Business Square Phase 7, Bahria Town, District Rawalpindi **Status: Valid** **Valid Upto: 10.03.2028**
	Name and address of marketing authorization holder (abroad)	**M/s** Anhui Zhifei Longcom Biopharmaceutical Co., Ltd
	Name, address of manufacturer(s)	**M/s** Anhui Zhifei Longcom Biopharmaceutical Co., Ltd **Address:** No. 100, Fushan Road, the Hi-Tech Zone, Hefei City, 230088, Anhui Province, P.R. China
	Name of exporting country	Anhui Province, P.R. China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Type of Document: CoPP/FSC/GMP** **Certificate No:** No.Anhui20230030 **Issuance Date:** 27, Feb 2023 **Validity:** 26, Feb 2025 **Name and address of Issuing Regulatory Authority:** Anhui Medical Products Administration, China

	Details of letter of authorization / sole agency agreement	Attached Firm has submitted product specific letter of authorization from Anhui Zhifei Longcom Biopharmaceutical Co., Ltd The letter specifies that the manufacturer appoints HealthBee Projects Private Limited to register & sell 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	Tracking. No. DW2-YNX-HET9, Date: 12-06-2024
	Details of fee submitted	Challan No. 753183274225 Amount: 300,000 /- Date of submission: 12.06.2024
	The proposed proprietary name / brand name	**CTST**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) 1.0 ml/vial
	Pharmaceutical form of applied drug	Vial
	Pharmacotherapeutic Group of (API)	According to the category of Pharmacotherapeutic Group of API, the category of this product is Tuberculosis.
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1.0ml/vial 1vial/box The product comes with three different packing as mentioned, 0.3 ml/vial, 0.5 ml/vial and 1.0 ml/vial while the dosage for each human use is 0.1 ml per human dose.
	Proposed unit price	Retail price as per SRO
	The status in reference regulatory authorities	Not provided
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Subject to verification
	Name, address of drug substance manufacturer	**M/s** Anhui Zhifei Longcom Biopharmaceutical Co., Ltd **Address:** No. 100, Fushan Road, the Hi-Tech Zone, Hefei City, 230088, Anhui Province, P.R. China No. 5008 Mingzhu Avenue, the Hi-tech Zone, Hefei, Anhui Province, China

	Module-III Drug Substance:	Drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer description of manufacturing process and control, impurities, specifications, analytical procedure and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance are subject to verification
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study data of 3 batches of API at accelerated as well as real time conditions which are are subject to verification. Accelerated stability data: 2-8^{O}C for 36 months Long term stability data: $\leq$ -70^{O}C for 36 months Batch no: M20171101, M20171102, and M20171201
	Module-III Drug Product:	Data of drug product including its description, composition, pharmaceutical development, manufacturing process control, process validation protocol, control of excipients, control of drug product, specification, analytical procedures, verification, batch analysis, justification of specification, reference standard or materials container closure system and stability are subject to verification
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Analytical method validation/verification of product	Analytical method validation/ verification of product including accuracy, stability, precision, and solution stability are subject to verification
	Container closure system of the drug product	(Pall Allegro TM Disposable System) Disposable liquid storage bag
	Stability study data of drug product, shelf life and storage conditions	Shelf life: 24months Storage condition: Refrigerated (2^{O}C -8^{O}C) Stability study data is subject to verification.
Evaluator's remarks:		
The firm has not provided the evidence of availability in reference countries.		
Decision: Deferred for provision of evidence of the status in reference regulatory authorities.		

Agenda Item No. 2. Deferred cases of previous meetings of the Registration Board (other than export)

S #	Requirement	Details
12.	**Name, address of Applicant / Importer**	**M/s Eastern Medical Care (Pvt) Ltd.**
	Details of the Drug Sale License of the importer	**Address:** 7A, Block N, Model Town, Lahore. **Validity: 17.10.2022** **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	M/s. Private Joint Stock Company, On the production of Insulin "INDAR". Address: 5, Zroshuvalna, Str. Kyiv, Ukraine
	Name, and address of the manufacturer(s)	M/s. Private Joint Stock Company, On the production of Insulin "INDAR". Address: 5, Zroshuvalna, Str. Kyiv, Ukraine
	Name of the exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted an original, legalized CoPP certificate (No.CPP/UA/24/20/7) and letter of authorization valid till December 20, 2027.
	Details of letter of authorization / sole agency agreement	Letter of Authorization valid till December 20, 2027.
	Status of the applicant	☐ Manufacturer ☒ I**mporter** ☐ Is involved in none of the above (contract giver)
	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. 2409___25 Jan 2023
	Details of fee submitted	PKR 75,000/-:
	The proposed proprietary name / brand name	**Protamin Sulphate** Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains Protamin Sulphate… 10mg
	Pharmaceutical form of applied drug	Solution for Injection

S #	Requirement	Details
	Pharmacotherapeutic Group of (API)	Antidote of Heparin
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	1's Vial (5ml)
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved in USFDA.(10mg/ml)
	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies.
	Name, address of drug substance manufacturer	**Manufacturer**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan **Responsibility**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan **Manufacturing**: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan
		Testing, Subdividing, Labeling, Packaging, Storage and distribution: Alps Pharmaceuticals Ind. Co. Ltd. Address: 10-50, Furukawacho Mukaimachi, Nichome, Hida, Gifu, 509-4241, Japan
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for related to nomenclature, characterization, general properties, solubilities, physical form, manufacturers, specifications analytical procedures, batch analysis and justification of specification and reference standards.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -25ºC ± 2ºC & 60%RH±5%RH. The stability study data is till 60 months. The accelerated stability data is conducted at 40ºC ± 2ºC & 75%RH±5%RH. The stability study data is till 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, excipients, physical, chemical and biological properties, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

S #	Requirement	Details
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A in case of new product
	Analytical method validation/ verification of product	Firm has submitted analytical method from European Pharmacopoeia.
	Container closure system of the drug product	Medicinal product is filled in injection vial made of a transparent, colorless glass of 1 hydrolytic class (Type I), hermetically sealed under aseptic conditions with closure component-Flips for injection vials (combi seal), The Flip consists of a rubber liner, and aluminum crimp cap and a plastic lid of the type " Flip-Off".
	Stability study data of drug product, shelf life and storage conditions	Shelf Life 3 years below 25℃. Firm has submitted stability study data of 3 batches The real time stability studies are conducted at (30℃±2℃/65%RH±5%RH for 48 months for 10ml and 5ml vial accelerated stability study data is conducted at (40℃±2℃/75%RH±5%RH for 6 months for 10ml vials only.
	Module IV	Single dose toxicity studies are performed only
	Module V	Open label, comparative and parallel group study was carried on 86 patients: 43 patients in the main group and 43 patients in the reference group
Evaluator's remarks:		
Previously the case was considered by the Board in its 336th meeting and the Board has decided as under" ***Decision of 336th meeting of the Registration Board held on 4-5th June, 2024.*** ***Registration Board deferred the case for submission of following:*** • ***Repeat dose toxicity & overdose toxicity studies of applied formulation.*** • ***Double blind Phase III clinical trials OR Evidence of guideline supporting Open label trials.*** • ***Clarification regarding pack size of applied formulation whether it is 5ml or 10ml.***		

S #	Requirement	Details

The firm has submitted response vide Ref. No. T247OO2-Protamine-02L, dated 02-10-2024, as under:

S. No.	Clarification Needed By DRAP	Response by Principal (INDAR)	Enclosed document
01	Repeat dose toxicity & overdose toxicity studies of applied formulation.	Please be informed that Protamine sulfate is a P medicinal product of animal origin, which was first registered in the USA in 1969. In the country of manufacture (Ukraine), Protamine sulfate produced by PrJSC "INDAR" has been registered since 2009. All of the above allows classifying Protamine sulfate as a medicinal product with well-studied use. In accordance with the EU Directive 2001/83/EC Article 10 paragraph 1, preclinical and clinical trials are not required for well- studied medicinal products for parenteral administration.	PrISC "Indar" conducted open-label clinical study in 2008 in accordance with requirements of Ukrainian regulations at that time. The report of this study is presented in the registration dossier and copy is enclosed for your record as well.
02	Double blind Phase III clinical trials OR Evidence of guideline supporting Open label trials.		
03	Clarification regarding pack size of applied formulation whether it is 5ml or 10ml.	Please be informed that PrJSC "INDAR" applied for registration in Pakistan the package size of 5 ml.	

Decision: Keeping in view submitted CoPP indicating the product availability in country of origin; Registration Board approved the product in compliance of current Import Policy for finished drugs.

13.	Name, address of Applicant / Importer	**M/s Mediflow Pharmaceutical (Pvt) Ltd., Company Address: Plot # ID-100 Sector 30 Korangi Industrial Area Site Address: Plot: ID -100, Sector 30 Korangi Industrial Area, Karachi,**
	Details of Drug Sale License of importer	Address 15 & 33, Sec:30 K.I.A Karachi Status: License to sell drugs by way of wholesale. Validity: 10-07-2023. Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s Suzhou Abogen Biosciences Co. Ltd. Building 19,Area Phase 5, Biomedical Industrial Park, No.21 Chaoqian Road, Suzhou Industrial Park.
	Name, address of manufacturer(s)	Suzhou Abogen Biosciences Co. Ltd. Building 18 No. 218 Sangtian street, Suzhou Industrial Park, Jiangsu, China. **As per Drug Manufacturing Certificate** 2nd Floor, Building 32, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Warehouse Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Prophylactic biological products (SARS-Co V-2(Variant)mRNA manufacturing Vaccine)
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original Legalized and Valid COPP** Not submitted by the applicant. **GMP Compliance Statment**

		The Chinese drug regulatory authority no longer issues GMP Certificate; however, GMP Compliance Statement is attached. And Drug Manufacturing Certificate is also attached. The GMP compliance statement does not mention the site address.
	Details of letter of authorization / sole agency agreement	**Scanned Copy of Letter of Authorization Issued on 13th November 2024** We Suzhou Abogen Biosciences Co., Ltd., Building 19, Area C, Phase 5, Biomedical Industrial Park, No. 21 Chaoqian Road, Suzhou Industrial Park, hereby appoint Mediflow Pharmaceutical Pvt. Ltd. Situated at Plot ID 100, Sector 30, Korangi industrial Area, Karachi-74900, Pakistan To apply for the registration of our pharmaceutical product: **Product Name:** SARS-CoV-2 Variant (BA.4/5) mRNA vaccine **Dosage form and strength:** Injection, 0.5ml:15ug **Pack size:** Pre-filled 1ml glass syringe with rubber plunger With the drug regulatory authority in Pakistan on our behalf and Suzhou Abogen Biosciences Co., Ltd., Building 19, Area C, Phase 5, Biomedical Industrial Park, No. 21 Chaoqian Road, Suzhou Industrial Park will be marketing authorization holder of the registration certificate and be responsible for all the matters pertaining to the registration of this product. This letter is valid for 3 years from Nov 13, 2024, unless specifically extended. -
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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	Tracking ID:6XM-J4D-G842 Application Number:35198 Receiving Date :25-10-2024
	Details of fee submitted	Challan Number: 7529209634 Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-07-24 Fee Head: DML.
	The proposed proprietary name / brand name	**ARCoVE Pre-filled syringe for Intramuscular Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial contains 0.5 mL for one dose:** **Each dose contains 15ug mRNA**
	Dosage form of applied drug	Pre-filled syringe for injection.
	Pharmacotherapeutic Group of (API)	Indicate pharmacological class of the API (drug substance) & WHO ATC code for each distinct therapeutic indication: both are not available, whether they are mandatory and suitable for this vaccine, as it is the first time and there is no relevant guidance either.

	Finished product specifications	**Chinese Pharmacopoeia (Form 5 F)** **(Should be as per innovator)**
	Proposed Pack size	1's vial.
	Proposed unit price	Each vial will be 3000 Rupees.
	Shelf life	12 months
	Storage conditions	2-8°C.
	The status in reference regulatory authorities	The application is for Innovator product, - Product is registered in Indonesia (PICs country). - Trials approved in 4 countries UAE, Philippines, Indonesia (PICs countries) and Pakistan (Annexure 1). 15752 participants were screened, out of which 14138 enrolled however Pakistan nationals mostly in UAE part of trials. Evidence of Trial Approvals UAE, Philippines,Indonesia : A Randomized, Double blind, Placebo controlled Clinical Study to Evaluate the Efficacy , Safety, and Immunogenicity of SARS CoV 2 Variant BA.4 /5 mRNA Vaccine ABO1020 in Healthy Subjects Aged 18 Years and Older Who Have Completed the Full Vaccination Pakistan Title of trial or study: A Randomized, Double-Blind, Controlled Clinical Study to Evaluate the Effrcacy, Safety and SARs-CoV-2 Variant @A.4/5) mRNA Vaccine (ABO1020) in Healthy Subjects 18 (1) of Physiological-Saline Years and Older who have full Vaccination".
	For generic drugs (me-too status)	N/a
	Module-II (Quality Overall Summary)	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 and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Suzhou Abogen Biosciences Co., Ltd. Address: Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Based on the analysis of the completed stability study results, the drug substance is sensitive to temperature, can tolerate some degree of freezethaw, can be stored stably under the currently selected long-term stability conditions (-20 ± 5 °C), and long-term exposure to higher temperature should be avoided during use. The available stability studies support 12 months of storage at -20 ± 5 °C.
	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	The analytical procedures used for ABO1020 testing are compendial analytical procedures or in-house platform test methods. The method qualification of compendial methods such as bacterial endotoxin test and sterility test has been performed, and all other analytical procedures have been fully validated. The analytical method validation is summarized in Table 3.2.P.5.3-1, and the validation results of each analytical procedure are shown in Table 3.2.P.5.3-2 to Table 3.2.P.5.3- 12. The results of the validation parameters in all analytical procedures met the acceptance criteria, indicating that the established analytical method is suitable for the testing of ABO1020.
Container closure system of the drug product	The container closure system of ABO1020 uses BD's prefilled syringe (1 mL) and rubber plunger, and the primary packaging materials used for this product have been strictly controlled
Stability study data of drug product	Based on the analysis of the completed stability study results, the finished product can be stored at 5±3 °C. The finished product is sensitive to temperature, and should be protected from light. The available stability study results support the 12-month shelf life of this product when stored at 2-8 °C.

Non-clinical (Module-IV)

Module 4 (Non-clinical / Safety)			
4.2	Study Reports		
4.2.1	Pharmacology		
	4.2.1.1	Primary Pharmacodynamics	A total of 5 research reports for the primary pharmacodynamic studies of ABO1020 was shown below including the expression analysis in vitro, the evaluation of the humoral and cellular response in Naïve mice, the immunogenicity evaluation based on AWcorna primed mice, and the study of mouse challenge.
	4.2.1.2	Secondary Pharmacodynamics	Not Applicable.
	4.2.1.3	Safety Pharmacology	We refer the safety pharmacology study data of AWcorna to support the safety pharmacology of ABO1020 as both are produced from the same platform technology with the same LNP, albeit the mRNA sequences are different between the two vaccines. Attachment 4.2.1.3-1 AWcorna: 3 cycles of repeated intramuscular administration in Cynomolgus monkeys to recover 2 weeks toxicity with Safety Pharmacology (DT-2016-068).
	4.2.1.4	Pharmacodynamic Drug Interactions	NA
4.2.2	Pharmacokinetics		Vaccines usually do not require pharmacokinetic studies in animals. During the development of the prototype vaccine AWcorna, a series of studies were carried out on the biodistribution of the vaccine and the novel ionizable lipid 9001 in the lipid delivery vector, which can be used as a reference for this product.
4.2.3	Toxicology		ABO1020 is a pharmaceutical basis and technology platform based on the available prototype vaccine AWcorna. Based on this platform technology, a novel coronavirus Omicron BA.1 mRNA vaccine ABO1009-DP has been developed. Toxicology data from AWcorna and ABO1009-DP have important reference significance for ABO1020.

	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	A single-dose toxicity study with a total of 1 study report was conducted with AWcorna, Attachment 4.2.3.1-1 AWcorna: a Single-Dose Intramuscular Toxicity Study in Cynomolgus Monkeys with a 21-Day Recovery Period with an Immunogenicity, Biodistribution Study (DT2016-067
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	ABO1020 conducted 1 repeat-dose toxicity study, with reference to the repeat-dose toxicity study with prototype vaccine AWcorna, a total of 2 study reports are shown in Table 4.2.3.2-1. Attachment 4.2.3.2-1 ABO1020: 3-Cycle Repeat Dose Toxicity Study via Intramuscular Injection in SD Rats with a 2-Week Recovery Period Accompanied with Immunogenicity Study(DT-2287- 451) Attachment 4.2.3.2-2 AWcorna: a 3-Week Repeated Dose Intramuscular Toxicity Study in Cynomolgus Monkeys with a 2-Week Recovery Period with Biodistribution,
	4.2.3.3	Genotoxicity	AWcorna conducted 2 in vitro genotoxicity assays with a total of 2 study reports. AWcorna conducted an in vivo genotoxicity assay with a total of 1 study report.
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	Not applicable. The mRNA vaccine does not involve relevant studies because it does not need to enter the nucleus to function, does not integrate into the genome, and does not pose a safety risk of insertional mutations.
	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	An embryo-fetal developmental toxicity in combination with pre- and postnatal toxicity of ABO1020 was performed in Sprague-Dawley rats with a study report, Attachment 4.2.3.5-1 ABO1020: Embryo-Fetal Developmental (EFD) and Pre- and Postnatal Developmental (PPND) toxicity study via intramuscular injection in SD rats(DT-2287-501).
	4.2.3.6	Local Tolerance	A muscle stimulation study was conducted with ABO1020 with 1 study report, Attachment 4.2.3.6-1 ABO1020: Local Muscle Irritation Study in New Zealand Rabbits (DT-2287-482).

Clinical (Module-V)

Sr. No.	Name	Comments
	5.2 Tabular Listing of All Clinical Studies	

Table 5.2-1 Listing of Clinical Studies

Study Type	Study Number	Study Objectives	Study Design and Type of Control	Investigational Product: dose Regimen: route of Administration:	Number of subjects	Healthy subjects or patient diagnosis	Immunization duration	Study Status: report Type
Phase 3-Efficacy and Safety	ABO1020-301	Protective efficacy, immunogenicity, and safety	1: 1 randomized, double-blind, multicenter, placebo-controlled	ABO1020; injection (injected intramuscularly into the lateral area of the deltoid muscle of the upper arm); 0.5 ml : 15 µg ; Two vaccinations 28 days apart	14138	Healthy subjects	2 doses	Ongoing, the primary clinical endpoint has been reached and is currently in the long-term efficacy, long-term immunogenicity and long-term safety follow-up; completed protective efficacy, immunogenicity and safety analysis report
Phase 1-Safety	ABO1020-301	Safety	2: 1 Randomized, double-blind, placebo-controlled	ABO1020; injection (injected intramuscularly into the lateral area of the deltoid muscle of the upper arm); 0.5 ml : 15 µg ; Two vaccinations 28 days apart	30	Healthy subjects	2 doses	Ongoing, the primary endpoint has been reached and is currently in the long-term safety follow-up phase; safety and Immunogenicity Analysis Report Completed

5.3 Cl**inical Study Reports**

5.3.1 Reports of Biopharmaceutic Studies

5.3.1.1 Bioavailability (BA) Study Reports

NA

5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports

NA

5.3.1.3 *In vitro-In vivo* Correlation Study Reports

NA

5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

A total of 2 sets of bioanalytical and analytical method reports for the Phase 1 study of the novel coronavirus variant (BA.4/5) mRNA vaccine, including detection of live virus neutralizing antibodies and RT-PCR assays, were completed at the G42 laboratory in the United Arab Emirates. A total of 9 sets of bioanalytical and analytical method reports for Phase 3 study were conducted in the G42 laboratory in the United Arab Emirates for all countries (methods were consistent with those used for Phase I); SARS-COV-2 sequencing of the UAE samples was performed at the local G42 laboratory, and the sequencing of the Philippines samples was performed at the local Detoxicare laboratory; RT-PCR testing of UAE samples was performed in the local G42 laboratory (method was consistent with Phase I), and RT-PCR testing of Philippines samples was performed in 4 local laboratories, including Detoxicare, Davao One World, Next Gen, and MJSH; RT-PCR testing of Indonesian samples was performed at the local EBDC laboratory

		<table><tr><th>Test contents</th><th>Laboratory Name</th></tr><tr><td>Detection of Live Virus Neutralizing Antibodies in Samples from All Countries in Phase 1 and Phase 3</td><td>G42 LABORATORY L.L.C</td></tr><tr><td>RT-PCR testing of Phase 1 and Phase 3 UAE samples</td><td>G42 LABORATORY L.L.C</td></tr><tr><td>SARS-COV-2 Sequencing of Phase 3 UAE Samples</td><td>G42 LABORATORY L.L.C</td></tr><tr><td>Sequencing of SARS-COV-2 in Phase III Philippines Samples</td><td>Detoxicare Molecular Diagnostics Laboratory</td></tr><tr><td rowspan="4">RT-PCR Detection of Phase III Philippines Samples</td><td>Detoxicare Molecular Diagnostics Laboratory</td></tr><tr><td>Next Gen PCR Diagnostic Laboratory Corp.</td></tr><tr><td>Davao One World Diagnostic Center, Inc.</td></tr><tr><td>Manuel J. Santos Hospital molecular Laboratory</td></tr><tr><td>RT-PCR Testing of Phase 3 Indonesian Samples</td><td>PT. Excellent Beneficial Diagnostic Center (EBDC)</td></tr></table>
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials	NA
	5.3.3 Reports of Human Pharmacokinetic (PK) Studies	NA
	5.3.4 Reports of Human Pharmacodynamic (PD) Studies	NA
	5.3.5 Reports of Efficacy and Safety Studies 5.3.5.2 Study Reports of Uncontrolled Clinical Studies 5.3.5.3 Reports of Analyses of Data from More Than One Study	**5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication** One each report of the Phase I and Phase III Clinical Study Reports of a Novel Coronavirus Variant (BA.4/5) mRNA Vaccine. **Phase I Studies** Name of Study Drug SARS-CoV-2 Variant (BA.4/5) mRNA Vaccine (ABO1020) Active Pharmaceutical Ingredient mRNA encoding for the spike protein (S protein) receptor binding domains (RBD) of BA.4/5 (BA.4 and BA.5 have identical S protein

				sequence) **Study Title** **A Randomized, Double-blind, Placebo-controlled Clinical Study to** **Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV2 Variant (BA.4/5) mRNA Vaccine (ABO1020) in Healthy** **Subjects Aged 18 Years and Older Who Have Completed the Full Vaccination** **Investigation al Site** AI Kuwait Hospital (AI Baraha Hospital) Duration This report only summarizes the safety and immunogenicity results of 30 patients enrolled in Phase 1. The data analysis cutoff date is 30 Apr 2023, and long-term safety follow-up is still ongoing. The Phase 3 study results are detailed in a separate Phase 3 Clinical Study Report. Start time of the Phase 1 study (first subject signed the informedconsent form): 28 Nov 2022 The long-term safety follow-up of the study specified in the protocol is still ongoing. The data cutoff date for this Phase 1 analysis: 30 Apr 2023 Study Phase Phase 1. Conclusions The results of this study suggest that the sequential booster study vaccination (ABO1020) is safe and well tolerated, can induce a high level of humoral immune response against Omicron variant BA.5, and has a good cross-neutralizing ability against XBB variant at the same time, highlighting the broad-spectrum advantage that sequential booster vaccination of ABO1020 can provide good vaccine effect against both the strain of the vaccine antigen and the currently major pandemic strains **Phase III Studies** **Study Title A Randomized, Double-blind, Placebo-controlled Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV-2 Variant (BA.4/5) mRNA Vaccine (ABO1020) in Healthy Subjects Aged 18 Years and Older Who Have Completed the Full** Vaccination. Investigational Site: University of the Philippines - Philippine General Hospital Al Kuwait Hospital (Al Baraha Hospital) RSUP Persahabatan Jakarta. **Conclusion** 2 sequential booster doses of ABO1020 in people who had previously received 2 or 3 doses of inactivated COVID-19 vaccine produced high protective efficacy against COVID-19 caused by the currently prevalent variants, with predictable and controllable safety risks and the benefits outweighing the risks upon	

		comprehensive analysis; this further enhances the immune effect for the vaccinated population, thus providing safe and effective protection. Based on the above, ABO1020 presents a safer and more effective and convenient vaccination option for personal protection and public health in the prolonged, repeated outbreaks of COVID-19 **5.3.5.2 Study Reports of Uncontrolled Clinical Studies** NA
	5.3.6 Reports of Post-Marketing Experience.	NA
	5.3.7 Case Report Forms and Individual Patient Listings	The case report forms (CRFs) for the Phase I and Phase III clinical study of the novel coronavirus variant (BA.4/5) mRNA vaccine are available. Individual patient listings for the Phase III clinical studies of the novel coronavirus variant (BA.4/5) mRNA vaccine are provided in Module 5.3.7-3 and the individual patient listings for the Phase I clinical studies are provided in Module 5.3.7-4.

Evaluation by BE& R

S. No.	Deficiency	Response	Evaluator Remarks
1.	(Form 5F) The application and fee should be submitted under the head/license category of DSL instead of DML for imported drug products	The submitted application "ARCOVE Pre-filled syringe 15 ug mRNA" and fee were submitted under the division of Biological Evaluation & Registration, payment head was Biological Drugs Registration Fee. By default, DML. No mentioned when we log in e-portal, it is appeared automatically. The category DSL not available on e-portal for submission.	**Submission of fee under the head of DSL is required.**
2.	(a) Original, legalized and valid Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and valid GMP certificate of the Manufacturer issued by relevant certifying regulatory authority in the country of origin and name of exporting country.	(a) The Chinese drug regulatory authority no longer issues GMP Certificate; however, GMP Compliance Statement is attached. And Drug Manufacturing Certificate is also attached. (b) Letter of authorization is attached.	**Clarification for variation in Building No. mentioned on Drug Manufacturing Certificate i.e. (2nd Floor Building 32) and Form 5 A (Building 18).** **GMP compliance statement doesn't mention the Site address.** Requirements for drug GMP and GSP administration

				As from December 1, 2019, drug GMP and GSP certifications shall be cancelled, and the corresponding applications / certificates shall be no longer accepted / issued. Certification applications accepted before December 1, 2019 shall be processed in accordance with the relevant provisions of the original drug GMP and GSP certification. To applications with on-site inspection completed and conformance to requirements before December 1, 2019, drug GMP and GSP certificates can be issued. On-site inspection shall be carried out even after December 1, 2019, where the current regulations require it, and the corresponding results shall be notified to the enterprise; non-compliance found in the inspections shall be dealt with in accordance with regulations pursuant to the Law/ Clarification is required for different MAH address on letter of authorization.
	3.	(1.3.4) Drug Sale License (DSL) issued by relevant licensing authority has expired.	Updated Drug Sale License has been attached.	Submitted.
	4.	(1.5.6) The pharmacopeial reference mentioned in this section is Chinese Pharmacopeia whereas, product general details mention Innovator Specifications.	Refer to the description document for analysis methods, 3.2.S.4 & 3.2.P.5.2	Innovator Specs.
	5.	1.5.9(a) The regulatory status (Approval, Emergency use authorization, under approval/not applied yet) of applied strain (SARS-CoV-2 Omicron variant BA.4/5) in any one of the reference regulatory	ABO1020 has been in the process of Pre-NDA review by China Center for Drug Evaluation and its Pre-NDA submission is attached.	Applicant has submitted Appointment Consultation Request Form submitted in NPMA. **No evidence of approval submitted in any one of**

		authority specified by Registration Board in 275th meeting and country of origin 1.5.9(b) Data regarding prevalence of SARS-CoV-2 Omicron variant BA.4/5 in Pakistan.	Regarding the COVID-19 variant prevalence data for Pakistan in 2022-2023, it appears that the information might not be readily available on WHO's website. However, there are national analysis studies that provide insights into the pandemic waves in Pakistan. For instance, a study published in PLOS One analyzed five distinct pandemic waves in Pakistan, detailing the impact of different virus variants on the contours and features of each wave. **Pakistan's National Emergency Operations Centre (NEOC) in Islamabad is a likely source for such data**, as they prepare daily national situation reports (Sitreps). The study mentioned above sourced its data from these reports. I recommend reaching out to the NEOC or similar national public health departments in Pakistan. They would be the most equipped to provide detailed COVID-19 research data, including variant prevalence and epidemiological trends for the years in question. Please note that the data available may not be as detailed as what is required for a comprehensive analysis, and it might be necessary to work directly with these departments to obtain the necessary information.	**the reference regulatory authority specified by Registration Board in 275th meeting and country of origin** Applicant has no data regarding prevalence of variant.	
	6.	(3.2.S.2.2-2.6) Information on the manufacturing process, starting materials used in the manufacture of the drug substance, Controls of Critical Steps and Intermediates,	See 2.3.S.2 Manufacture_ABO1020-20241029	Submitted. Name: Jiangsu GenScript ProBio Biotechology Co., Address (Zhenjiang): Building 50, No. 99	

	process validation and manufacturing process development is required.		DingmouJingShiwu Road, Zhenjiang, Jiangsu, China ➢ Preparation of ABO1020-MSL, ABO1020- WSL of the strain containing VCABOP-127-2 Name: Suzhou Abogen Biosciences Co., Ltd. Address: Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China ➢ Manufacturing and release of bulk purified mRNA (ABO1020-DS) ➢ Stability study
7.	3.2.S.4.1-4.2(a) Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient is required. 3.2.S.4.1-4.2 (b) Monograph of drug substance of Chinese Pharmacopoeia shall be submitted.	See 3.2.S.4 Control of Drug Substance_ABO1020-20241029 The drug substance of ABO1020 is an innovator product, and is solely for the production of ABO1020 drug product.	Submitted.
8.	(3.2.S.4.3) Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for compendial drug substance shall be submitted	See 3.2.P.5.3 Validation of Analytical Procedures	The Analytical Method validation studies for drug substance required as provided reports are of drug product..
9.	(3.2.S.7) Stability data of drug substance at long term condition till claimed shelf life as provided data is of only 9 months	See 3.2.S.7.2 Stability_ABO1020-20241029	Stability data of drug substance at long term condition till claimed shelf life i.e. 12 months have been provided.
10.	(3.2.P.2.1) List of all components with their amount on a per unit basis and the function of the components	2.3.P.1 Description and Composition of the Drug Product_ABO1020-20241029	Submitted.
11.	(3.2.P.3.2) A batch formula should be provided that includes a list of all components of the	See 3.2.P.3.2 Batch Formula_ABO1020-20241029	Submitted.

	dosage form to be used in the manufacturing process, their amounts on a per batch basis and a reference to their quality standards.		
12.	(3.2.P.4.5) A certificate shall be provided, confirming that the excipient including cholesterol is free from BSE and TSE.	Attachment : 3.2. P.4.9 Cholesterol-TSE BSE statement	Submitted.
13.	(3.2.P.5.2) Detailed analytical procedures used for testing the drug product shall be provided.	See 3.2.P.5.2 Analytical Procedures	**Not submitted.** **Only method overview has been provided.**
14.	(3.2.P.5.4) The copies of complete analysis of all batches for which stability data is provided in section 3.2.P.8.3.	See 3.2.P.5.4 Batch Analyses- BN 202209012 & BN 202209014 & BN 202209015	Submitted.
15.	(a). Submit supporting documents of stability data of drug product like raw data sheets, COAs etc. at each time point (b). Record of Digital data longer for temperature and humidity monitoring of stability chambers (real time and accelerated stability (conditions).	Reply not submitted	(a**) Supporting documents of stability data of drug product like raw data sheets, COAs etc. at each time point not submitted, only COA's of initial testing are attached**. (b). Record of Digital data longer for temperature and humidity monitoring of stability chambers (real time and accelerated stability (conditions). Submitted.
16.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	Reply not submitted.	**Summary protocol for production and testing for COVID-19 mRNA Vaccine has been submitted as an evidence for BMR. Justification is required.**
17.	(Module-4, non-clinical data) Complete non-clinical studies as per ICH safety guidelines and proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study reports.	ABO1020 has completed all non-clinical study content in accordance with the WHO vaccine guidelines	The applicant has provided WHO guidelines on nonclinical evaluation of vaccines, instead of providing justification for not applicable against each section. The guidelines have been reviewed and submitted data is in line WHO requirements which includes following studies:

				Characterization of candidate vaccines. • Immunogenicity and other pharmacodynamics studies • Toxicity assessment • Basic toxicity assessment • Additional toxicity assessments
18.	(a) Complete Phase 2 clinical studies as per ICH efficacy guidelines or scientific justification with evidence of reference guidelines for it.	**INC-E8: GENERAL CONSIDERATIONS FOR CLINICAL STUDIES** 4.3 Clinical Studies Clinical drug development, defined as studying the drug in humans, is conducted in a sequence that builds on knowledge accumulated from non-clinical and previous clinical studies. The structure of the drug development programme will be shaped by many considerations and comprised of studies with different objectives, different designs, and different dependencies. Although clinical drug development is often described as consisting of four temporal phases (phases 1-4), **it is important to appreciate that the phase concept is a description and not a requirement, and that the phases of drug development may overlap or be combined. Phase II Clinical Trials: After the safety and dosage of the drug have been established in Phase I trials, Phase II trials further evaluate the drug's efficacy and safety, as well as determine the optimal dosage.** ABO1020, which is developed using the same platform technology as the first-generation vaccine (AWcorna) that has already received EUA in Indonesia, has a formulation	a) Justification for not performing phase II has been provided. b) Study reports for Phase 1 and Phase III submitted by the applicant. **c)** Guidelines for the Development and Evaluation of Prophylactic Vaccines Against SARS-CoV2 Variant issued by CDE in November 2021 has been submitted. **d) Clinical study Protocols not submitted, only reports are provided.** **e) Regulatory status of trails applicant has submitted approvals of Clinical Trials. Indonesia(PICS member), Philippines and UAE.** f) Data on Adverse Events Following Immunization

			specification of 15µg, the same as Acrona. Therefore, a conventional Phase II study is not required. After Phase I safety exploration, it can directly proceed to Phase III clinical trials to verify its protective efficacy, immunogenicity, and safety in a large population. ABO1020-301_Phase I_CSR_V2.0-20231013 (attached with CSR Phase III, Section d)	(AEFIs) data of the vaccine in country of origin or any other NRAs. g) Immunization (AEFIs) data of the vaccine of following countries have been provided: Philippines, UAE and Indonesia.	
		(b) Complete clinical trial data of Phase 1 and Phase 2 is required as per ICH efficacy guidelines			
		(c) Submit evidence of Guidelines for the Development and Evaluation of Prophylactic Vaccines Against SARS-CoV2 Variant issued by CDE in November 2021.	Guidelines for the Development and Evaluation of COVID-19 Variant Preventive Vaccines 202109 Guiding Principles for the Development and Evaluation of Vaccines for Preventive Use of New Coronavirus Variant Strain (Trial)		
		(d) Clinical study protocol, clinical study sites, summary results of Phase 1 and 3 along with regulatory status of these trails in relevant NRAs.	1. Clinical study report "ABO1020-301_PhaseI_CSR_V2.0-20231013" 2. Clinical study report "ABO1020-301_Phase III_CSR_V2.0-20231013" 3. Regulatory approvals from UAE-MOH, CTA Philippines, and Indonesia Guideline attached (Section c)		
		(e)Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for clinical study reports.			

	(f) Adverse Events Following Immunization (AEFIs) data of the vaccine in country of origin or any other NRAs.	Adverse Events Following Immunization (AEFIs) data for ABO1020——20241031	

Adverse Events Following Immunization (AEFIs) data for ABO1020

Stage	Country	Site	Number of enrolled subjects	Number of AE	Incidence of AE	Number of ≥G3 AE	Incidence of ≥G3 AE	Number of SAE	Incidence of SAE
Phase I	UAE	801	30	11	36.70%	2	6.70%	0	0.00%
Phase III	Philippines	301	1717	313	18.20%	60	3.50%	0	0.00%
		302	800	328	**41.00%**	74	9.30%	10	1.30%
		303	904	133	14.70%	13	1.40%	1	0.10%
		304	600	87	14.50%	14	2.30%	1	0.20%
		305	620	77	12.40%	4	0.60%	0	0.00%
		305A	807	191	23.70%	16	2.00%	2	0.20%
		306	621	129	20.80%	14	2.30%	3	0.50%
		307	739	244	33.00%	46	6.20%	2	0.30%
	UAE	401	**4338**	744	17.40%	61	1.40%	3	0.10%
		404	889	283	31.90%	26	2.90%	8	0.90%
		405	103	61	**59.80%**	2	2.00%	0	0.00%
	Indoenesia	101	928	630	**68.20%**	106	**11.50%**	22	**2.40%**
		102	86	65	**75.60%**	12	**14.00%**	0	0.00%
		104	132	89	**67.40%**	10	7.60%	3	**2.30%**
		105	571	363	**63.70%**	69	**12.10%**	3	0.50%
		106	283	179	**63.50%**	26	9.20%	7	**2.50%**
	Total		**14138**	**3916**	**27.84%**	**553**	**3.93%**	**65**	**0.46%**

Decision of 343rd Meeting: The Registration Board deferred the applied formulation for submission of the following documents:

- *The fee should be submitted under the head of DSL instead of DML.*
- *Clarification for variation in Building No. mentioned on Drug Manufacturing Certificate i.e. (2nd Floor Building 32) and Form 5 A (Building 18).*
- *GMP compliance statement doesn't mention the Site address.*
- *Clarification is required for different MAH address on letter of authorization.*
- *Evidence of approval submitted in any one of the reference regulatory authority specified by Registration Board in 275th meeting and country of origin*
- *Data regarding prevalence of omicron variant.*
- *The Analytical Method validation studies for drug substance required as provided reports are of drug product.*
- *Stability data of drug substance at long term condition till claimed shelf life,as 12 months stability analysis have been provided.*
- *Detailed analytical procedures used for testing the drug product shall be provided as only method overview has been submitted.*
- *Supporting documents of stability data of drug product like raw data sheets, COAs etc. at each time point not submitted, only COA's of initial testing are attached.*
- *Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.*
- *Clinical study Protocols as only study reports are provided.*
- *Evidence of published clinical studies.*
- *Complete listing/classification of ADRs and organ systems most commonly involved in ADRs."*

Post meeting (343rd) proceedings:

In this connection, a meeting was also held on 9th December, 2024 at 2nd Floor, Special Investment Facilitation Council (SIFC), PM Office in pursuance to SIFC letter No.U.O.No.11(16)/Health/Misc-2024/SIFC dated December 5, 2024. After threadbare deliberations and keeping in view the non-availability of the said vaccine in the country of origin i.e., China and non-submission of any such evidence by the applicant, of approval of applied formulation in Reference Regulatory Authorities (RRAs) as recognized/approved by Registration Board, it was concluded in the meeting to seek opinion on the matter of registration of said mRNA Vaccine namely "ARCoVE" PFS of the undermentioned panel of experts already constituted in DRAP for assessment/evaluation of clinical trial data (Module-5 of CTD) of Covid-19 vaccines from Non-Reference Regulatory Authorities under Rule 24 (6) of the Drugs (Licensing, Registration & Advertising) Rules, 1976

Accordingly, in the best public health interest, extract of agenda item of referred Registration Board meeting along with clinical data (Module-5 of CTD) submitted in the registration application of the said mRNA Vaccine was forwarded through email on 11-12-2024 to the above panel of experts for assessment/evaluation of clinical data with request to hold a zoom meeting on 13th December, 2024. Representative of SIFC, was requested to attend a zoom meeting. The zoom meeting of the above panel of experts was held on 13th December, 2024 at 10am.

In the light of deliberations, discussions and recommendations, the working group reached the conclusion and did not recommend registration of ARCoVE Pre-filled syringe for Intramuscular Injection which contains 15µg mRNA per 0.5 mL vial of single dose by the said applicant. Report is reproduced as under:

Report on recommendation of expert working group on the matter of registration of said mRNA Vaccine namely "ARCoVE" PFS

This refers to an application filed by M/s Mediflow Pharmaceutical (Pvt) Ltd., located at Plot # ID-100 Sector 30 Korangi Industrial Area, Karachi for registration of ARCoVE Pre-filled syringe for Intramuscular Injection which contains 15µg mRNA per 0.5 mL vial of single dose to be imported from Marketing Authorization Holder namely; M/s Suzhou Abogen Biosciences Co. Ltd Building 19,Area Phase 5, Biomedical Industrial Park, No.21 Chaoqian Road, Suzhou Industrial Park and manufacturer Suzhou Abogen Biosciences Co. Ltd. Building 18 No.218 Sangtian Street, Suzhou Industrial Park, Jiangsu, China. ***As per Drug Manufacturing Certificate*** *2nd Floor, Building 32, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Warehouse Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Prophylactic biological products (SARS-Co V-2(Variant)mRNA manufacturing Vaccine).*

2. The application is under examination and was also placed before 343rd meeting of the Registration Board held on 2nd to 4th December, 2024. In this connection, a meeting was also held on 9th December, 2024 at 2nd Floor, Special Investment Facilitation Council (SIFC), PM Office in pursuance to SIFC letter No.U.O.No.11(16)/Health/Misc-2024/SIFC dated December 5, 2024. After threadbare deliberations and keeping in view the non-availability of the said vaccine in the country of origin i.e., China and non-submission of any such evidence by the applicant, of approval of applied formulation in Reference Regulatory Authorities (RRAs) as recognized/approved by Registration Board, it was concluded in the meeting to seek opinion on the matter of registration of said mRNA Vaccine namely "ARCoVE" PFS of the undermentioned panel of experts already constituted in DRAP for assessment/evaluation of clinical trial data (Module-5 of CTD) of Covid-19 vaccines from Non-Reference Regulatory Authorities under Rule 24 (6) of the Drugs (Licensing, Registration & Advertising) Rules, 1976.

i. *Prof. Brig.(R) Muzammil Hassan Najmi, Professor of Pharmacology, Foundation University Medical College, Islamabad (Chairman)*
ii. *Prof. Dr. Saeed Sadiq Hamid Director, Clinical Trials Unit Department of Medicine, The Aga Khan University & Hospital, Karachi*
iii. *Prof. Dr. Sadia, Head of Molecular Biology, Dow University of Health Sciences Vice President of Pakistan Biological Safety Association*
iv. *Dr. Farhana Badar, Epidemiologist and Biostatistian, Shaukat Khanum Memorial Cancer Hospital and Research Centre.*
v. *Prof. Dr. Zulfiqar Bhutta, The Aga Khan University & Hospital, Karachi*
vi. *Dr. Asad Ali, the Aga Khan University & Hospital, Karachi.*
vii. *Additional Director (BER) DRAP will be non-member, Secretary*

3. Accordingly, in the best public health interest, extract of agenda item of referred Registration Board meeting along with clinical data (Module-5 of CTD) submitted in the registration application of the said mRNA Vaccine, to be imported from non-reference Regulatory Authority were forwarded through email to the above committee members for assessment/evaluation of clinical data. The above panel, comprised of experts and representative of SIFC, was requested to attend a zoom meeting scheduled to be held on 13th December, 2024.

4. Accordingly, the zoom meeting of the above panel of experts was held on 13th December, 2024 at 10am which was attended by the following:

i. *Prof. Brig.(R) Muzammil Hassan Najmi, Professor of Pharmacology, Foundation University Medical College, Islamabad (Chairman)*
ii. *Prof. Dr.Sadia, Head of Molecular Biology, Dow University of Health Sciences Vice President of Pakistan Biological Safety Association*
iii. *Dr Farhana Badar, Epidemiologist and Biostatistian, Shaukat Khanum Memorial Cancer Hospital and Research Centre.*
iv. *Dr.Asad Ali, the Aga Khan University & Hospital, Karachi.*
v. *Additional Director (BER) DRAP will be non-member Secretary*
vi. *Ms Iqra Aftab, Deputy Director Biological Drugs, DRAP, Islamabad*

Prof. Dr. Zulfiqar Bhutta, and Prof. Dr. Saeed Sadiq Hamid forwarded their comments/opinion through electronically (email/whatsApp).

5. *Prof. Dr. Zulfiqar Bhutta communicated his comments through email as under:*

> *"Colleagues*
> *I am traveling and hence unable to join this zoom call.*
> *For me this is a straightforward matter. No real compelling phase 3 data are available and the vaccine isn't licensed for public health use in China. At this stage with a global glut of COVID19 mRNA vaccines, especially against newer variants, I don't see any value in registering this product for use in Pakistan. The case load is also too low for any reasonable trial or evaluation*
>
> *Thanks*
>
> *ZAB"*

6. *Prof. Dr. Saeed Sadiq Hamid communicated his comments through whatsApp as under:*

> *"My apologies I could not join, as I had a bad cold and sore throat. I have looked at the application and agree with the points that Dr Bhutta had made in his email. I do not see the value of registering this vaccine in the country.*
> *Thank you."*

7. *On zoom call, Dr. Asad Ali, the Aga Khan University & Hospital, Karachi stated that so far, he went through the contents of application, he understands that DRAP is satisfied with the evaluation criteria set for registration of a product in terms of SOPs that can be followed, production, facility and safety studies. To the extent of the GMP certification, it looks like that China does not officially issue GMP certificates, he said that his personal opinion is to be sympathetic to this approach since if such GMP certificates are not provided by China then we won't be able to bring non-GMP vaccine in Pakistan. This means that we can use only those vaccines which are used in 1st world countries. He further opined that with evolving world we should brand minded and flexible. He was of the view that for registration of any drug, need should not be the criteria and trials of this vaccine have also been*

conducted. He was clarified that this product is not registered in the country of origin and the applicant has not provided any evidence of this vaccine registration in any country globally.

8. The expert member, Dr Farhana stated that as per clinical trial data, there are 27.8% incidence of Adverse Effects which is on higher side and the applicant has not specified the types of adverse effects, these may be minor or major; they have put all together. She was further of the view that to the extent of number of individuals for clinical trials, that is fine in Philippines. She also supported views of Prof. Dr. Zulfiqar Bhutta and she concluded her remarks as non-satisfactory being un-conformable in recommending the registration of the said vaccine.

9. Dr. Sadia, while endorsing the remarks of Dr Farhana, showed her concerns over Severe Adverse Effects. On her question, she was updated about the sample size as 6000 individuals in Philippines, 5000 in UAE, 2000 in Indonesia and 2000 in Pakistan. She also showed her concern of non-registration of the vaccine in China being country of origin. Dr.Sadia through email on 16-12-2024 advised to include her following remarks in the report:

> *"Please mention the Nature of AEs reported during Phase III Execution, as 67% of AEs were reported in the trial site as per the last pages of the extract report. The types of the event were not mentioned in the report, the same is the case with SAE. A few percentages of SAE were also reported but the nature of events is not mentioned.*
> *In a Clinical trial report, it is mandatory to show how many and which types of events were reported during Phase III execution and the relation of AEs or SAEs with IPs, whether the AEs were related to the drug, not related, or likely related."*

10. Prof. Brig. (R) Muzammil Hassan Najmi inquired about the publication of the study of 40,000 individuals. It was informed that no such evidence has been provided for publication of the study. He recommended to adhere to follow the general principal of fulfilling the regulatory requirements already set out for registration of a biological/drug in the country. Based on non-availability of the said vaccine in the country of origin (China), no evidence of registration of the said vaccine in any country of world and in the absence of any data of clinical trials in Pakistan despite the pharmaceutical concern obtained approval in March, 2023 to conduct clinical trial in Pakistan, booster to cover variants of Covid-19, absence of justification of need of vaccine in China where the Covid-19 originated, big issue of adverse effects of the vaccine in terms of %age which is very quiet high and also the applicant did not explain the nature and severity of the adverse effects, Brig. Najmi concluded not to recommend registration of such product in Pakistan.

11. In the light of above deliberations, expert working group reached the conclusion and did not recommend registration of ARCoVE Pre-filled syringe for Intramuscular Injection which contains 15µg mRNA per 0.5 mL vial of single dose applied by M/s Mediflow Pharmaceutical (Pvt) Ltd., located at Plot # ID-100 Sector 30 Korangi Industrial Area, Karachi to be imported from Marketing Authorization Holder namely; M/s Suzhou Abogen Biosciences Co. Ltd Building 19,Area Phase 5, Biomedical Industrial Park, No.21 Chaoqian Road, Suzhou Industrial Park and manufacturer Suzhou Abogen Biosciences Co. Ltd. Building 18 No.218 Sangtian Street, Suzhou

Industrial Park, Jiangsu, China. (As per Drug Manufacturing Certificate) 2nd Floor, Building 32, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Warehouse Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Prophylactic biological products (SARS-Co V-2(Variant)mRNA manufacturing Vaccine).

Ended: 13th December, 2024

Matter was placed before 344th meeting of the Drug Registration Board.

Decision: The Registraion Board, keeping in view the shortcomings observed by the Board in its 343rd meeting and recommendations of the Expert Working Group regarding not to register *"ARCoVE Pre-filled syringe for Intramuscular Injection which contains 15µg mRNA per 0.5 mL vial of single dose",* decided to reject the application as it does not qualify criteria for safety, efficacy and quality.

Agenda Item No.3. Generic / Biosimilar (Hard dossiers)

14.	**Name, address of Applicant / Importer**	**M/s Revive Healthcare,** Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.
	Details of Drug Sale License of importer	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity:** 21-05-2027 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	**Virchow Biotech Private Limited** Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	Name, address of manufacturer(s)	**Virchow Biotech Private Limited** Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original valid legalized CoPP Certificate No. 3889888/TS/2023 Valid upto 10-01-2026 issued by by Drug Control Administration, Government of Telangana State, India. The COPP confirms free sale status of the product (PEGAPAR- PEG L-Asparaginase Injection 3750 I.U/5ml) in exporting country as well as GMP status of the manufacturing site. The submitted legalized GMP is valid upto 10-01-2026
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from Virchow Biotech Private Limited. The letter species that the manufacturer appoints M/s Revive Healthcare Lahore to register their products in Pakistan. The authorization letter is issued on 13-03-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No.14908 : dated 13-06-2023
	Details of fee submitted	PKR 150,000/-: 09-06-2023
	The proposed proprietary name / brand name	**PEGAPAR INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL vial contains: Pegaspargase (Pegylated L-Asparaginase).....3750 IU (Innovator's specs.)
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent ATC Code: L01XX02
	Reference to Finished product specifications	Inhouse
	Proposed Pack size	1's
	Proposed unit price	AS PER SRO
	The status in reference regulatory authorities	ONCASPAR (pegaspargase) injection 3750 IU by Servier. **USFDA Approved**
	For generic drugs (me-too status)	Pegaspargase Injection (Peg-L-Asparaginase of LDS (Reg#105067)
	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	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted DS stability study data of 3 batches of API Batch # 1- PVBPEA00118 2- PVBPEA00218 3- PVBPEA00318 at accelerated (6 Months) as well as real time conditions (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 complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results of pharmaceutical equivalence against the reference product which is Oncaspar Injection 750IU/mL.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Clear colorless solution filled in 5.0 mL USP Type I clear transparent glass Vial with 20 mm bromobutyl rubber stopper and sealed with 20 mm orange flip off seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Batch No. 1- PVPEA00118 2- PVPEA00218 3- PVPEA00318 The accelerated stability study data is conducted at 25°C ±2°C / 60% ± 5% RH for 6 months and real time stability study data conducted at 5°C ±3°C for 36 months with the claimed shelf life of 24 months.
	Non-clinical (Module-IV)	The firm has submitted non-clinical data following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity
	Clinical (Module-V)	Firm has submitted clinical data of • Reports of Biopharmaceutic Studies • Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials

		• Reports of Human Pharmacokinetic (PK) Studies • Reports of Human Pharmacodynamic (PD) Studies • Reports of Efficacy and Safety Studies

Evaluator's remarks:

The firm has provided incomplete data of non-clinical and clinical studies.

Decision: After detailed discussion and deliberation, the Board decided to defer the case for provision of following data:

i. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**
ii. **Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**
iii. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**
iv. **Post-marketing surveillance (Pharmacovigilance) study reports.**

15.	**Name, address of Applicant / Importer**	**M/s Revive Healthcare,** Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.
	Details of Drug Sale License of importer	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity:** 21-05-2027 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	**Virchow Biotech Private Limited** Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	Name, address of manufacturer(s)	**Virchow Biotech Private Limited** Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original valid legalized CoPP Certificate No. 4222631/TS/2023 Valid upto 11-12-2025 issued by by Drug Control Administration, Government of Telangana State, India. The COPP confirms free sale status of the product (Osteotide Injection 750mcg/3mL, prefilled cartridge with pen device) in exporting country as well as GMP status of the manufacturing site. The submitted legalized GMP is valid upto 11-12-2025
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from Virchow Biotech Private Limited . The letter species that the manufacturer appoints M/s Revive Healthcare Lahore to register their products in Pakistan. The authorization letter is issued on 13-03-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.1298 : dated 08-11-2023
	Details of fee submitted	PKR 75,000/-: 26-10-2023
	The proposed proprietary name / brand name	**OSTEOTIDE INJECTION 750 mcg/3mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL of prefilled pen device contains: Teriparatide ……. 250mcg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent ATC Code: H05AA02
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	AS PER SRO
	The status in reference regulatory authorities	FORSTEO INJECTION (250mcg/mL) by Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands **MHRA Approved**
	For generic drugs (me-too status)	Not applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, 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	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
	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.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted DS stability study data of 3 batches of API Batch # 4- BOST00120 5- BOST00220 6- BOST00320 at accelerated as well as real time conditions. The real time stability data provided for claimed shelf life of 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results of pharmaceutical equivalence against the reference product which is Forteo Injection by Lilly, France.
	Analytical method validation/verification of product	Firm has submitted analytical verification validation studies for the applied product.

	Container closure system of the drug product	The drug product is filled into 3.0 mL sterile USP Type-I siliconized glass cartridges closed with lined seals, followed by solid plunger.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Batch No. 1- 5400119 2- 5400219 3- 5400319 The accelerated stability study data is conducted at 25ºC ±2ºC / 60% ± 5% RH and real time stability study data conducted at 5ºC ±3ºC for 36 months with the claimed shelf life of 24 months.
	Non-clinical (Module-IV)	The firm has submitted non-clinical data following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity
	Clinical (Module-V)	Firm has submitted clinical data of • Reports of Biopharmaceutic Studies • Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials • Reports of Human Pharmacokinetic (PK) Studies • Reports of Human Pharmacodynamic (PD) Studies • Reports of Efficacy and Safety Studies

Evaluator's remarks:

The firm has provided incomplete data of non-clinical and clinical studies.

Decision: After detailed discussion and deliberation, the Board decided to defer the case for provision of following:

i. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**
ii. **Documented and published clinical studies, biosimilarity studies including In vitro-In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for**

	Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication: **iii. Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:** **iv. Post-marketing surveillance (Pharmacovigilance) study reports**

16.	**Name, address of Applicant / Importer**	**M/s Revive Healthcare,** Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.
	Details of Drug Sale License of importer	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity:** 21-05-2027 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	**United Biotech (P) Limited** Bagbania, Baddi- Nalagarh Road, Distt. Solan (H.P.)-174 101, India
	Name, address of manufacturer(s)	**United Biotech (P) Limited** Bagbania, Baddi- Nalagarh Road, Distt. Solan (H.P.)-174 101, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP Valid upto 22-02-2024 issued by by Heallth & Family welfare Department, Government of Himachal Pradesh, India. The COPP confirms free sale status of the product (ONCONASE PEG Injection 3750 I.U/5ml) in exporting country as well as GMP status of the manufacturing site. The submitted legalized GMP is valid upto 22-02-2024
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from United Biotech (P) Limited . The letter species that the manufacturer appoints M/s Revive Healthcare Lahore to register their products in Pakistan. The authorization letter is issued on 01-01-2021
	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.1688: dated 07-12-2023
	Details of fee submitted	PKR 150,000/-: 05-12-2023
	The proposed proprietary name / brand name	ONCONASE PEG INJECTION
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL vial contains: Pegaspargase (Pegylated L-Asparaginase).....3750 IU
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent ATC Code: L01XX02
	Reference to Finished product specifications	Inhouse
	Proposed Pack size	1's
	Proposed unit price	AS PER SRO
	The status in reference regulatory authorities	ONCASPAR (pegaspargase) injection 3750 IU by Servier. **USFDA Approved**
	For generic drugs (me-too status)	Pegaspargase Injection (Peg-L-Asparaginase of LDS (Reg#105067)
	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	Loka Biosciences Pvt. Ltd Plot No. 14 & 15,ALEAP Industrial Estate, Pragathinagar, Hyderabad, R.R.District -500090, Telangana, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted DS stability study data of 3 batches of API Batch # 7- 7596363 8- 7596364 9- 7596365

		at accelerated (6 Months) as well as real time conditions (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 complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results of pharmaceutical equivalence against the reference product which is Oncaspar Injection 750IU/mL.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	5ml clear & colorless solution filled in 5ml clear moulded glass vial stoppered & sealed with 20mm white color flip off seal having embossed "United Biotech" labelled & placed in plastic tray. Such single plastic tray packed in a printed mono carton along with insert.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Batch No. 4- PAIE8A1 5- PAIF8A2 6- PAIF8A3 The accelerated stability study data is conducted at 25ºC ±2ºC / 60% ± 5% RH for 6 months and real time stability study data conducted at 5ºC ±3ºC for 24 months with the claimed shelf life of 24 months.
	Non-clinical (Module-IV)	The firm has submitted non-clinical data following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity

	Clinical (Module-V)	Firm has submitted clinical data of • Reports of Biopharmaceutic Studies • Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials • Reports of Human Pharmacokinetic (PK) Studies • Reports of Human Pharmacodynamic (PD) Studies • Reports of Efficacy and Safety Studies

Evaluator's remarks:
The firm has provided incomplete data of non-clinical and clinical studies.

Decision: After detailed discussion and deliberation, the Board decided to defer the case for provision of following:

i. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**
ii. **Documented and published clinical studies, biosimilarity studies including In vitro-In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**
iii. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**
iv. **Post-marketing surveillance (Pharmacovigilance) study reports.**

17.	**Name, address of Applicant/Importer**	**M/s Bristol Pharmaceutical & Biologics** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514
	Details of Drug Sale License of importer	**License No:** 05-352-0068-107331D **Address:** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514 **Address of Godown:** NA **Validity:** 14.07.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP (No. 4225314/TS/2023) issued by Drugs Control Administration Government of Telangana for **Inductin 75 IU (Menotropin for injection BP 75 IU/Vial) (Human Menopausal Gonadotropin for injection)** valid upto 08/03/2026. The CoPP states that the product is **on free sale in exporting country**.

		Free Sale Certificate: Firm has submitted original, legalized copy of Free Sale Certificate (L. Dis. No: 116385/TS/2023) dated 25/04/2023 issued by Drugs Control Administration Government of Telangana for **Inductin 75 IU** valid upto 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exporting country.** **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (L. Dis No: 100098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid upto 08/03/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Pharmaceutical & Biologics to register their products in Pakistan. The authorization letter is valid till 27th November, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging as for export purpose only
	Dy. No. and date of submission	Dy. No: Date of submission: 14-Nov-2023
	Details of fee submitted	Rs: 150,000 Slip number: 97246041537 Dated: 02-Nov- 2023
	The proposed proprietary name/ brand name	**Inductin 75 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Menotropin for injection BP 75 IU/Vial**
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 ml ampoule Sodium Chloride 0.9% w/v for reconstitution
	Pharmacotherapeutic Group of (API)	Gonadotropins **ATC code:** G03GA02
	Reference to Finished product specifications	BP
	Proposed Pack size	1's vial & 1's ampoule (1ml)
	Proposed unit price	Rs.3500 /1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.

	The status in reference regulatory authorities	AFMPS (Belgium Approved) Federal Agency for Medicines and Health Products Menopur Ferring 75 IU inj. sol. (pwdr. +solv.) s.c./i.m.amp. vial
	For generic drugs (me-too status)	**Reg. No:**059243 **Company Name:** Genome Pharma **Brand Name:** Folinis 75IU **Formulation:** Each vial contains:- Menotropin for injection and isotonic sodium chloride injection for reconstitution **Pack Size:**1's (vial & ampoule)
	Module-II (Quality Overall Summary)	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	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	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 drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at (40±2°C / 75±5% RH) for 6 months. The long-term stability study is conducted at (25±2°C/60±5% RH) & (2~8°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	Not Required
	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 Vial:** 2mL USP Type I clear glass vial with 13 mm mouth outer diameter **Rubber stoppers:** 13mm slotted grey bromobutyl rubber stopper

		Flip off seal: 13mm aluminum red flip off seal. **Accompanying Diluent:** 2mL USP Type – I clear glass yellow dot ampoule.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product 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±3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. ***Single-dose toxicity 4.2.3.1 and Repeat-dose toxicity 4.2.3.2 data was presented.***
	Module-V Clinical	***5.3.1.1 Bioavailability (BA) Study reports are provided showing comparative Bioavailability & Bioequivalence with reference product.*** *"An open label, balanced, randomized, two-treatment, two-sequence, two-period, Single-dose, crossover bioequivalence study of HMG (Human Menopausal Gonadotropin) 75 IU (Test product T) of Sanzyme Private Limited. India with MENOPUR 75 IU of (Reference product R) Ferring GmbH, Wittland 11, 24109 Kiel, Germany in normal, healthy, adult, human female subjects under fasting condition."* ***Under 5.3.1.4 Reports of Bio-analytical and analytical methods for Human Studies are presented.*** *5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 165 subjects.* Clinical Study Report (5.3.5.1) with title ***"A Prospective, Randomized, Open-Label, Controlled, Clinical Study to Compare the Clinical Efficacy and Tolerability of Two Highly Purified Human Menopausal Gonadotropin Preparations Administered Subcutaneously in Women Undergoing In Vitro Fertilization".*** The data from this study showed that we can conclude that *Gynogen HP is comparable to Menopur* in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the 2 treatment groups. In terms of number of oocytes retrieved, using PP Analysis Set, since the lower limit of the 95% CI of LS mean difference was greater than the noninferiority limit i.e. -2.0, it indicated that Gynogen HP was noninferior and equivalent to Menopur in terms of efficacy. ***Under 5.3.6 Reports of post marketing experience, Periodic safety update report*** is also presented for *Gynogen HP 75 IU* from time period starting from *01-01- 2022 to 31-12- 2022.*
	Evaluator's remarks: • The same product with a different brand name from the same manufacturer/MAH i.e M/s Sanzyme (P) Limited, Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India, is already registered. • It is mentioned on the provided Free Sale Certificate that the product is for Export Market. • The name of the importer is different on provided LOA • Non-clinical and Clinical data is incomplete.	
	Decision: Deferred for the submission of following documents:	

	i. **Clarification regarding submission of application of same product with brand name "Inductin 75 IU" that is already registered with Brand name "Gynogen HP 75 IU" by M/s. Bristol Mayer Biotech Pakistan having same MAH i.e. M/s Sanzyme (P) Limited.** ii. **Clarification from marketing authorization holder for grant of authorization to two different importers.** iii. **Clarification for availabity in the courny of origin since free sale certicate indicates the product is registered for "export purpose only".** iv. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:** v. **Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:** vi. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:** vii. **Post-marketing surveillance (Pharmacovigilance) study reports.**

18.	**Name, address of Applicant/Importer**	**M/s Bristol Pharmaceutical & Biologics** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514
	Details of Drug Sale License of importer	**License No:** 05-352-0068-107331D **Address:** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514 **Address of Godown:** NA **Validity:** 14.07.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8, Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No. 8,Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP (No. 4225315/TS/2023) issued by Drugs Control Administration Government of Telangana for **Inductin 150 IU** **(Menotropin for injection BP 150 IU/Vial) (Human Menopausal Gonadotropin for injection)** valid upto 08/03/2026. The CoPP states that the product is **on free sale in exporting country**. **Free Sale Certificate:** Firm has submitted original, legalized copyof Free Sale Certificate (L. Dis. No: 116385/TS/2023) dated 25/04/2023 issued by Drugs

		Control Administration Government of Telangana for **Inductin 150 IU** valid upto 23/04/2024. The Free Sale Certificate states that the product is **on free sale in exportingcountry** **GMP Certificate:** Firm has submitted original, legalized copyof GMP certificate (L. Dis No: 100098/TS/2023) dated 10/03/2023 issued by Drugs Control Administration Government of Telangana valid upto 08/03/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Pharmaceutical & Biologics to register their products in Pakistan. The authorization letter is valid till 27th November, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging as for export purpose only
	Dy. No. and date of submission	Dy. No: Date of submission: 14-Nov-2023
	Details of fee submitted	Rs: 150,000 Slip number: 51838416532 Dated : 02-Nov-2023
	The proposed proprietary name/ brand name	**Inductin 150 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Menotropin for injection BP 150 IU/Vial**
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 ml ampoule Sodium Chloride 0.9% w/v for reconstitution
	Pharmacotherapeutic Group of (API)	Gonadotrophins **ATC code:** G03G A02
	Reference to Finished product specifications	BP
	Proposed Pack size	1's (vial & ampoule)
	Proposed unit price	Rs. 5206/1's
	Shelf Life	3 years
	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.
	The status in reference regulatory authorities	AFMPS (Belgium Approved) Federal Agency for Medicines and Health Products

		Menopur Ferring 150 IU inj. sol. (pwdr. +solv.) s.c./i.m.amp. vial
	For generic drugs (me-too status)	**Reg. No:**062255 **Company Name:** Genome Pharma **Brand Name:** Folinis 150 IU **Formulation:**Each vial contains:- Menotropin for injection and isotonic sodium chloride injection for reconstitution **Pack Size:**1's (vial & ampoule)
	Module-II (Quality Overall Summary)	Firm has summarized informationrelated to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	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 drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at (40±2°C / 75±5% RH) for 6 months. The long-term stability study is conducted at (25±2°C/60±5% RH) & (2~8°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	Not Required
	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 Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter **Rubber stoppers :**13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	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 Temperature at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. ***Single-dose toxicity 4.2.3.1 and Repeat-dose toxicity 4.2.3.2 data was presented***.
	Module-V Clinical	***5.3.1.1 Bioavailability (BA) Study reports are provided showing comparative Bioavailability*** ***& Bioequivalence with reference product.*** *"An open label, balanced, randomized, two-treatment, two-sequence, two-period,* *Single-dose, crossover bioequivalence study of HMG (Human Menopausal Gonadotropin) 75 IU (Test product T) of Sanzyme Private Limited. India with MENOPUR 75 IU of (Reference product R) Ferring GmbH, Wittland 11, 24109 Kiel, Germany in normal, healthy, adult, human female subjects under fasting condition."* ***Under 5.3.1.4 Reports of Bio-analytical and analytical methods for Human Studies are presented.*** *5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 165 subjects*. Clinical Study Report (5.3.5.1) with title ***"A Prospective, Randomized, Open-Label, Controlled, Clinical Study to Compare the Clinical Efficacy and Tolerability of Two Highly Purified Human Menopausal Gonadotropin Preparations Administered Subcutaneously in Women Undergoing In Vitro Fertilization".*** The data from this study showed that we can conclude that *Gynogen HP is comparable to Menopur* in terms of primary and secondary efficacy endpoints, and that no statistical significant difference was observed between the 2 treatment groups. In terms of number of oocytes retrieved, using PP Analysis Set, since the lower limit of the 95% CI of LS mean difference was greater than the noninferiority limit i.e. -2.0, it indicated that Gynogen HP was noninferior and equivalent to Menopur in terms of efficacy. ***Under 5.3.6 Reports of post marketing experience, Periodic safety update report*** is also presented for

		Gynogen HP 75 IU from time period starting from *01-01- 2022 to 31-12- 2022.*
	Evaluator's remarks: • The same product with a different brand name from the same manufacturer/MAH i.e M/s Sanzyme (P) Limited, Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India, is already registered. • It is mentioned on the provided Free Sale Certificate that the product is for Export Market. • The name of the importer is different on provided LOA • Non-clinical and Clinical data is incomplete.	
	Decision: Deferred for the submission of following documents: **i. Clarification regarding submission of application of same product with brand name "Inductin 150 IU" that is already registered with Brand name "Gynogen HP 150 IU" by M/s. Bristol Mayer Biotech Pakistan having same MAH i.e. M/s Sanzyme (P) Limited.** **ii. Clarification from marketing authorization holder for grant of authorization to two different importers.** **iii. Clarification for availabity in the cournty of origin since free sale certicate indicates the product is registered for "export purpose only".** **iv. Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:** **v. Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:** **vi. Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:** **vii. Post-marketing surveillance (Pharmacovigilance) study reports.**	

18	**Name, address of Applicant/Importer**	**M/s Bristol Pharmaceutical & Biologics** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514
	Details of Drug Sale License of importer	**License No:** 05-352-0068-107331D **Address:** First Floor 73-B, Guldasht Town, Zarrar Shaheed Road, Khewat No. 1354, Khatoni No. 1514 **Address of Godown:** NA **Validity:** 14.07.2028 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**Sanzyme (P) Limited** Plot No. 8, Sy.No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name, address of manufacturer (s)	**Sanzyme (P) Limited** Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India
	Name of exporting country	India

	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP **(No. 4225313/TS/2023)** issued by Drugs Control Administration Government of Telangana for **Gonastim 5000IU** **(Human Chorionic Gonadotropin for injection 5000 IU/Vial) valid** up to 08/03/2026.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **Sanzyme (P) Ltd.** The letter specifies that the manufacturer appoints M/s Bristol Pharmaceutical & Biologics to register their products in Pakistan. The authorization letter is valid till 27th November, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging as for export purpose only
	Dy. No. and date of submission	Dy. No: 1364 Date of submission: 14-Nov-2023
	Details of fee submitted	Rs: 150,000 Slip number:1630965904 Dated : 02-Nov-2023
	The proposed proprietary name/ brand name	**Gonastim 5000 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of sterile freeze dried product contains: Chorionic Gonadotropin(hCG) USP….5000IU. Mannitol USP…. q.s. Potassium dihydrogen Phosphate BP…. q.s. Dipotassium Hydrogen phosphate BP…. q.s. **Diluent:** Sodium chloride 0.9% w/v …. 1ml
	Pharmaceutical form of applied drug	Lyophilized powder for Injection (vial) packed along with 1 ml ampoule Sodium Chloride 0.9% w/v for reconstitution
	Pharmacotherapeutic Group of (API)	Gonadotrophins **ATC code: G03GA01**
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (vial & ampoule)
	Proposed unit price	Rs: 4941
	Shelf Life	3 years

	Storage Conditions	2°C to 8°C. It should not be allowed to freeze.
	The status in reference regulatory authorities	AFMPS (Belgium Approved) Federal Agency for Medicines and Health Products Pregnyl 5000 IU sol. inj. (pdr. + solv.)s.c./i.m. flac.
	For generic drugs (me-too status)	**Reg. No:** 059244 **Company Name:** Genome Pharma **Brand Name:** Presage 5000 IU **Formulation:** Chorionic Gonadotropin for injection 5000 IU **Pack Size:** 1's
	Module-II (Quality Overall Summary)	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	Shanghai Techwell Biopharmaceutical Co., Ltd. Address: No. 4258, Jindu Road, Shanghai 201108, China Tel: +86-21-54427100 Fax: +86-21-54426560 Email: liyan@techwell-cn.com Website: http://www.techwell-cn.com
	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 051101,051102,051201 of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C, RH 75% ± 5% for 6 months. The real time stability data is conducted at 25 °C ± 2°C RH 60% ± 5% & (2~8°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.
	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 Vial:** 2 ml USP Type I Clear glass vial with 13 mm mouth outer diameter

		Rubber stoppers :13mm slotted grey bromobutyl rubber stopper(Type-I),(RFU) **Flip off seals:**13mm Aluminium flip off seal **Accompanying Diluent :**2ml USP Type-I, Clear glass ampoules(OPC) for diluent
	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 Temperature at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted Temperature 5± 3°C for 36 months as per ICH guidelines.
	Module-IV Non-Clinical	Toxicology studies were performed. ***Single-dose toxicity 4.2.3.1 and Repeat-dose toxicity 4.2.3.2 data was presented***.
	Module-V Clinical	*5.3.5.1 Study Reports of Controlled clinical Studies Pertinent to the claimed Indication were presented on 174 subjects.* Clinical Study Report (5.3.5.1) with title ***"A Prospective, Randomized, Open-label, Concurrent-controlled, Three-arm Study to Compare the Clinical Efficacy and Tolerability of Different Follicle-stimulating Hormone (Endogen® HP, Sanzyme vs Fostimon®, IBSA) and Human Chorionic Gonadotropin (Pubergen® HP, Sanzyme vs Pregnyl®, MSD Ltd.) Combinations in Women Undergoing In Vitro Fertilization".*** Pubergen® HP is noninferior and therapeutically equivalent to Pregnyl® with respect to number of oocytes retrieved when administered as an ovulation trigger to female subjects undergoing COS for IVF. ***Under 5.3.6 Reports of post marketing experience, Periodic safety update report*** is also presented for *Pubergen* from time period starting from 01-01- 2021 to 31-12- 2021
	Remarks of Evaluator	i. **Pubergen 5000IU** (Human Chorionic Gonadotropin) is already approved from same manufacturer in the name of M/s. Bristol Mayer Biotech Pakistan & this seems to be the same product with Brand name **Gonastim 5000 IU** by M/s Bristol Pharmaceutical & Biologics.

Evaluator's remarks:

- The same product with a different brand name from the same manufacturer/MAH i.e M/s Sanzyme (P) Limited, Plot No. 8, Sy. No. 542, Koltur (V), Shamirpet (M), Medchal-Malkajgiri (D) - 500101, Telangana State, India, is already registered.
- It is mentioned on the provided Free Sale Certificate that the product is for Export Market.
- The name of the importer is different on provided LOA
- Non-clinical and Clinical data is incomplete.

Decision: Deferred for the submission of following documents:

i.	**Clarification regarding submission of application of same product with brand name "Gonastim 5000 IU" that is already registered with Brand name "Pubergen 5000 IU" by M/s. Bristol Mayer Biotech Pakistan having same MAH i.e. M/s Sanzyme (P) Limited.**
ii.	**Clarification from marketing authorization holder for grant of authorization to two different importers.**
iii.	**Clarification for availabity in the cournty of origin since free sale certicate indicates the product is registered for "export purpose only".**
iv.	**Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**
v.	**Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**
vi.	**Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**
vii.	**Post-marketing surveillance (Pharmacovigilance) study reports.**

19.	**Name, address of Applicant / Importer**	M/s **OBS AGP (Private) Limited.** Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
	Details of Drug Sale License of importer	**License No: 024** **Address:** OBS AGP Private Limited **Address of Godown:** PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter **Valid Upto:** 27-03-2028
	Name and address of marketing authorization holder (abroad)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name, address of manufacturer(s)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name of exporting country	INDIA

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. COPP/CERT/KD/120672/2022/11/42600/208255) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. **The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29-March, 2025** **GMP:** Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051Maharashtra state.India.
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited 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. 15845, 22-06-2023
	Details of fee submitted	PKR 150,000/-: 14-06-2023
	The proposed proprietary name / brand name	**Foligraph 75I.U.** [Recombinant-Human Follicle Stimulating Hormone for Injection (Freeze Dried)]
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Recombinant- Follitropin Concentrated Solution ….75.IU. (Freeze Dried) ***Diluent for Reconstitution*** One ampoule of sterile water for injection 0.5ml
	Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
	Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	Each pack of Foligraph 75I.U. contains:

		1 vial of Recombinant- Human Follicle Stimulating Hormone for Injection (Freeze Dried) 1 ampoule of Sterile Water for Injection 0.5ml
	Proposed unit price	-
	The status in reference regulatory authorities	**Gonal-f** (Follitropin alpha) developed by Serono International, SA
	For generic drugs (me-too status)	Gonadopin 75 I.U. Injection by M/s Matrix Pharma (Pvt.) Ltd
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane-421506, Maharashtra, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (BB1116002, BB1116006, BB1117001) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C 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 bioequivalence studies against reference product Gonal-f (Follitropin alpha) developed by Serono International, SA (formerly, Ares-Serono SA)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	One tray contains one vial (2 ml USP Type I) with one ampoule of sterile water for injection 0.5ml. One carton contains one tray with one insert.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (B08616004, B08616005, B08617001) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 24 months.

Decision: Deferred for the submission of following along with comparative clinical data with reference product:

i. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**

ii. **Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**

iii. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**

iv. **Post-marketing surveillance (Pharmacovigilance) study reports.**

20.	**Name, address of Applicant / Importer**	M/s **OBS AGP (Private) Limited.** Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
	Details of Drug Sale License of importer	**License No: 024** **Address:** OBS AGP PRIVATE LlMlTED **Address of Godown:** PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter **Valid Upto:** 27-03-2028
	Name and address of marketing authorization holder (abroad)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name, address of manufacturer(s)	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
	Name of exporting country	INDIA

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.COPP/CERT/KD/120672/2022/11/42600/208254) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. **The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29-March,2025** **GMP:** Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051Maharashtra state.India.
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited 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. 15846, 22-06-2023
	Details of fee submitted	PKR 150,000/-: 14-06-2023
	The proposed proprietary name / brand name	**Foligraph 150IU** [Recombinant-Human Follicle Stimulating Hormone for Injection (Freeze Dried)]
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Recombinant- Follitropin Concentrated Solution ….150.IU. (Freeze Dried) ***Diluent for Reconstitution*** One ampoule of sterile water for injection 0.5ml
	Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
	Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone

	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	Each pack of Foligraph 150.IU. contains: 1 vial of Recombinant- Human Follicle Stimulating Hormone for Injection (Freeze Dried) 1 ampoule of Sterile Water for Injection 0.5ml
	Proposed unit price	-
	The status in reference regulatory authorities	**Gonal-f** (Follitropin alpha) developed by Serono International, SA
	For generic drugs (me-too status)	Follitrope 150 I.U. Injection by M/s Galaxy Pharmaceuticals (Pvt.) Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**M/s Bharat Serums and Vaccines Limited** Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane-421506, Maharashtra, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (BB1116002, BB1116006, BB1117001) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C 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 bioequivalence studies against reference product Gonal-f (Follitropin alpha) developed by Serono International, SA (formerly, Ares-Serono SA)

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	One tray contains one vial (2 ml USP Type I) with one ampoule of sterile water for injection 0.5ml. One carton contains one tray with one insert.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (B08717002, B08717004, B08718002) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 24 months.

Decision: Deferred for the submission of following along with comparative clinical data with reference product:

i. **Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:**

ii. **Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**

iii. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**

iv. **Post-marketing surveillance (Pharmacovigilance) study reports.**

21.	**Name, address of Applicant / Importer**	M/s **Medi Mark Pharmaceuticals** 588/B-I ,Karbala Road ,Liaquat Chowk , Sahiwal
	Details of Drug Sale License of importer	**License No:** 02-367-0154-049333D 588/B-I ,Karbala Road ,Liaquat Chowk , Sahiwal. **Valid Upto:** 20-12-2028
	Name and address of marketing authorization holder (abroad)	**M/S** Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1-No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China. 2-JieErNian,Zhonghe, Hi-Tech zone , Chengdu , P.R.C,China.
	Name, address of manufacturer(s)	**M/s** Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1-No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China. 2-JieErNian,Zhonghe, Hi-Tech zone , Chengdu , P.R.C,China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original legalized CoPP certificate No.Sichuan 20220079 dated 23-09-2022 issued by **Sichuan Medical Products Administration No.98 ,Yu Sha Road ,Chengdu ,Sichuan Province, China**. The certificate was valid till 17-08-2024.

	Details of letter of authorization / sole agency agreement	Firm has submitted Original legalized letter of authorization from **Sichuan Yuanda Shuyang Pharmaceiticals Co.,Ltd 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, China** in favour of Medi Mark Pharmaceuticals Liaquat Chowk ,Sahiwal , Pakistan, as their sole distributor for applied product. The LOA is issued on 11-10-2022 which is valid for 05 years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	R & I Dy. No. 676, Date Jan 09,2023
	Details of fee submitted	Challan No.067101816592 Amount: 150,000 Date of submission: 03-01-2023
	The proposed proprietary name / brand name	**Medigam Inj 2.5gm**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Immunoglobulin 2.5gm/vial , I.V (5% ,50ml)
	Pharmaceutical form of applied drug	Liquid Injection I.V
	Pharmacotherapeutic Group of (API)	Immunoglobulins /Immune sera
	Reference to Finished product specifications	In House Chinese Pharmacopoeia but More stringent than U.S.P /B.P
	Proposed Pack size	1,s vial & 1 x 10,s
	Proposed unit price	As Per SRO + CPI
	The status in reference regulatory authorities	Intraglobin Inj. (Nabiqasim) Mnf. by Biotest Pharma Germany , Germany
	For generic drugs (me-too status)	Intraglobin Inj. (Nabiqasim) Mnf. by Biotest Pharma Germany , Germany
	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	**M/S** Sichuan Yuanda Shuyang Pharmaceiticals Co.,LTd 1-No. 888, 5th Antai Road, High-tech Zone, Chengdu, 611730, Sichuan, 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.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated stability. The accelerated stability study data is conducted at 25°C ± 2°C up to 6 months & long term Stability data for three batches conducted at 5°C ± 3°C for the period of 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 Pharmaceutical Equivalence and Comparative Dissolution Profile
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection vial made of neutral borosilicate glass closed with halogenated butyl rubber SP8-06. The rubber stoppers are sealed with aluminium plastic cap (Polypropylene) Attachment 3.2.P.7
	Stability study data of drug product, shelf life and storage conditions	The accelerated stability study data is conducted at 25°C ± 2°C / 60% RH ± 5% RH up to 6 months. The long Term stability study data is conducted at 5°C ± 3°C up to 36 months. 36 Month 2 C to 8 C
Decision: Deferred for the submission of following along with comparative clinical data with reference product: **i. Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and**		

developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:

ii. **Documented and published clinical studies, biosimilarity studies including In-vitro, In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:**

iii. **Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:**

iv. **Post-marketing surveillance (Pharmacovigilance) study reports.**

Agenda Item No.4. Cases for Export

1. Following applications of Semaglutide Tablets 3mg, 7mg and 14mg applied for export registration by M/s Highnoon Laboratories Ltd, Lahore:

Sr. No.	Name of Drug(s) with composition	RRA Status	Dy. No. /Fee with date
1	**Semaglu 3mg Tablets**	RYBELSUS (semaglutide) tablets, for oral use Initial U.S. Approval: 2017 Novo Nordisk	Dy No. 12710 R&I 23May 2023 Fee challan of Rupee 75000/-(Slip No., 516913761796) is submitted by firm
2.	**Semaglu 7mg Tablets**	RYBELSUS (semaglutide) tablets, for oral use Initial U.S. Approval: 2017 Novo Nordisk	Dy No. 12711 R&I 23May 2023 Fee challan of Rupee 75000/-(Slip No., 88529717) is submitted by firm
3.	**Semaglu 14mg Tablets**	RYBELSUS (semaglutide) tablets, for oral use Initial U.S. Approval: 2017 Novo Nordisk	Dy No. 12709 R&I 23May 2023 Fee challan of Rupee 75000/-(Slip No., 99831688666) is submitted by firm

Matter was considered by the Drug Registration Board in its 340th meeting held on 1-2nd October, 2024 and deferred the case for submission of the following:

i. *Evidence of section approval, Source of API & GMP certificate of API manufacturer.*
ii. *Evidence of approval of finished product from same API in country of origin, if any.*
iii. *Safety/Efficacy studies OR Bio similarity studies data OR Sameness Evaluation data.*
iv. *Analytical method for test analysis of applied formulation.*
v. *Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ color do not resemble with already registered brands in importing country*

The applicant was advised to comply the decision of the board. They have withdrawn their applications and replied as under:

> ***"this is with reference to your letter No.2-2/2024-DD(BD) (M-240) dated 08th November, 2024 (attached as reference). We withdraw our export-only application for registration due to the lack of biological section approval Kindly proceed accordingly".***

Evaluator's remarks:

The BE&R Division requested the Licensing Division to confirm the availability of Biological Section of the firm. The Licensing Division has confirmed that as of today the firm does not possess the said section.

Decision of 344th meeting of the Registration Board:

Keeping in view the non availability of the manufacturing facility / section required for manufacturing of above said products, the Board decided to reject the application.

2. Following applications of Semaglutide Tablets 3mg, 7mg and 14mg applied for export

registration by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML No.000348).

S. No.	Brand Name & Composition	Dy. No., Date of Application & Fee Status
01	**SimaGlu Tablet** Each film coated tablet contains: Semaglutide…3mg	Dy. No.9370, Dated 06-04-2023, Fee Paid Rs.75000/-
02	**SimaGlu Tablet** Each film coated tablet contains: Semaglutide…7mg	Dy. No.9371, Dated 06-04-2023, Fee Paid Rs.75000/-
03	**SimaGlu Tablet** Each film coated tablet contains: Semaglutide…14mg	Dy. No.9372, Dated 06-04-2023, Fee Paid Rs.75000/-

Evaluator's remarks:
The BE&R Division requested the Licensing Division to confirm the availability of Biological Section of the firm. The Licensing Division has confirmed that as of today the firm does not possess the said section.
Decision of 344th meeting of the Registration Board:
Keeping in view the non availability of the manufacturing facility / section required for manufacturing of above said products, the Board decided to reject the application.

3. Following applications of Liraglutide Injection 6mg/ml applied for local manufacturing by M/s Genix Pharma Pvt Ltd, Plot no.44-45-B, Korangi Creek Road, Karachi (DML No.000351).

S. No.	Brand Name & Composition	Dy. No., Date of Application & Fee Status
01	**Liratid Injection** (Solution for injection in pre-filled syringe) Each ml contains: Liraglutide.…6mg	Dy. No.8512, Dated 01-04-2022, Fee Paid Rs.75000/-

Evaluator's remarks:
The BE&R Division requested the Licensing Division to confirm the availability of Biological Section of the firm. The Licensing Division has confirmed that as of today the firm does not possess the said section.
Decision of 344th meeting of the Registration Board:
Keeping in view the non availability of the manufacturing facility / section required for manufacturing of above said products, the Board decided to reject the application.

Agenda Item No.5. Registration Application of Veterinary Biological Products

a. Registration of Imported Veterinary Biological Products

1.	**Name of Importer &** Address	**M/s Hi-Tech Pharmaceuticals (Pvt) Ltd** 1-C, Shadman Chowk, Jail Road, Lahore
	DSL Details	License to Sell Drugs as Distributor No: 05-352-0063-066935D

		valid till 3 Mar 2028
	Type of Form Dy. No. Date of Application Fee submitted	Form – 5A Dy.No.144, dated 23-08-2023. Rs. 150,000/- Slip No. 3736626371, dated 21-08 2023
	Name of Manufacturer & Address	**ZOETIS Inc.** 601 West Cornhusker Highway, Lincoln, NE 68521-3577, USA.
	Name of exporting country	USA
	Brand Name Dosage Form Strength	**Inforce™ 3** **Freeze Dried Vaccine with sterile diluent** **Each dose of 2ml contains;** Bovine Rhinotracheitis Virus…..$\geq 10^{6.0}$ $TCID_{50}$ at release Strain RLB 106……...$\geq 10^{5.5}$ $TCID_{50}$ at expiration Bovine Parainfluenza$_3$ Virus…..$\geq 10^{5.5}$ $TCID_{50}$ at release Strain RLB 103……...$\geq 10^{5.0}$ $TCID_{50}$ at expiration Bovine Respiratory Syncytial Virus…$\geq 10^{5.3}$ $TCID_{50}$ at release Strain BRSV/375…….$\geq 10^{4.8}$ $TCID_{50}$ at expiration
	Composition	**Each dose of 2ml contains;** Bovine Rhinotracheitis Virus……..$\geq 10^{6.0}$ $TCID_{50}$ at release Strain RLB 106……...$\geq 10^{5.5}$ $TCID_{50}$ at expiration Bovine Parainfluenza$_3$ Virus……..$\geq 10^{5.5}$ $TCID_{50}$ at release Strain RLB 103……$10^{5.0}$ $TCID_{50}$ at expiration Bovine Respiratory Syncytial Virus…$\geq 10^{5.3}$ $TCID_{50}$ at release Strain BRSV/375…….$\geq 10^{4.8}$ $TCID_{50}$ at expiration
	Finished Product Specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf Life	18 Months (2 – 7ºC)
	International Availability	United State of America (USA)
	Products already Registered in Pakistan	**Not Registered**
	Demanded Price Demanded Pack Size	1x10 doses vial with 20ml sterile diluent
	Certificates Submitted	**CoPP/FSc:** Legalized Certification of Licensing and Inspection (Free Sale) has been provided. **GMP:** Legalized GMP Certificate of foreign manufacturer has been provided. **LOA:** Legalized LOA has been provided.
	Remarks of the Evaluator	During evaluation, following deficiencies have been observed in the application; • **As per available record, the formulation is not already registered in Pakistan.** • The GMP certificate of the principal manufacturer was issued on 03-10-2018 which has been expired. • The data pertaining to diluent, has not been submitted by the company.
	Decision:	

	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application; • **The GMP certificate of the principal manufacturer was issued on 03-10-2018 which has been expired.** • **The data pertaining to diluent, has not been submitted by the company.**	
2.	Name and address of Applicant	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy.No 19681 Dated 08-08-2023 Rs: 75,000/- , Dated 01-08-2023 (slip No. 65421824772)
	Detail of Drug Sale License	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan. Validity: 29th June 2028 Status: Drug License By Way of Wholesale (Form No.07). DSL No: DHO (East) Drug/- 504
	Name and address of marketing authorization holder	**M/s IZO S.r.l. a socio unico** Address: Via San Zeno 99/A ,25124 Bresica ,Italy
	Name and address of manufacturer	**M/s IZO S.r.l. a socio unico** Address: S.S. 234 per Cremona Km 28.2, 27013 Chignolo Po (PV), Italy
	Name of exporting country	Italy
	Brand Name +Dosage Form + Strength	**VAXXON MD CVI N VACCINE** **Suspension for Injection** One dose (0.2ml) of reconstituted vaccine contains: Live apathogenic virus of Marek's Disease strain Rispens CVI 988 (serotype 1) : ≥ 2000 PFU
	Composition	One dose (0.2ml) of reconstituted vaccine contains: Live apathogenic virus of Marek's Disease strain Rispens CVI 988 (serotype 1) : ≥ 2000 PFU
	Finished Product Specification	As per Innovator's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	24 months (In Liquid Nitrogen at -196°C)
	Demanded Price	Decontrolled
	Pack size	1000 Doses & 2000 Doses
	International availability	Italy
	Products already Registered in Pakistan	CEVAC MD RISPENS-Marush (Pvt.) Ltd.
	Certificates Submitted	**CoPP:** Valid Original Legalized CoPP No. 326/2022/C dated 12-12-2022 issued by Ministry of Health -Directorate General for Animal Health and Veterinary Medical Product, Italy

		GMP: Copy of GMP Certificate No. NBF/45/2022/V, dated 21-07-2022, issued by Ministry of Health -Directorate General for Animal Health and Veterinary Medical Product, Italy **LOA/Power of Attorney:** Power of attorney issued dated 24-January-2023 valid for two years provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiencies have been observed; • The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited. • The copy of GMP certificate of foreign manufacturer provided, is not legalized. • The letter of Power of Attorney provided, is not legalized. • As the product is available in multiple pack sizes, the applied pack size needs to be specified.
	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited.** • **The copy of GMP certificate of foreign manufacturer provided, is not legalized.** • **The letter of Power of Attorney provided, is not legalized.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.**	
3.	Name and address of Applicant	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan.
	Detail of Drug Sale License	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan. Validity: 29th June 2028 Status: Drug License By Way of Wholesale (Form No.07). DSL No: DHO (East) Drug/- 504
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy.No 19680, Dated 08-08-2023 Rs: 75,000/- Dated 01-08-2023 (slip No. 3651728009)
	Name and address of marketing authorization holder	**M/s IZO S.r.l. a socio unico** Address: IZO S.r.l a socio unico Via San Zeno 99/A 25124 Bresica Italy
	Name and address of manufacturer	**M/s IZO S.r.l. a socio unico** Address: S.S. 234 per Cremona Km 28.2, 27013 Chignolo Po (PV), Italy
	Name of exporting country	Italy
	Brand Name +Dosage Form + Strength	**VAXXON MD DILUENT** Each container of diluent of 200ml (for 1000 doses of vaccine) contains; Tryptose…..2g Glucose……200mg Red Phenol….2mg Phosphate Buffer Solution pH 7.4 q.s. to… 200ml
	Composition	Each container of diluent of 200ml (for 1000 doses of vaccine) contains;

		Tryptose…..2g Glucose……200mg Red Phenol….2mg Phosphate Buffer Solution pH 7.4 q.s. to… 200ml
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Diluent for frozen vaccines against Marek's disease
	Shelf life	36 months (25°C ± 2°C)
	Demanded Price	Decontrolled
	Pack size	200 ml & 400 ml
	International availability	Italy
	Products already Registered in Pakistan	Not Available
	Certificates Submitted	**CoPP:** Valid Original Legalized CoPP No. 326/2022/C dated 12-12-2022 issued by Ministry of Health -Directorate General for Animal Health and Veterinary Medical Product, Italy **GMP:** Copy of GMP Certificate No. NBF/45/2022/V, dated 21-07-2022, issued by Ministry of Health -Directorate General for Animal Health and Veterinary Medical Product, Italy **LOA/Power of Attorney:** Power of attorney issued dated 24-January-2023 valid for two years, provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiencies have been observed; • The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited. • The copy of GMP certificate of foreign manufacturer provided, is not legalized. • The letter of Power of Attorney provided, is not legalized. • As the product is available in multiple pack sizes, the applied pack size needs to be specified.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited.** • **The copy of GMP certificate of foreign manufacturer provided, is not legalized.** • **The letter of Power of Attorney provided, is not legalized.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **Justification of separate registration of diluent rather than combo pack with vaccine, is required.**	
4.	Name and address of Applicant	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan.
	Detail of Drug Sale License	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan. Validity: 29th June 2028 Status: Drug License By Way of Wholesale (Form No.07). DSL No: DHO (East) Drug/- 504
	Type of Form	Form-5A

	Dy. No. Date of Application Fee submitted	Dy.No 1031, Dated 20-10-2023 Rs: 75,000/- Dated 16-10-2023
	Name and address of manufacturer	**Inner Mongolia Bigvet Biotech Co., Ltd.** East Side of Culina, Shida East Road, Shengle Economic Park, Helinger County, Hohhot Inner Mongolia Autonomous Region, People's Republic of China 011517.
	Name and address of marketing authorization holder	**Inner Mongolia Bigvet Biotech Co., Ltd.** Shida East Road, Shengle Economic Park, Helinger County, Hohhot Inner Mongolia Autonomous Region, People's Republic of China 011517.
	Name of exporting country	People's Republic of China
	Brand Name +Dosage Form + Strength	**RINVAC FMD** Each dose contains; Inactivated FMD virus Type O (strain OHM/02).....$\geq 6PD_{50}$ Inactivated FMD virus Type A (strain AKT-III) .....$\geq 6PD_{50}$ Inactivated FMD virus Type Asia 1 (strain Asia 1 KZ/03).....$\geq 6PD_{50}$
	Composition	Each dose contains; Inactivated FMD virus Type O (strain OHM/02).....$\geq 6PD_{50}$ Inactivated FMD virus Type A (strain AKT-III) .....$\geq 6PD_{50}$ Inactivated FMD virus Type Asia 1 (strain Asia 1 KZ/03).....$\geq 6PD_{50}$
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	24 months (2 - 8ºC)
	Pack size /Demanded Price	20mlx100bottles/ Decontrolled 50mlx50bottles/ Decontrolled 100mlx50bottles/ Decontrolled
	International availability	China
	Products already Registered in Pakistan	FMD Vaccine-Mustafa Brothers AFTOVAC-Huzaifa International
	Certificates Submitted	**CoPP/FSC:** Original, Legalized FSC has been provided. **GMP:** Original, Legalized GMP certificate of foreign manufacturer, has been provided. **LOA/Power of Attorney:** Original, Legalized LOA from MAH, has been provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiencies have been observed; • The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited. • As the product is available in multiple pack sizes, the applied pack size needs to specified.
	Decision: **Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited.** • **As the product is available in multiple pack sizes, the applied pack size needs to specified.**	
5.	Name and address of Applicant	**M/s Ghazi Brothers.**

		D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan.
	Detail of Drug Sale License	**M/s Ghazi Brothers.** D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan. Validity: 29th June 2028 Status: Drug License By Way of Wholesale (Form No.07). DSL No: DHO (East) Drug/- 504
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy.No 4612, Dated 17-02-2023 Rs. 75,000/- Dated 26-01-2023
	Name and address of manufacturer	**DYNTEC spol. S r. o.,** Prazska 328, 411 55 Terezin, Czech Republic.
	Name and address of marketing authorization holder	**DYNTEC spol. S r. o.,** Prazska 328, 411 55 Terezin, Czech Republic.
	Name of exporting country	Czech Republic
	Brand Name +Dosage Form + Strength	**Canglob P** Each ml contains; Immunoglobulinum anti parvovirosis canis….NLT 1024 HIU
	Composition	Each ml contains; Immunoglobulinum anti parvovirosis canis….NLT 1024 HIU
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Heterologous Immunoglobulins for dogs.
	Shelf life	18 Months (2 – 8ºC)
	Pack size /Demanded Price	5ml/Decontrolled 6ml/Decontrolled
	International availability	Colombia-MA Ecuador-MA India-MA Iran-MA Kuwait-MA Malaysia-MA
	Products already Registered in Pakistan	Not Registered
	Certificates Submitted	**FSC/CoPP:** Copy of FSC & CoPP submitted. **GMP:** Copy of GMP certificate of foreign manufacturer, submitted. **LOA:** Copy of LOA/Power of Attorney Submitted.
	Remarks of the Evaluator	During Evaluation of application, following deficiencies have been observed; • **As per available record, the formulation is not already registered in Pakistan.** • The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited. • The copy of GMP certificate of foreign manufacturer provided, has not been legalized and the GMP certificate has expired in June 2023. • The copy of CoPP provided has not been legalized. • The copy of FSC provided, has not been legalized.

		• The copy of Power of Attorney provided, has not been legalized. • As the product is available in multiple pack sizes, the applied pack size needs to specified.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied product in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The firm has deposited fee of Rs. 75,000/-. Differential fee of Rs. 75,000/- is required to be deposited.** • **The copy of GMP certificate of foreign manufacturer provided, has not been legalized and the GMP certificate has expired in June 2023.** • **The copy of CoPP provided has not been legalized.** • **The copy of FSC provided, has not been legalized.** • **The copy of Power of Attorney provided, has not been legalized.** • **As the product is available in multiple pack sizes, the applied pack size needs to specified.**	
6.	Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
	Detail of DSL	M/s Snam Pharma, 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D Valid till: 14 November, 2027.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 515 Dated 14th September 2023 Rs. 150,000/-, Date: 21-02-2022, Challan No. 1484397123
	Name of Manufacturer & MAH/PLH	**Manufacturer:** Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic **MAH:** Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic
	Name of exporting country	Czech Republic
	Brand Name + Dosage Form + Strength	**Orniprim, lyof. ad us. vet.** Lyophilizate for suspension for domestic fowl Paramyxovirus pseudopestis avium, strain Bio 52: NDV B1 min. $10^{6.0}$ EID_{50} - max. $10^{7.5}$ EID_{50}
	Composition	One vaccination dose contains: Paramyxovirus pseudopestis avium, strain Bio 52: NDV B1 min. $10^{6.0}$ EID_{50} - max. $10^{7.5}$ EID_{50} * EID50 – 50% infection dose for chicken embryos
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	30 months (2°C - 8°C)
	International availability	Czech Republic, Armenia, Egypt, Greece, Kuwait, Lebanon, Nigeria, Pakistan, Syria, Ukraine.
	Products already registered in Pakistan	Brand Name: Orniprim, lyof. ad us. vet. (10's x 1000 doses)
	Demanded Price / Pack size	De-controlled 10's x 2500 doses

	Certificates Submitted	**CoPP:** Original, Valid, Legalized CoPP has been provided. **GMP:** Legalized copy of valid GMP certificate has been provided. **LOA:** Copy of LOA issued by Marketing & Sales Director MAH, has been provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiency has been observed; • The copy of LOA provided, has been issued by Marketing & Sales Director and is not legalized.
	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **The copy of LOA provided, has been issued by Marketing & Sales Director and is not legalized.**	
7.	**Name and address of Importer**	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
	Detail of DSL	**M/s Snam Pharma,** 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D Valid till: 14 November, 2027.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 362 Dated 07th September 2023 Rs. 150,000/- Date: 05-09-2023, Challan No. 48003524344
	Name of Manufacturer & MAH	**Manufacturer:** Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic **MAH:** Bioveta, a.s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic
	Name of exporting country	Czech Republic
	Brand Name + Dosage Form + Strength	**ORNIBRON H120+D274, lyophilisate for suspension for chicken** **Lyophilizate for suspension for domestic fowl** Active substances: Virus bronchitidis infectiosae avium, strain H120 min. $10^{3.0}$ EID_{50} - max. $10^{4.8}$ EID_{50} Virus bronchitidis infectiosae avium, strain D274 min. $10^{3.0}$ EID_{50} - max. $10^{4.8}$ EID_{50}
	Composition	One vaccination dose contains: Active substances: Virus bronchitidis infectiosae avium, strain H120 min. $10^{3.0}$ EID_{50} - max. $10^{4.8}$ EID_{50} Virus bronchitidis infectiosae avium, strain D274 min. $10^{3.0}$ EID_{50} - max. $10^{4.8}$ EID_{50} * EID_{50} – 50% infection dose for chicken embryos
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	30 months (2°C - 8°C)
	International availability	Czech Republic, Armenia, Azerbaijan, Egypt, Jordan, Uzbekistan, Moldova, Belarus, United Arab Emirates.

	Products already registered in Pakistan	Not Registered.
	Demanded Price / Pack size	De-controlled 10's x 1000 doses
	Certificates Submitted	**CoPP:** Original, Valid, Legalized CoPP has been provided. **GMP:** Legalized copy of valid GMP certificate has been provided. **LOA:** Copy of LOA issued by Sales Representative of MAH, has been provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiency has been observed; • **As per available record, the formulation with Avian Infectious Bronchitis Virus Strain D-274, is not already registered in Pakistan.** • The copy of LOA provided, has been issued by Sales Representative of MAH and is not legalized.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The copy of LOA provided, has been issued by Sales Representative of MAH and is not legalized.**	
8.	**Name and address of Importer**	**M/s Snam Pharma,** 61-G, Phase-1, Commercial Area, DHA, Lahore
	Detail of DSL	**M/s Snam Pharma,** 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D Valid till: 14th November, 2027.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. Dated 17-03-2023 Rs. 150,000/- , Dated 15-02-2023
	Name of MAH	**Tianjin Ringpu Bio-technology Co., Ltd.,** Airport Economic Zone Branch No. 168, Huanhe South Road, Airport Economic Zone, Tianjin, China.
	Name of Manufacturer	**Tianjin Ringpu Bio-technology Co., Ltd.,** Airport Economic Zone Branch No. 168, Huanhe South Road, Airport Economic Zone, Tianjin, China.
	Name of exporting country	People's Republic of China
	Brand Name + Dosage Form + Strength	**Rinvac ND + IB + AI** Each 0.1ml contains; Newcastle Disease Virus (La Sota Strain)…$\geq 3x10^8$ EID_{50} Infectious Bronchitis Virus (M41 Strain) …$\geq 3x10^6$ EID_{50} Avian Influenza Virus H9 Subtype (HP Strain)…$\geq 3x10^7$ EID_{50}
	Composition	Each dose (0.1ml) contains; Newcastle Disease Virus (La Sota Strain)…$\geq 3x10^8$ EID_{50} Infectious Bronchitis Virus (M41 Strain) …$\geq 3x10^6$ EID_{50} Avian Influenza Virus H9 Subtype (HP Strain)…$\geq 3x10^7$ EID_{50}
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)

	International availability	China.
	Products already registered in Pakistan	GPVAC ND+IB+H9 Injection- Grand Pharma
	Demanded Price / Pack size	500ml/De-controlled
	Certificates Submitted	**CoPP/FSC:** Legalized FSC has been provided. **GMP:** Legalized copy of valid GMP certificate has been provided. **LOA:** Copy of LOA from MAH is provided.
	Remarks of the Evaluator	During Evaluation of application, following deficiency has been observed; • Legalized LOA form MAH is required.
	Decision: **Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **Legalized LOA form MAH is required.**	
9.	Name and address of Importer	**M/s Al-Asar Enterprises,** Gulshan e Gulab Colony, Behind Abdullah Heart Care Hospital, House No.12, Near Pull Wasil Chowk, Suraj Miani Road, Multan
	Detail of DSL	License No: 04-361-0159-96972D Valid up to: 05.08.2027
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 1828 dated 21st December 2023, Rs. 150,000/-
	Name of Manufacturer & MAH	**Egyptian Company for Biological & Pharmaceutical Industries** Block No. 101 sixth industrial zone, 6 of October city Giza, Egypt.
	Name of exporting country	Arab Republic of Egypt
	Brand Name + Dosage Form + Strength	**ValleyVac H9-ND^{G7}** Inactivated Avian Influenza Virus subtype H9N2, Newcastle disease Virus, genotype VII - HA antigen titer of each not less than 9 Log_2 / dose
	Composition	Inactivated Avian Influenza Virus subtype H9N2, Newcastle disease Virus, genotype VII - HA antigen titer of each not less than 9 Log_2 / dose
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Virus Vaccine
	Shelf life	24 Months (4 – 8 °C)
	International availability	Kuwait, Iraq, Oman, Qatar & Bahrain
	Products already registered in Pakistan	**Jova Zeit 1,7-Jova Global**
	Demanded Price / Pack size	**De-controlled /Not Provided**
	Certificates Submitted	**CoPP/FSC:** Original, Valid, Legalized FSC, has been provided. **GMP:** The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required. **LOA:** Not provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required.

		• Copy of Legalized sole agency agreement has been provided wherein name of product has not been mentioned. Legalized copy of valid Letter of Authorization of the product from MAH, is required. • The composition mentioned on label of the product contains two genotypes (VII & II) of NDV while composition mentioned on the FSC, contains single genotypes (VII) of NDV. • As the product is available in multiple pack sizes, the applied pack size has not been specified.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required.** • **Copy of Legalized sole agency agreement has been provided wherein name of product has not been mentioned. Legalized copy of valid Letter of Authorization of the product from MAH, is required.** • **The composition mentioned on label of the product contains two genotypes (VII & II) of NDV while composition mentioned on the FSC, contains single genotypes (VII) of NDV.** • **As the product is available in multiple pack sizes, the applied pack size has not been specified.**	
10.	Name and address of Importer	**M/s Al-Asar Enterprises,** Gulshan e Gulab Colony, Behind Abdullah Heart Care Hospital, House No.12, Near Pull Wasil Chowk, Suraj Miani Road, Multan
	Detail of DSL	License No: 04-361-0159-96972D Valid up to: 05.08.2027
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 1881 dated 21st December 2023, Rs. 150,000/-
	Name of Manufacturer & MAH	**Egyptian Company for Biological & Pharmaceutical Industries** Block No. 101 sixth industrial zone, 6 of October city Giza, Egypt.
	Name of exporting country	Arab Republic of Egypt
	Brand Name + Dosage Form + Strength	**ValleyVac H5 Plus -ND^{G7}** Inactivated Avian Influenza Virus subtype H5N1, Inactivated Avian Influenza Virus subtype H5N8 and Newcastle disease Virus, genotype VII - HA antigen titer of each not less than 9 Log_2 / dose
	Composition	Inactivated Avian Influenza Virus subtype H5N1, Inactivated Avian Influenza Virus subtype H5N8 and Newcastle disease Virus, genotype VII - HA antigen titer of each not less than 9 Log_2 / dose
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Virus Vaccine
	Shelf life	24 Months (4 – 8 °C)
	International availability	Kuwait, Iraq, Oman, Qatar & Bahrain
	Products already registered in Pakistan	**Not Registered**
	Demanded Price / Pack size	**De-controlled /Not Provided**
	Certificates Submitted	**CoPP/FSC:** Original, Valid, Legalized FSC, has been provided. **GMP:** The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required. **LOA:** Not provided.

	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, the formulation with applied strains, is not already registered in Pakistan.** • The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required. • Copy of Legalized sole agency agreement has been provided wherein name of product has not been mentioned. Legalized copy of valid Letter of Authorization of the product from MAH, is required. • The composition mentioned on label of the product contains two genotypes (VII & II) of NDV while composition mentioned on the FSC, contains single genotypes (VII) of NDV. • As the product is available in multiple pack sizes, the applied pack size has not been specified.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The copy of legalized valid GMP certificate of foreign manufacturer has been provided. Original legalized copy of valid GMP certificate is required.** • **Copy of Legalized sole agency agreement has been provided wherein name of product has not been mentioned. Legalized copy of valid Letter of Authorization of the product from MAH, is required.** • **The composition mentioned on label of the product contains two genotypes (VII & II) of NDV while composition mentioned on the FSC, contains single genotypes (VII) of NDV.** • **As the product is available in multiple pack sizes, the applied pack size has not been specified.**	
11.	Name and address of Importer	**M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad
	Detail of DSL	**M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad **DSL No.** Distribution License/DHO-ISB-433 **Expiry: 08-11-2024**
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 48460 dated 20th Feb, 2023 Rs. 150,000/-
	Name of Manufacturer & MAH	**Jinyu Baoling Bio-pharmaceutical Co., Ltd.** No. 1 Jinyu Street, Shaerqin Industrial Park of Economic and Technological Development Zone, Hohhot, Inner Mongolia, China
	Name of exporting country	People's Republic of China
	Brand Name + Dosage Form + Strength	**Combined Bovine Viral Diarrhea/Mucosal Disease and Infectious Bovine Rhinotracheitis Vaccine, Inactivated (Strain NMG + Strain LY).** Inactivated antigen of bovine viral diarrhea/mucosal disease virus (Strain NMG)….before inactivation is not less than $10^{7.5}TCID_{50}$/ml. Inactivated antigen of infectious bovine rhinotracheitis virus (Strain LY)…. before inactivation is not less than $10^{7.5}TCID_{50}$/ml.
	Composition	Inactivated antigen of bovine viral diarrhea/mucosal disease virus (Strain NMG)….before inactivation is not less than $10^{7.5}$TCID50/ml.

		Inactivated antigen of infectious bovine rhinotracheitis virus (Strain LY)…. before inactivation is not less than $10^{7.5}$TCID50/ml.
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Virus Vaccine
	Shelf life	12 Months (2-8 ºC)
	International availability	China
	Products already registered in Pakistan	Not registered
	Demanded Price / Pack size	Decontrolled/ 20ml bottle
	Certificates Submitted	**CoPP/FSC:** Original, Valid, Legalized FSC, has been provided. **GMP:** Legalized copy of Valid GMP certificate of foreign manufacturer has been provided. **LOA:** Legalized copy of Valid LOA from MAH has been provided but is not signed. .
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied strains, is not already registered in Pakistan.** • The DSL of the firm has expired on 08-11-2024. • Letter of Authorization from MAH submitted, is unsigned. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The DSL of the firm has expired on 08-11-2024.** • **Letter of Authorization from MAH submitted, is unsigned.** • **Information regarding international availability of the product is required to be submitted.**	
12.	Name and address of Importer	**M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad
	Detail of DSL	**M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad **DSL No.** Distribution License/DHO-ISB-433 **Expiry: 08-11-2024**
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 256686 dated 08th Dec, 2022 Rs. 150,000/-
	Name of Manufacturer & MAH	**Jinyu Baoling Bio-pharmaceutical Co., Ltd.** No. 1 Jinyu Street, Shaerqin Industrial Park of Economic and Technological Development Zone, Hohhot, Inner Mongolia, China
	Name of exporting country	People's Republic of China
	Brand Name + Dosage Form + Strength	**Brucellosis Vaccine, Live (Strain A19)** Brucella abortus (Strain A19) (CVCC 70202)…. $\geq 6.0\times10^{10}$ CFU per dose
	Composition	Brucella abortus (Strain A19) (CVCC 70202)…. $\geq 6.0\times10^{10}$ CFU per dose

	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Bacterial Veterinary Vaccine
	Shelf life	12 Months (2-8 ºC or below -15ºC)
	International availability	China
	Products already registered in Pakistan	Not Registered.
	Demanded Price / Pack size	Decontrolled. 20ml/bottle
	Certificates Submitted	**CoPP/FSC:** Original, Valid, Legalized FSC, has been provided. **GMP:** Legalized copy of Valid GMP certificate of foreign manufacturer has been provided. **LOA:** Legalized copy of Valid LOA from MAH has been provided but is not signed. .
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied strain, is not already registered in Pakistan.** • The DSL of the firm has expired on 08-11-2024. • Letter of Authorization from MAH submitted, is unsigned. • Stability Studies of three batches is required. • Saftey & efficacy studies data is required. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The DSL of the firm has expired on 08-11-2024.** • **Letter of Authorization from MAH submitted, is unsigned.** • **Stability Studies of three batches is required.** • **Safety & efficacy studies data is required.** • **Information regarding international availability of the product is required to be submitted.**	
13.	Name and address of Importer	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad.
	Detail of DSL	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad. **DSL No.** 1605-ICT/2013 **Expiry: 16-09-2023**
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 2718 dated 31st Jan, 2023. Rs. 150,000/-
	Name of Manufacturer & MAH	**Veterinary Serum and Vaccine Research Institute (VSVRI).** E1-Sekka E1-Beda St. Abbassia, Cairo, Arab Republic of Egypt.
	Name of exporting country	Arab Republic of Egypt

	Brand Name + Dosage Form + Strength	**Servac Polyvalent Clostridial Vaccine** Each 1ml of Polyvalent Clostridial Vaccine contains ; Clostridium Strains : C. chauvoei……..5 Opacity units/ml at 625nm C. perfringes (α. Toxin type A)…..40MLD/ml C. perfringes (β. Toxin type B)…..100L+/ml C. perfringes (ε. Toxin type D)…..70L+/ml C. septicum (α. Toxin)……..75L+/ml C. novyi (α. Toxin)……..90LF/ml
	Composition	Each 1ml of Polyvalent Clostridial Vaccine contains ; Clostridium Strains : C. chauvoei……..5 Opacity units/ml at 625nm C. perfringes (α. Toxin type A)…..40MLD/ml C. perfringes (β. Toxin type B)…..100L+/ml C. perfringes (ε. Toxin type D)…..70L+/ml C. septicum (α. Toxin)……..75L+/ml C. novyi (α. Toxin)……..90LF/ml
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Bacterial Veterinary Vaccine
	Shelf life	12 Months (4-8 ºC)
	International availability	Arab Republic of Egypt
	Products already registered in Pakistan	TOXIPRA-S7-Hipra
	Demanded Price / Pack size	Decontrolled/Not specified-Multiple packs
	Certificates Submitted	**CoPP/FSC:** Original FSC, issued by the manufacturer, has been provided. **GMP:** Not provided. **LOA:** Copy of LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • The DSL of the firm has expired on 16-09-2023. • Copy of Letter of Authorization from MAH submitted, is not legalized. • The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. • Legalized, valid GMP certificate of manufacturer is required to be submitted. • The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. • Stability studies data of the product is required to be submitted. • Safety & efficacy studies data of the product is required to be submitted. • Finished product specifications and testing methods are required to be submitted. • The label of the product does not bear name of the importer. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **The DSL of the firm has expired on 16-09-2023.** • **Copy of Letter of Authorization from MAH submitted, is not legalized.**	

	• **The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin.** • **Legalized, valid GMP certificate of manufacturer is required to be submitted.** • **The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized.** • **Stability studies data of the product is required to be submitted.** • **Safety & efficacy studies data of the product is required to be submitted.** • **Finished product specifications and testing methods are required to be submitted.** • **The label of the product does not bear name of the importer.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **Information regarding international availability of the product is required to be submitted.**	
14.	Name and address of Importer	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad.
	Detail of DSL	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad. **DSL No.** 1605-ICT/2013 **Expiry: 16-09-2023**
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 2719 dated 31st Jan, 2023. Rs. 150,000/-
	Name of Manufacturer & MAH	**Veterinary Serum and Vaccine Research Institute (VSVRI).** E1-Sekka E1-Beda St. Abbassia, Cairo, Arab Republic of Egypt.
	Name of exporting country	Arab Republic of Egypt
	Brand Name + Dosage Form + Strength	**Servac Polyvalent Inactivated FMD Oil Vaccine** Each 1ml vaccine contains; FMD virus serotypes : Type O subtype panasia2…$10^{8.5}$ $TCID_{50}$ Type A (Iran 05)…$10^{8.5}$ $TCID_{50}$ SAT2 Egypt 12…$10^{8.5}$ $TCID_{50}$ SAT2 Egypt 18…$10^{8.5}$ $TCID_{50}$
	Composition	Each 1ml vaccine contains; FMD virus serotypes : Type O subtype panasia2…$10^{8.5}$ $TCID_{50}$ Type A (Iran 05)…$10^{8.5}$ $TCID_{50}$ SAT2 Egypt 12…$10^{8.5}$ $TCID_{50}$ SAT2 Egypt 18…$10^{8.5}$ $TCID_{50}$
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	24 Months (4-8 °C)
	International availability	Arab Republic of Egypt
	Products already registered in Pakistan	Not Registered.
	Demanded Price / Pack size	30ml, 45ml, 75ml & 90ml/Decontrolled
	Certificates Submitted	**CoPP/FSC:** Original FSC, issued by the manufacturer, has been provided. **GMP:** Not provided. **LOA:** Copy of LOA has been provided.

	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied strain, is not already registered in Pakistan.** • The DSL of the firm has expired on 16-09-2023. • Copy of Letter of Authorization from MAH submitted, is not legalized. • The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. • Legalized, valid GMP certificate of manufacturer is required to be submitted. • The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. • Stability studies data of the product is required to be submitted. • Safety & efficacy studies data of the product is required to be submitted. • Finished specifications and testing methods are required to be submitted. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The DSL of the firm has expired on 16-09-2023.** • **Copy of Letter of Authorization from MAH submitted, is not legalized.** • **The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin.** • **Legalized, valid GMP certificate of manufacturer is required to be submitted.** • **The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized.** • **Stability studies data of the product is required to be submitted.** • **Safety & efficacy studies data of the product is required to be submitted.** • **Finished product specifications and testing methods are required to be submitted.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Information regarding international availability of the product is required to be submitted.**	
15.	Name and address of Importer	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad.
	Detail of DSL	**M/s Innovegic Pharmaceuticals,** Plot No.C-19, 2nd Floor, Main Road RCCI, Industrial Area, Rawat, Islamabad. **DSL No.** 1605-ICT/2013 **Expiry: 16-09-2023**
	Type of Form Dy. No. Date of Application	Form 5A Dy. No. 2720 dated 31st Jan, 2023.

	Fee submitted	Rs. 150,000/-
	Name of Manufacturer & MAH	**Veterinary Serum and Vaccine Research Institute (VSVRI).** E1-Sekka E1-Beda St. Abbassia, Cairo, Arab Republic of Egypt.
	Name of exporting country	Arab Republic of Egypt
	Brand Name + Dosage Form + Strength	**Servac BEF Attenuated Vaccine** Each dose contains; Bovine Ephemeral Fever virus (BEF/Abasya/2000) not less than 5.5 $\log_{10}$ $TCID_{50}$
	Composition	Bovine Ephemeral Fever virus (BEF/Abasya/2000) not less than 5.5 log10 TCID50
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Attenuated Viral Veterinary Vaccine
	Shelf life	24 Months (-20 °C)
	International availability	Arab Republic of Egypt
	Products already registered in Pakistan	Not Registered.
	Demanded Price / Pack size	10 dose Vial/Decontrolled
	Certificates Submitted	**CoPP/FSC:** Original FSC, issued by the manufacturer, has been provided. **GMP:** Not provided. **LOA:** Copy of LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied strain, is not already registered in Pakistan.** • The DSL of the firm has expired on 16-09-2023. • Copy of Letter of Authorization from MAH submitted, is not legalized. • The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin. • Legalized, valid GMP certificate of manufacturer is required to be submitted. • The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized. • Stability studies data of the product is required to be submitted. • Safety & efficacy studies data of the product is required to be submitted. • Finished product specifications and testing methods are required to be submitted. • The label of the product does not bear name of the importer. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The DSL of the firm has expired on 16-09-2023.** • **Copy of Letter of Authorization from MAH submitted, is not legalized.**	

	• **The address of manufacturer is not mentioned on the product registration letter issued by regulatory body of country of origin.** • **Legalized, valid GMP certificate of manufacturer is required to be submitted.** • **The FSC provided, has been issued by the manufacturer, not the regulatory body of country of origin and the same has also not been legalized.** • **Stability studies data of the product is required to be submitted.** • **Safety & efficacy studies data of the product is required to be submitted.** • **Finished product specifications and testing methods are required to be submitted.** • **The label of the product does not bear name of the importer.** • **Information regarding international availability of the product is required to be submitted.**	
16.	Name and address of Importer	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of DSL	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha. **DSL No.** 08-384-0120-022405D **Expiry:** 20-11-2028
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 19198 dated 08th July, 2021. Rs. 100,000/-
	Name of Manufacturer & MAH	VETAL HAYVAN SAGLIGI URUNLERI A.S. Petrol Mah. 14 Cad. No: 1 Adiyaman, Turkey.
	Name of exporting country	Turkey
	Brand Name + Dosage Form + Strength	**Poxvac** Each 0.5ml dose of vaccine contains ; Freez dried, live attenuated sheep & goat pox virus not less than $10^{2.5}$ $TCID_{50}$
	Composition	Each 0.5ml dose of vaccine contains ; Freez dried, live attenuated sheep & goat pox virus not less than $10^{2.5}$ $TCID_{50}$
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live attenuated Viral Veterinary Vaccine
	Shelf life	36 Months (2 - 8 ºC)
	International availability	Turkey
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	Decontrolled/50 doses
	Certificates Submitted	**FSC:** Legalized, valid FSC has been submitted. **GMP:** Copy of legalized GMP certificate dated 08-05-2018 has been submitted. **LOA:** Original LOA from MAH has been submitted.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied virus strain, is not already registered in Pakistan.** • Differential fee of Rs.50,000/-, is required to be deposited. • LOA submitted is not legalized. • Copy of legalized GMP certificate dated 08-05-2018 has been submitted. Fresh, Legalized, valid GMP certificate of the foreign manufacturer, is required.

		• Stability studies data of three batches of the product with same pack size is required. • As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Differential fee of Rs. 50,000/-, is required to be deposited.** • **LOA submitted is not legalized.** • **Copy of legalized GMP certificate dated 08-05-2018 has been submitted. Fresh, Legalized, valid GMP certificate of the foreign manufacturer, is required.** • **Stability studies data of three batches of the product with same pack size is required.** • **As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified.** • **Information regarding international availability of the product is required to be submitted.**	
17.	Name and address of Importer	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of DSL	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha. **DSL No.** 08-384-0120-022405D **Expiry:** 20-11-2028
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 476 dated 13-09-2023. Rs. 75,000/-
	Name of Manufacturer & MAH	VETAL HAYVAN SAGLIGI URUNLERI A.S. Petrol Mah. 14 Cad. No: 1 Adiyaman, Turkey
	Name of exporting country	Turkey
	Brand Name + Dosage Form + Strength	**Aborvac S Cow vaccine with Diluent** **Composition (Lyophilized vaccine):** Each 1m dose of lyophilized vaccine contains; Live attenuated freeze dried *Brucella abortus* (S19 strain…….. ≥ 1-3x10^9 CFU **<u>Diluent Composition:</u>** Each 1000 ml contains: Sodium chloride (NaCl)….8000 mg Potassium chloride (KCl)….200 mg Disodium phosphate (Na_2HPO_4)…..1140 mg Potassium dihydrogen phosphate (KH_2PO_4)….200 mg Distilled water…..upto 1000 ml
	Composition	**Composition (Lyophilized vaccine):** Each 1m dose of lyophilized vaccine contains; Live attenuated freeze dried *Brucella abortus* (S19 strain…….. ≥ 1-3x10^9 CFU **<u>Diluent Composition:</u>** Each 1000 ml contains: Sodium chloride (NaCl)….8000 mg Potassium chloride (KCl)….200 mg Disodium phosphate (Na_2HPO_4)…..1140 mg

		Potassium dihydrogen phosphate (KH_2PO_4)….200 mg Distilled water…..upto 1000 ml
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Attenuated Bacterial Vaccine
	Shelf life	Vaccine: 12 Months (2 – 8°C) Diluent: 24 Months (25°C)
	International availability	Turkey
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	2 doses with 2ml diluent 5 doses with 5ml diluent 10 doses with 10ml diluent 20 doses with 20ml diluent 50 doses with 50ml diluent Price is decontrolled.
	Certificates Submitted	**FSC:** Legalized, valid FSC has been submitted. **GMP:** Copy of GMP certificate has been submitted. **LOA:** Copy of legalized LOA from MAH has been submitted.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied bacterial strain, is not already registered in Pakistan.** • Differential fee of Rs.75,000/-, is required to be deposited. • Safety & efficacy studies data of applied vaccine is required. • The copy of GMP certificate of foreign manufacturer provided, is not legalized. Moreover, GMP certificate has expired on 11-04-2024. • As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified. • Original, legalized LOA from MAH, is required. • LOA submitted is not legalized.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Differential fee of Rs. 75,000/-, is required to be deposited.** • **Safety & efficacy studies data of applied vaccine is required.** • **The copy of GMP certificate of foreign manufacturer provided, is not legalized. Moreover, GMP certificate has expired on 11-04-2024.** • **As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified.** • **Original, legalized LOA from MAH, is required.** • **LOA submitted is not legalized.**	
18.	Name and address of Importer	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of DSL	**M/s Huzaifa International,** Commercial Area, Aziz Bhatti Town, Sargodha. **DSL No.** 08-384-0120-022405D **Expiry:** 20-11-2028

	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 856 dated 11-10-2023. Rs. 75,000/-
	Name of Manufacturer & MAH	**Jilin Zhengye Biological Products Co., Ltd.** No.1 Lianmeng Street, Jilin Economic and Technological Development, Jilin Province, People's Republic of China.
	Name of exporting country	People's Republic of China
	Brand Name + Dosage Form + Strength	**POLY-VAC G7 ND.H9 Vaccine** Each single dose contains: Reassortant Inactivated Newcastle disease virus (aSG10 strain) before Inactivated at least…...$2.0x10^{8.5}EID_{50}$/0.1ml Inactivated Avian influenza virus (H9N2 subtype),before Inactivated at least…$2.0x10^{8.0}$ EID_{50}/0.1ml
	Composition	Each single dose contains: Reassortant Inactivated Newcastle disease virus (aSG10 strain) before Inactivated at least…...$2.0x10^{8.5}EID_{50}$/0.1ml Inactivated Avian influenza virus (H9N2 subtype),before Inactivated at least…$2.0x10^{8.0}$ EID_{50}/0.1ml
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	18 Months (2 – 8°C)
	International availability	China
	Products already registered in Pakistan	Sinvac ND + H9-Hivet
	Demanded Price / Pack size	250ml/decontrolled 500ml /Decontrolled
	Certificates Submitted	**FSC:** Legalized, valid FSC has been submitted. **GMP:** Legalize, valid GMP certificate has been submitted. **LOA:** legalized LOA from MAH has been submitted.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • Differential fee of Rs.75,000/-, is required to be deposited. • Safety & efficacy studies data of applied vaccine is required. • As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **Differential fee of Rs. 75,000/-, is required to be deposited.** • **Safety & efficacy Studies data of applied vaccine is required.** • **As multiple pack sizes of the vaccine have been mentioned on FSC, the applied pack size is needed to be specified.**	
19.	Name and address of Importer	**U.M. Enterprises,** Plot # 12, Sector 15 Korangi Industrial Area, Karachi, Pakistan.
	Detail of DSL	DSL License No**. 313** valid up to **23-02-2028**.
	Type of Form Dy. No. Date of Application Fee submitted	Form 5A Dy. No. 223 dated 30th August, 2023. Rs. 75,000/-
	Name of Manufacturer & MAH	**Phibro Animal Health Limited.** Finisklin Business Park, Sligo F91 R772, Ireland.

	Name of exporting country	Ireland
	Brand Name + Dosage Form + Strength	**Phivax MB Effervescent Tablet for Suspension** Live attenuated IBD virus, M.B. strain: min $10^{2.5}$ EID_{50} per dose
	Composition	Live attenuated IBD virus, M.B. strain: min $10^{2.5}$ EID_{50} per dose
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Oral Viral Vaccine
	Shelf life	18 Months (2 - 8°C)
	International availability	Not Available
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	Decontrolled Pack Size (2000 Doses)
	Certificates Submitted	**CoPP:** Legalized, valid CoPP provided. **GMP:** Copy of Legalized GMP certificate, provided. **LOA:** Copy of Legalized LOA provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in application; • **As per available record, formulation with applied Viral strain, is not already registered in Pakistan** • Differential fee of Rs. 75,000/-, is required to be deposited. • **The CoPP issued by HPRA mentions that the product is not licensed to be placed on the market of country of origin since the IBD virus or Gumboro Disease is not endemic in domestic fowl in Ireland.** • Original legalized copy of valid GMP certificate of the foreign manufacturer is required. Moreover, the GMP certificate provided was issued on the basis of inspection conducted on 15-04-2021 and more than three years have lapsed since the date of said inspection. • Original, legalized LOA of the product is required. • Complete stability studies data of three batches is required. • Information regarding international availability of the product is required to be submitted.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Differential fee of Rs. 75,000/-, is required to be deposited.** • **The CoPP issued by HPRA mentions that the product is not licensed to be placed on the market of country of origin since the IBD virus or Gumboro Disease is not endemic in domestic fowl in Ireland.** • **Original legalized copy of valid GMP certificate of the foreign manufacturer is required. Moreover, the GMP certificate provided was issued on the basis of inspection conducted on 15-04-2021 and more than three years have lapsed since the date of said inspection.** • **Original, legalized LOA of the product is required.** • **Complete stability studies data of three batches is required.** • **Information regarding international availability of the product is required to be submitted.**	

20.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18055 dated 18th July 2023 Rs.150,000/-, Dated 12/07/2023
	Name of MAH Holder	PT. VAKSINDO SATWA NUSANTARA Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	PT. VAKSINDO SATWA NUSANTARA Jl. Barokah No.7 RT 001/RW 008 Wanaherang, Gunung Putri, Bogor, West Java 16965, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune IBD MHV** Each dose (0.5 ml) contains: IBD virus of MVN 002 strain at least ..... $10^{2.0}$ EID_{50}
	Composition	IBD virus of MVN 002 strain at least ..... $10^{2.0}$ EID_{50}
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	Indonesia.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1000 dose vial / Decontrolled 2000 doses vial / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied Viral strain, is not already registered in Pakistan**. • As the product is available in multiple pack sizes, applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & efficacy studies data is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **As the product is available in multiple pack sizes, applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required as the LOA has expired.** • **Safety & efficacy studies data is required.**	

21.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18054 dated 18th July 2023 Rs.150,000/-, Dated 12/07/2023
	Name of MAH Holder	**PT. VAKSINDO SATWA NUSANTARA** Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	**PT. VAKSINDO SATWA NUSANTARA** Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune NDL Multi IB Plus EDS** Each dose (0.5 ml) contains: ND virus Genotype VII-i of N018 strain, at least .....$\geq 10^{7.5}$ EID_{50} ND virus Genotype VII-h of N406 strain, at least..... $\geq 10^{7.5}$ EID_{50} IB virus Massachusetts-41 strain, at least..... $\geq 10^{5.9}$ EID_{50} IB virus Serotype Qx of B008 strain, at least..... $\geq 10^{5.9}$ EID_{50} IB virus Serotype Qx of B003 strain, at least..... $\geq 10^{5.9}$ EID_{50} EDS'76 virus of E001 strain, at least..... $\geq 10^{6.1}$ EID_{50}
	Composition	Each dose (0.5 ml) contains: ND virus Genotype VII-i of N018 strain, at least .....$\geq 10^{7.5}$ EID_{50} ND virus Genotype VII-h of N406 strain, at least..... $\geq 10^{7.5}$ EID_{50} IB virus Massachusetts-41 strain, at least..... $\geq 10^{5.9}$ EID_{50} IB virus Serotype Qx of B008 strain, at least..... $\geq 10^{5.9}$ EID_{50} IB virus Serotype Qx of B003 strain, at least..... $\geq 10^{5.9}$ EID_{50} EDS'76 virus of E001 strain, at least..... $\geq 10^{6.1}$ EID_{50}
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivate Viral Veterinary Vaccine
	Shelf life	24 months (2°C-8°C)
	International availability	Indonesia.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	500 doses bottle (250ml)/ Decotrolled 1000 doses bottle (500ML) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied Viral strain, is not already registered in Pakistan**. • As the product is available in multiple pack sizes, applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & efficacy studies data is required.
	Decision:	

	The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application; • **As the product is available in multiple pack sizes, applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required as the LOA has expired.** • **Safety & efficacy studies data is required.**	
22.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18056 dated 18th July 2023 Rs.150,000/-, Dated 12/07/2023
	Name of MAH Holder	**PT. VAKSINDO SATWA NUSANTARA** Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	**PT. VAKSINDO SATWA NUSANTARA** Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune Coryza LE** Each dose (0.5 ml) contains: Avibacterium paragallinarum Serotype A of 0083 strain, at least.... $10^{8.0}$ CFU Avibacterium paragallinarum Serotype B of SPROSS strain, at least .....$10^{8.0}$ CFU Avibacterium paragallinarum Serotype B Local Isolate of V5 strain, at least ..... $10^{8.5}$ CFU Avibacterium paragallinarum Serotype C of Modesto strain, at least.....$10^{8.5}$ CFU
	Composition	Each dose (0.5 ml) contains: Avibacterium paragallinarum Serotype A of 0083 strain, at least.... $10^{8.0}$ CFU Avibacterium paragallinarum Serotype B of SPROSS strain, at least .....$10^{8.0}$ CFU Avibacterium paragallinarum Serotype B Local Isolate of V5 strain, at least ..... $10^{8.5}$ CFU Avibacterium paragallinarum Serotype C of Modesto strain, at least.....$10^{8.5}$ CFU
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivate Bacterial Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	Indonesia.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1000 dose bottle (500ML) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed;

		• **As per available record, formulation with applied Bacterial strain, is not already registered in Pakistan**. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & efficacy studies data is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required as the LOA has expired.** • **Safety & efficacy studies data is required.**	
23.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18057 dated 18th July 2023 Rs.150,000/-, Dated 12/07/2023
	Name of MAH Holder	**PT. VAKSINDO SATWA NUSANTARA** Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	**PT. VAKSINDO SATWA NUSANTARA** Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune NDL Multi Inaktif** Each dose (0.5 ml) contains: ND virus Genotype VII-i of N018 strain, at least .....$10^{8.1}$ EID_{50} ND virus Genotype VII-h of N046 strain, at least.....$10^{8.1}$ EID_{50}
	Composition	ND virus Genotype VII-i of N018 strain, at least .....$10^{8.1}$ EID_{50} ND virus Genotype VII-h of N046 strain, at least.....$10^{8.1}$ EID_{50}
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivate Viral Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	Indonesia.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	500 doses bottle (250ml) / Decontrolled 1000 dose bottle (500ML) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied Viral strain, is not already registered in Pakistan**.

		• As the product is available in multiple pack sizes, applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & efficacy studies data is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **As the product is available in multiple pack sizes, applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required as the LOA has expired.** • **Safet & efficacy studies data is required.**	
24.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18053 dated 18th July 2023 Rs.150,000/-, Dated 12/07/2023
	Name of MAH Holder	**PT. VAKSINDO SATWA NUSANTARA** Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	**PT. VAKSINDO SATWA NUSANTARA** Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune ND Inaktif 0.1** Each dose (0.5 ml) contains: ND virus of lasota strain at least ……$\geq 10^{8.1}$ EID_{50}
	Composition	ND virus of lasota strain at least ……$\geq 10^{8.1}$ EID_{50}
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivate Viral Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	N/A
	Products already registered in Pakistan	AVI ND LASOTA Vaccine-Vetline
	Demanded Price / Pack size	2000 doses bottle (200ml) / Decontrolled 5000 dose bottle (500ML) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy of legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • As the product is available in multiple pack sizes, applied pack size needs to be specified.

		• The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required as the LOA has expired. • Safety & efficacy studies data is required.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **As the product is available in multiple pack sizes, applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required as the LOA has expired.** • **Safety & Efficacy studies data is required.**	
25.	Name and address of Importer	**M/s Hivet Animal Health Business,** 1st Floor,667-P. MA, Johar Town, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040985D valid till 23-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 18490 dated 01st July, 2021 Rs.150,000/-, Dated 29/06/2021
	Name of MA Holder	**Sanfer Salud Animal S.S. de C.V.** Boulevard Adolfo Lopez Mateos 314-PB, Colonia Tlaco[ac, ALVARO Obregon C.P.0049 Ciudad de Mexico.
	Name of Manufacturer	**Sanfer Salud Animal S.S. de C.V.** Boulevard Adolfo Lopez Mateos 314-PB, Colonia Tlaco[ac, ALVARO Obregon C.P.0049 Ciudad de Mexico.
	Name of exporting country	Mexico.
	Brand Name + Dosage Form + Strength	**Genovax N5** Each ml contains; Attenuated ND virus Genotype V strain rP05…..minimum $10^{7.5}$ $DIEP_{50}$
	Composition	Each ml contains; Attenuated ND virus Genotype V strain rP05….minimum $10^{7.5}$ $DIEP_{50}$
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	18 months (2 - 4°C)
	International availability	Azerbaijan, Peru, Bolivia EI Salvador
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1,000 doses Vial (5ml) / Decontrolled 2,500 doses Vial (5ml) / Decontrolled 10,000 doses Vial (30ml) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Copy of LOA from MAH, has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied Viral strain, is not already registered in Pakistan**. • The strain is not registered as per available data.

		• As the product is available in multiple pack sizes, applied pack size needs to be specified. • The label of the product does not bear name of the importer. • Original, legalized GMP certificate of foreign manufacturer is required. • Original, legalized and valid LOA from MAH, is required. • Stability studies data of three batches is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **The strain is not registered as per available data.** • **As the product is available in multiple pack sizes, applied pack size needs to be specified.** • **The label of the product does not bear name of the importer.** • **Original, legalized GMP certificate of foreign manufacturer is required.** • **Original, legalized and valid LOA from MAH, is required.** • **Stability studies data of three batches is required.**	
26.	Name and address of Importer	**M/s Vet Line International** 939-A, Block-j, Phase-1, LDA Avenue-1, Lahore, Pakistan
	Detail of DSL	License to sell drugs as a distributor No. 05-352-0066-040712D valid till 09-02-2028 .
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 354 dated 17th January, 2024 Rs.150,000/-, Dated 11/12/2023
	Name of MA Holder	**QYH Nanjing Biotech Co., Ltd** No.35 Xiangfeng Road, Jiangning Sub-District, Nanjing city, Jiangsu Province, P.R.China.
	Name of Manufacturer	**QYH Nanjing Biotech Co., Ltd** No.35 Xiangfeng Road, Jiangning Sub-District, Nanjing city, Jiangsu Province, P.R.China.
	Name of exporting country	People's Republic of China.
	Brand Name + Dosage Form + Strength	**QVAC ND G7** Each ml contains. Newcastle Disease Virus A-VII Strain….$10^{8.0}$ EID_{50} Induce min. 6.0 log2HI
	Composition	Each ml contains. Newcastle Disease Virus A-VII Strain….$10^{8.0}$ EID_{50} Induce min. 6.0 log2HI
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	2 Years (2 - 8°C)
	International availability	NA
	Products already registered in Pakistan	Medivac ND G7B -Hilton
	Demanded Price / Pack size	500ml Vial / Decontrolled
	Certificates Submitted	**FSC:** Original Legalized FSC has been provided. **LOA:** Original Legalized LOA has been provided. **GMP:** Original Legalized GMP certificate has been provided.

	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • It has not been mentioned of FSC that the product is available in country of origin.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **It has not been mentioned of FSC that the product is available in country of origin.**	
27.	Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** Plot No. 77, Street No.6, I-10/3, Islamabad.
	Detail of DSL	No. DSL-156 ICT/2013 Expiry 30-12-2022
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 1612, dated 01-12-2023 Rs.150,000/-, Dated 30-11-2023
	Name of MA Holder	**Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.
	Name of Manufacturer	**Batch Release:** Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands. **Production:** B-Braun Medical SA Route de Sorge 9, 1023 Crissier, Switzerland.
	Name of exporting country	Netherlands
	Brand Name + Dosage Form + Strength	**Nobilis Diluent CA** Each ml contains; Sucrose…..50mg Pancreatic digest of casein….13.9mg Potassium dihydrogen Phosphate….1.1mg Phenolsulfonophthalein….0.02mg
	Composition	Each ml contains; Sucrose…..50mg Pancreatic digest of casein….13.9mg Potassium dihydrogen Phosphate….1.1mg Phenolsulfonophthalein….0.02mg
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Diluent for cell associated veterinary vaccines
	Shelf life	Glass Vials & PE Bags - 36 Months (15-25°C) MLP Bags - 25 Months (15-25°C)
	International availability	NA
	Products already registered in Pakistan	Nobilis Diluent CA, 400ml
	Demanded Price / Pack size	800ml/ Decontrolled
	Certificates Submitted	**CoPP:** Original Legalized CoPP has been provided. **LOA:** Original Legalized LOA from MAH has been provided. **GMP:** Original Legalized GMP certificates of foreign manufacturer, has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • GMP certificate of M/s Intervet International B.V. performing batch releasing activity, has expired on 15-07-2023.

		• As the product is available in multiple types of containers i,e., glass vials, PE Bags & MLP bags, the applied type of container needs to be specified. • Copy of Valid DSL is required.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **GMP certificate of M/s Intervet International B.V. performing batch releasing activity, has expired on 15-07-2023.** • **As the product is available in multiple types of containers i,e., glass vials, PE Bags & MLP bags, the applied type of container needs to be specified.** • **Copy of Valid DSL is required.** • **Justification of submission of separate registration of diluent without vaccine is required.**	
28.	Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** Plot No. 77, Street No.6, I-10/3, Islamabad.
	Detail of DSL	No. DSL-156 ICT/2013 Expiry 30-12-2022
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 1611, dated 01-12-2023 Rs.150,000/-, Dated 30-11-2023
	Name of MA Holder	**Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.
	Name of Manufacturer	**Batch Release:** **Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands. **Production:** **B-Braun Medical SA** Route de Sorge 9, 1023 Crissier, Switzerland.
	Name of exporting country	Netherlands
	Brand Name + Dosage Form + Strength	**Nobilis Diluent CA** Each ml contains; Sucrose…..50mg Pancreatic digest of casein….13.9mg Potassium dihydrogen Phosphate….1.1mg Phenolsulfonophthalein….0.02mg
	Composition	Each ml contains; Sucrose…..50mg Pancreatic digest of casein….13.9mg Potassium dihydrogen Phosphate….1.1mg Phenolsulfonophthalein….0.02mg
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Diluent for cell associated veterinary vaccines
	Shelf life	Glass Vials & PE Bags - 36 Months (15-25°C) MLP Bags - 25 Months (15-25°C)
	International availability	NA
	Products already registered in Pakistan	Nobilis Diluent CA, 400ml
	Demanded Price / Pack size	200ml/ Decontrolled
	Certificates Submitted	**CoPP:** Original Legalized CoPP has been provided. **LOA:** Original Legalized LOA from MAH has been provided. **GMP:** Original Legalized GMP certificates of foreign manufacturer, has been provided.

	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • GMP certificate of M/s Intervet International B.V. performing batch releasing activity, has expired on 15-07-2023. • As the product is available in multiple types of containers i,e., glass vials, PE Bags & MLP bags, the applied type of container needs to be specified. • Copy of Valid DSL is required.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **GMP certificate of M/s Intervet International B.V. performing batch releasing activity, has expired on 15-07-2023.** • **As the product is available in multiple types of containers i,e., glass vials, PE Bags & MLP bags, the applied type of container needs to be specified.** • **Copy of Valid DSL is required.** • **Justification of submission of separate registration of diluent without vaccine is required.**	
29.	Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** Plot No. 77, Street No.6, I-10/3, Islamabad.
	Detail of DSL	No. DSL-156 ICT/2013 Expiry 30-12-2022
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 22863, dated 12-08-2022 Rs.150,000/-, Dated 10-08-2022
	Name of MA Holder	**Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.
	Name of Manufacturer	**Batch Release:** Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands. **Production:** B-Braun Medical SA Route de Sorge 9, 1023 Crissier, Switzerland.
	Name of exporting country	Netherlands
	Brand Name + Dosage Form + Strength	NOBI-VAC RABIES Each dose contains; Inactivated Rabies virus antigen suspension inducing atleast 0.95 AIU equivalent to ≥ 2.0 I.U
	Composition	Each dose contains; Inactivated Rabies virus antigen suspension inducing atleast 0.95 AIU equivalent to ≥ 2.0 I.U
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	4 Years (2 – 8°C)
	International availability	
	Products already registered in Pakistan	NOBI-VAC RABIES- 1 x 10 doses
	Demanded Price / Pack size	10's x 10 doses/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided.

		LOA/Sole Agency Distribution: Original LOA from MAH, has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **The product applied is additional pack size of already registered product of the applicant.** • GMP certificate of M/s Intervet International B.V., has expired on 15-07-2023. • Legalized LOA from MAH, is required. • Copy of Valid DSL is required.
	Decision: **The Registration Board decided to reject the application since the applied product is additional pack size of already registered product of the applicant.**	
30.	Name and address of Importer	**M/s Brand Station,** 89 A2, Wapda Town Extension, Lahore
	Detail of DSL	**M/s. Brand Station** 69 Wocland villas Lahore, Near Raiwind Road, Lahore. Valid till: 10-08-2027
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 23947, dated 24-08-2022 Rs.150,000/-, Dated 14-03-2022
	Name of MA Holder	**Yebio Bioengineering Co., Ltd.** Head Office: No. 21 Aodong Nan Road, Hongdao, Qingdao, China. Plant: No. 260 Heyuan Road, Hongdao, Qingdao, China.
	Name of Manufacturer	**Yebio Bioengineering Co., Ltd.** Head Office: No. 21 Aodong Nan Road, Hongdao, Qingdao, China. Plant: No. 260 Heyuan Road, Economy Zone of Hongdao, Qingdao, China.
	Name of exporting country	People's Republic of China
	Brand Name + Dosage Form + Strength	**Yeflu H5 + H7 V3 500ml** Strength-Not clear
	Composition	Not clear
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	24 Months (2 – 8°C)
	International availability	China & Uzbekistan
	Products already registered in Pakistan	Not provided.
	Demanded Price / Pack size	500ml/Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Legalized, valid GMP certificate of foreign manufacturer, has been provided. **LOA:** Copy of LOA from MAH has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • Legalized LOA from MAH is required. • The name of importer, has not been mentioned on label. • The strength of active ingredients (virus) per dose is not clear.

		• The number of doses per pack of 500ml, needs to be clarified.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **Legalized LOA from MAH is required.** • **The name of importer, has not been mentioned on label.** • **The strength of active ingredients (virus) per dose is not clear.** • **The number of doses per pack of 500ml, needs to be clarified.**	
31.	Name and address of Importer	**M/s Mustafa Brothers,** 186-D, Peoples Colony No.1, Faisalabad.
	Detail of DSL	**M/s Mustafa Brothers,** 186-D, Peoples Colony No.1, Faisalabad. No. 06-331-0168-0317700 Validity: 21-06-2027
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 20452, dated 19-07-2022 Rs.150,000/-, Dated 05-07-2022 Rs.150,000/-, Dated 09-01-2023 (Pre-Registration Variation)
	Name of MA Holder	**CZ Vaccines S.A.U.,** A Relva, s/n – Torneiros, 36410 O Porrino, Pontevedra, Spain.
	Name of Manufacturer	**CZ Vaccines S.A.U.,** A Relva, s/n – Torneiros, 36410 O Porrino, Pontevedra, Spain.
	Name of exporting country	Spain
	Brand Name + Dosage Form + Strength	**Cubolac 250ml** Each dose (2ml) contains; α toxoid of *C. perfringens* Type A……≥0.3IU* β toxoid of *C. perfringens* Type C……≥10IU* ε toxoid of *C. perfringens* Type D……≥5IU* α toxoid of *C. septicum*……≥2.5IU* α toxoid of *C. novyi* Type B……≥3.5IU* Toxoid of *C. sordellii*…….100% protection** Inactivated *Cl. Chauvoei*……100% protection** * International Units of antitoxin per ml of rabit serum. ** Level of protection in guinea pigs according to (Ph. Eur)
	Composition	Each dose (2ml) contains; α toxoid of *C. perfringens* Type A……≥0.3IU* β toxoid of *C. perfringens* Type C……≥10IU* ε toxoid of *C. perfringens* Type D……≥5IU* α toxoid of *C. septicum*……≥2.5IU* α toxoid of *C. novyi* Type B……≥3.5IU* Toxoid of *C. sordellii*…….100% protection** Inactivated *Cl. Chauvoei*……100% protection** * International Units of antitoxin per ml of rabit serum. ** Level of protection in guinea pigs according to (Ph. Eur)
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Bacterial Veterinary Vaccine
	Shelf life	36 Months (2 – 8°C)
	International availability	Spain

	Products already registered in Pakistan	TOXIPRA-S7-Hipra
	Demanded Price / Pack size	250ml Vial/Decontrolled
	Certificates Submitted	**FSC/CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA from MAH has been provided.
	Evaluator Remarks	The applicant has provided the required documents.
	Decision: **Keeping in view the legalized CoPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	
32.	Name and address of Importer	**M/s Mustafa Brothers,** 186-D, Peoples Colony No.1, Faisalabad.
	Detail of DSL	**M/s Mustafa Brothers,** 186-D, Peoples Colony No.1, Faisalabad. No. 06-331-0168-0317700 Validity: 21-06-2027
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 1337, dated 16-01-2023 Rs.150,000/-, Dated 26-12-2022 Rs.75,000/-, Dated 26-12-2022 (Pre-Registration Variation)
	Name of MA Holder	**CZ Vaccines S.A.U.,** A Relva, s/n – Torneiros, 36410 O Porrino, Pontevedra, Spain.
	Name of Manufacturer	**CZ Vaccines S.A.U.,** A Relva, s/n – Torneiros, 36410 O Porrino, Pontevedra, Spain.
	Name of exporting country	Spain
	Brand Name + Dosage Form + Strength	**Cubolac 100ml** Each dose (2ml) contains; α toxoid of *C. perfringens* Type A……≥0.3IU* β toxoid of *C. perfringens* Type C……≥10IU* ε toxoid of *C. perfringens* Type D……≥5IU* α toxoid of *C. septicum*…….≥2.5IU* α toxoid of *C. novyi* Type B……≥3.5IU* Toxoid of *C. sordellii*…….100% protection** Inactivated *Cl. Chauvoei*……100% protection** * International Units of antitoxin per ml of rabit serum. ** Level of protection in guinea pigs according to (Ph. Eur)
	Composition	Each dose (2ml) contains; α toxoid of *C. perfringens* Type A……≥0.3IU* β toxoid of *C. perfringens* Type C……≥10IU* ε toxoid of *C. perfringens* Type D……≥5IU* α toxoid of *C. septicum*…….≥2.5IU* α toxoid of *C. novyi* Type B……≥3.5IU* Toxoid of *C. sordellii*…….100% protection** Inactivated *Cl. Chauvoei*……100% protection** * International Units of antitoxin per ml of rabit serum. ** Level of protection in guinea pigs according to (Ph. Eur)

	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Bacterial Veterinary Vaccine
	Shelf life	36 Months (2 – 8ºC)
	International availability	Spain
	Products already registered in Pakistan	TOXIPRA-S7-Hipra
	Demanded Price / Pack size	100ml Vial/Decontrolled
	Certificates Submitted	**FSC/CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA from MAH has been provided.
	Evaluator Remarks	The applicant has provided the required documents.
	Decision: **Keeping in view the legalized CoPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	
33.	Name and address of Importer	**M/s Orient Animal Health (Pvt.) Ltd.,** Commercial-6, Block-A, 1st Floor, Kazimabad, Model Colony, Karachi. **Godown:** Ground Floor, C-14, Block-A, 1st Floor, Kazimabad, Model Colony, Karachi
	Detail of DSL	DSL No. 011/2020 valid till 22-10-2022.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 27759, dated 20-10-2020 Rs.100,000/-, Dated 20-10-2020
	Name of MA Holder	**M/s Genera Inc.,** Svestonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Republic of Croatia.
	Name of Manufacturer	**M/s Genera Inc.,** Svestonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Republic of Croatia.
	Name of exporting country	Republic of Croatia.
	Brand Name + Dosage Form + Strength	Avishield IB GI-13 Lyophilisate for oculonasal suspension Each dose contains; Live virus of avian infectious bronchitis, variant strain V-173/11…….. $10^{2.7}$ – $10^{4.6}$ EID_{50}
	Composition	Each dose contains; Live virus of avian infectious bronchitis, variant strain V-173/11…….. $10^{2.7}$ – $10^{4.6}$ EID_{50}
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	18 Months (2 – 8ºC)
	International availability	Austria, Belgium, Croatia, Czech Republic, Denmark etc.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1000 doses/Decontrolled 2500 doses/Decontrolled 5000 doses/Decontrolled

	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Not provided
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **The strain of the virus is not registered as per available dat**a. • Legalized LOA from MAH is required. • The GMP certificate of foreign manufacturer, has expired in Dec-2021. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • Stability studies data at intended storage conditions, is required. • Safety & efficacy studies data is required. • Copy of valid DSL is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Legalized LOA from MAH is required.** • **The GMP certificate of foreign manufacturer, has expired in Dec-2021.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **Stability studies data at intended storage conditions, is required.** • **Safety & efficacy studies data is required.** • **Copy of valid DSL is required.**	
34.	Name and address of Importer	**M/s Orient Animal Health (Pvt.) Ltd.,** Commercial-6, Block-A, 1st Floor, Kazimabad, Model Colony, Karachi. **Godown:** Ground Floor, C-14, Block-A, 1st Floor, Kazimabad, Model Colony, Karachi
	Detail of DSL	DSL No. 011/2020 valid till 22-10-2022.
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 31900, dated 01-12-2020 Rs.100,000/-, Dated 01-12-2020
	Name of MA Holder	**M/s Genera Inc.,** Svestonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Republic of Croatia.
	Name of Manufacturer	**M/s Genera Inc.,** Svestonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Republic of Croatia.
	Name of exporting country	Republic of Croatia.
	Brand Name + Dosage Form + Strength	Avishield IBD Plus Lyophilisate for use in drinking water Each dose contains; Live attenuated virus of infectious bursal disease, intermediate plus strain G6…….. $10^{1.9}$ – $10^{3.2}$ EID_{50}
	Composition	Each dose contains; Live attenuated virus of infectious bursal disease, intermediate plus strain G6…….. $10^{1.9}$ – $10^{3.2}$ EID_{50}
	Finished product specifications	Manufacturer's Specifications

	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	24 Months (2 – 8°C)
	International availability	Austria, Belgium, Croatia, Czech Republic, France, Germany etc.
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1000 doses/Decontrolled 2500 doses/Decontrolled 5000 doses/Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Not provided
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **The strain of the virus is not registered as per available data**. • Legalized LOA from MAH is required. • The GMP certificate of foreign manufacturer, has expired in Dec-2021. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • Stability studies data at intended storage conditions, is required. • Safety & efficacy studies data is required. • Copy of valid DSL is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Legalized LOA from MAH is required.** • **The GMP certificate of foreign manufacturer, has expired in Dec-2021.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **Stability studies data at intended storage conditions, is required.** • **Saftey & efficacy studies data is required.** • **Copy of valid DSL is required.**	
35.	Name and address of Importer	**M/s Lucky Core Industries Limited,** 5 West Wharf, Karachi
	Detail of DSL	DSL No. 013, Valid till 10-03-2026
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 721, dated 28-09-2023 Rs.150,000/-, Dated 22-09-2023
	Name of MA Holder	**Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.
	Name of Manufacturer	**Intervet International B.V.** Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.
	Name of exporting country	Netherlands.
	Brand Name + Dosage Form + Strength	**Bovilis Lumpyvax-E** **Lyophilisate and Solvent for Suspension for Injection for Cattle** Each 1ml dose of reconstituted vaccine contains; Live attenuated lumpy skin disease virus (Neethling)….$\geq 1x10^4$ and $\leq 5.0x10^5$ $TCID_{50}$

		Solvent: Disodium phosphate dihydrate….1.4mg Potassium dihydrogen phosphate…0.2mg Sodium chloride…..8mg Potassium chloride….0.2mg Water for Injection…..Upto 1ml
	Composition	Each 1ml dose of reconstituted vaccine contains; Live attenuated lumpy skin disease virus (Neethling)..$\geq 1x10^4$ and $\leq 5.0x10^5$ $TCID_{50}$ **Solvent:** Disodium phosphate dihydrate….1.4mg Potassium dihydrogen phosphate…0.2mg Sodium chloride…..8mg Potassium chloride….0.2mg Water for Injection…..Upto 1ml
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	24 Months (2 – 8°C)
	International availability	NA
	Products already registered in Pakistan	Bovivax LSD-N Vaccine-Snam Pharma
	Demanded Price / Pack size	20 doses of lyophilisate + 20ml solvent/Decontrolled 100 doses of lyophilisate + 100ml solvent/Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized copy of LOA from MAH is provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **It has been mentioned in the CoPP that the product is not licensed to be placed on the market of country of origin since the disease has never occurred there.** • The GMP certificate of foreign manufacturer, has expired in July-2023. • As the product is available in multiple pack sizes, the applied pack size needs to be specified. • The name of importer has not been mentioned on the label. • Stability studies data of three large scale batches at intended storage conditions, is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **It has been mentioned in the CoPP that the product is not licensed to be placed on the market of country of origin since the disease has never occurred there.** • **The GMP certificate of foreign manufacturer, has expired in July-2023.** • **As the product is available in multiple pack sizes, the applied pack size needs to be specified.** • **The name of importer has not been mentioned on the label.** • **Stability studies data of three large scale batches at intended storage conditions, is required.**	

36.	Name and address of Importer	**M/s Better Traders International,** 23-Z/E, Saifullah Shaheed Road, Madina Town, Faislaabad.
	Detail of DSL	DSL No. 06-331-0168-028576D Valid Upto: 15-02-2024
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. 361, dated 07-09-2023 Rs.150,000/-, Dated 19-07-2023
	Name of MA Holder	**Avac Vietnam Joint Stock Company,** Highway 5A, Ngoc Lich Village, Trung Trac Commune, Van Lam District, Hung Yen Province, Vietnam.
	Name of Manufacturer	**Avac Vietnam Joint Stock Company,** Highway 5A, Ngoc Lick, Trung Trac Province, Hung Yen City, Vietnam.
	Name of exporting country	Vietnam.
	Brand Name + Dosage Form + Strength	**Avac LSD Live** Each dose contains; Attenuated LSD Virus (Neethling Strain)……NLT $10^{3.5}$ $TCID_{50}$
	Composition	Each dose contains; Attenuated LSD Virus (Neethling Strain)……NLT $10^{3.5}$ $TCID_{50}$
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	24 Months (2 – 8°C)
	International availability	Vietnam, Cambodia & Bangladesh
	Products already registered in Pakistan	Bovivax LSD-N Vaccine-Snam Pharma
	Demanded Price / Pack size	50 doses Vial/Decontrolled
	Certificates Submitted	**CoPP/FSC:** Legalized FSC has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Copy of LOA from MAH is provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • Legalized LOA from MAH is required. • Copy of Valid DSL is required. • The name of importer has not been mentioned on the label.
	Decision: **Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **Legalized LOA from MAH is required.** • **Copy of Valid DSL is required.** • **The name of importer has not been mentioned on the label.**	
37.	Name and address of Importer	**M/s UMEX Biopharma Pvt. Limited,** Plot No.44 A & 45 A NACLASS No.24, DEH DIL TALUKS. Korangi Industrial Area. Karachi, Pakistan.
	Detail of DSL	DSL License No. 579 valid up to 12-09-2024
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. dated 23-11-2023 Rs.75,000/-, Dated 06-10-2023
	Name of MAH Holder	**PT. VAKSINDO SATWA NUSANTARA**

		Wisma Millenia 5th Floor, Jl. MT Haryono Kav.16 Jakarta- Indonesia.
	Name of Manufacturer	**PT. VAKSINDO SATWA NUSANTARA** Jl. Mercedes Benz No. 12, Cicadas, Gunung Putri, Bogor, West Java 16964, Indonesia.
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Vaksimune Coryza L** Each dose (0.5 ml) contains: Avibacterium paragallinarum Serotype A of 0083 strain, at least.... $10^{8.0}$ CFU Avibacterium paragallinarum Serotype B of SPROSS strain, at least .....$10^{8.0}$ CFU Avibacterium paragallinarum Serotype B V1 strain, at least ..... 10^{8} CFU Avibacterium paragallinarum Serotype C of Modesto strain, at least.....10^{8} CFU
	Composition	Each dose (0.5 ml) contains: Avibacterium paragallinarum Serotype A of 0083 strain, at least.... $10^{8.0}$ CFU Avibacterium paragallinarum Serotype B of SPROSS strain, at least .....$10^{8.0}$ CFU Avibacterium paragallinarum Serotype B V1 strain, at least ..... 10^{8} CFU Avibacterium paragallinarum Serotype C of Modesto strain, at least.....10^{8} CFU
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivate Bacterial Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	Indonesia, Vietnam, Lebanon and Myanmar
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	1000 dose bottle (500ML) / Decontrolled
	Certificates Submitted	**FSC:** Legalized FSC has been provided. **GMP:** Copy of legalized GMP certificate has been provided. **LOA:** Copy of legalized LOA has been provided.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied Bacterial strain, is not already registered in Pakistan**. • Differential fee of Rs. 75,000/- is required to be deposited. • The label of the product does bear contain name of the importer. • The copy of LOA submitted is not readable.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Differential fee of Rs. 75,000/- is required to be deposited.** • **The label of the product does bear contain name of the importer.** • **The copy of LOA submitted is not readable.**	
38.	Name and address of Importer	**M/s Hilton Pharma (Pvt.) Ltd.,** Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi.
	Detail of DSL	No. 559 Validity: 19-06-2029

	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. dated 29-12-2022 Rs.75,000/-, Dated 08-12-2022
	Name of MAH Holder	**PT. MEDION FARMA JAYA,** JI, Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia
	Name of Manufacturer	**PT. MEDION FARMA JAYA,** JI, Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Medivac ND T-Gumboro L Emulsion** Each dose contains: Inactivated Newcastle Disease Virus, La Sota Strain…at least $10^{7.0}$ EID_{50} Inactivated Newcastle Disease Virus, MD54 Strain…at least $10^{7.0}$ EID_{50} Inactivated Newcastle Disease Virus, MD65 Strain…at least $10^{7.0}$ EID_{50} Inactivated Infectious Bursal Disease Virus, Winterfield 2512 Strain…at least $10^{4.5}$ EID_{50} Inactivated Infectious Bursal Disease Virus, M21 Strain…at least $10^{4.5}$ EID_{50}
	Composition	Each dose contains: Inactivated Newcastle Disease Virus, La Sota Strain…at least $10^{7.0}$ EID_{50} Inactivated Newcastle Disease Virus, MD54 Strain…at least $10^{7.0}$ EID_{50} Inactivated Newcastle Disease Virus, MD65 Strain…at least $10^{7.0}$ EID_{50} Inactivated Infectious Bursal Disease Virus, Winterfield 2512 Strain…at least $10^{4.5}$ EID_{50} Inactivated Infectious Bursal Disease Virus, M21 Strain…at least $10^{4.5}$ EID_{50}
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	18 months (2-8°C)
	International availability	Indonesia
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	500ml/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized valid GMP certificate of foreign manufacturer has been provided. **LOA: Not Provided**.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, combination formulation with applied viral strains, is not already registered in Pakistan**. • Differential fee of Rs. 75,000/- is required to be deposited. • Legalized LOA from MAH, is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Differential fee of Rs. 75,000/- is required to be deposited.** • **Legalized LOA from MAH, is required.**	
39.	Name and address of Importer	**M/s Hilton Pharma (Pvt.) Ltd.,** Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi.
	Detail of DSL	No. 559

		Validity: 19-06-2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy. No. dated 29-12-2022 Rs.150,000/-, Dated 08-12-2022
	Name of MAH Holder	**PT. MEDION FARMA JAYA,** JI, Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia
	Name of Manufacturer	**PT. MEDION FARMA JAYA,** JI, Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia
	Name of exporting country	Indonesia.
	Brand Name + Dosage Form + Strength	**Medivac IBH Emulsion** Each dose contains: Inactivated Fowl Adenovirus, 8b Serotype…at least $10^{6.5}$ $TCID_{50}$ Inactivated Fowl Adenovirus, 11 Serotype…at least $10^{6.5}$ $TCID_{50}$
	Composition	Each dose contains: Inactivated Fowl Adenovirus, 8b Serotype…at least $10^{6.5}$ $TCID_{50}$ Inactivated Fowl Adenovirus, 11 Serotype…at least $10^{6.5}$ $TCID_{50}$
	Finished product specifications	Manufacturer's specification
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	24 months (2-8°C)
	International availability	Indonesia
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	500ml/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized valid GMP certificate of foreign manufacturer has been provided. **LOA: Not Provided**.
	Evaluator Remarks	During evaluation of the application, following shortcomings have been observed; • **As per available record, formulation with applied viral strains, is not already registered in Pakistan**. • Legalized LOA from MAH, is required.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **Legalized LOA from MAH, is required.**	

40.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No: 2778 Dated: 25/01/2021 Rs. 100,000/- Dated: 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.

	Name of exporting country	China
	Brand Name + Dosage Form + Strength	**Meilan K. ND+IB+EDS** Each dose contains: Newcastle Disease virus Strain La Sota before inactivation… ≥$3x10^{8.0}$ EID_{50}/0.1ml Infectious Bronchitis virus Strain M41 before inactivation ….≥$3x10^{6.0}$ EID_{50}/0.1ml. Egg Drop Syndrome virus Strain HE02 before inactivation ….≥$3x10^{6.0}$ $TCID_{50}$/0.1ml.
	Composition	Each dose contains: Newcastle Disease virus Strain La Sota before inactivation… ≥$3x10^{8.0}$ EID_{50}/0.1ml Infectious Bronchitis virus Strain M41 before inactivation ….≥$3x10^{6.0}$ EID_{50}/0.1ml. Egg Drop Syndrome virus Strain HE02 before inactivation ….≥$3x10^{6.0}$ $TCID_{50}$/0.1ml.
	Finished product specifications	Manufacturer's specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	250ml Bottle/Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • **As per available record, the formulation with EDS HE02 Strain, is not already registered in Pakistan.** • GMP of the foreign manufacturer has expired on 15-01-2023.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
41.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No : 2778 Dated : 25/01/2021 Rs : 100,000/- Dated : 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China

	Brand Name + Dosage Form + Strength	**Meilan K. ND+H9** Each dose contains: New castle Disease virus strain La Sota before inactivation…….≥$10^{8.175}$$EID_{50}$/0.1ml Avian Influenza H9 virus strain WD before inactivation…….≥$10^{7.175}$$EID_{50}$/0.1ml
	Composition	Each dose contains: New castle Disease virus strain Lasota before inactivation…….≥$10^{8.175}$$EID_{50}$/0.1ml Avian Influenza (H9 subtype) virus strain WD before inactivation…….≥$10^{7.175}$$EID_{50}$/0.1ml
	Finished product specifications	Manufacturer's specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China
	Products already registered in Pakistan	Newcastle Disease and Avian Influenza Vaccine-Vetline
	Demanded Price / Pack size	250ml Bottle/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • GMP of the foreign manufacturer has expired on 15-01-2023.
	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
42.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No : 2778 Dated : 25/01/2021 Rs : 100,000/- Dated : 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name + Dosage Form + Strength	**Meilan K. ND+IB+H9** Each dose contains: Newcastle Disease virus Strain La Sota before inactivation……. ≥ $10^{8.3}$ EID_{50}/0.1ml Infectious Bronchitis virus Strain M41 before inactivation……..≥$10^{6.3}$ EID_{50}/0.1ml. Avian Influenza virus Strain HZ before inactivation…….≥$10^{7.3}$ EID_{50}/0.1ml.
	Composition	Each dose contains: Newcastle Disease virus Strain La Sota before inactivation……. ≥ $10^{8.3}$ EID_{50}/0.1ml

		Infectious Bronchitis virus Strain M41 before inactivation……..≥$10^{6.3}$ EID_{50}/0.1ml. Avian Influenza (H9 Subtype) virus Strain HZ before inactivation…….≥$10^{7.3}$ EID_{50}/0.1ml.
	Finished product specifications	Manufacturer's specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	250ml Bottle/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • **As per available record, the formulation with AIV HZ Strain, is not already registered in Pakistan.** • GMP of the foreign manufacturer has expired on 15-01-2023.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
43.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No : 2778 Dated : 25/01/2021 Rs : 100,000/- Dated : 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name + Dosage Form + Strength	**Meilan K. ND+IB+EDS+H9** Each dose contains: Newcastle Disease virus Strain La Sota before inactivation……. ≥ $4x10^{8.0}$ EID50/0.1ml Infectious Bronchitis virus Strain M41 before inactivation……..≥$4x10^{6.0}$ EID50/0.1ml. Egg Drop Syndrome virus Strain HS25 before inactivation ……≥$4x10^{7}$ TCID50/0.1ml. Avian Influenza virus Strain HZ before inactivation……..≥$4x10^{7.0}$ EID50/0.1ml.
	Composition	Each dose contains: Newcastle Disease virus Strain La Sota before inactivation…….... ≥ $4x10^{8.0}$ EID50/0.1ml

		Infectious Bronchitis virus Strain M41 before inactivation……....≥$4x10^{6.0}$ EID50/0.1ml. Egg Drop Syndrome virus Strain HS25 before inactivation ……..…≥$4x10^{7}$ TCID50/0.1ml. Avian Influenza virus Strain HZ before inactivation……...≥$4x10^{7.0}$ EID50/0.1ml.
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Inactivated Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China
	Products already registered in Pakistan	Not Registered
	Demanded Price / Pack size	250 ml Bottle/ Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • **As per available record, the formulation with EDS HS25 Strain & AIV HZ Strain, is not already registered in Pakistan.** • GMP of the foreign manufacturer has expired on 15-01-2023.
	Decision: **The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strains in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
44.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No : 2778 Dated : 25/01/2021 Rs : 100,000/-Rs Dated : 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name + Dosage Form + Strength	**Meilan L.V. ND LaSota** Each dose contains: Newcastle Disease virus strain La Sota (CVCC AV1615)……..≥$10^{6.0}$ EID_{50}.
	Composition	Each dose contains: Newcastle Disease live virus strain La Sota (CVCC AV1615)……..≥$10^{6.0}$ EID_{50}.
	Finished product specifications	Manufacturer's specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China

	Products already registered in Pakistan	MYVAC 202-Al-Asar
	Demanded Price / Pack size	1000 Doses Vial / Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **GMP:** Legalized GMP certificate of foreign manufacturer, has been provided. **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • GMP of the foreign manufacturer has expired on 15-01-2023.
	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
45.	Name and address of Importer	**M/s Niraav Pharma (Pvt.) Ltd.,** 606, 6th Floor, Noor Estate Building, Shahrah-e-Faisal, Karachi.
	Detail of DSL	DSL No: 0839 Validity: 14/04/2029
	Type of Form Dy. No. Date of Application Fee submitted	Form-5A Dy No : 2778 Dated : 25/01/2021 Rs : 100,000/- Dated : 18/01/2021
	Name of MA Holder	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** **Address:** No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name + Dosage Form + Strength	**Meilan L.V. ND+IB H52** Each dose contains: Newcastle Disease virus strain La Sota (CVCC AV1615)……..$\geq 10^{6.0}$ EID_{50} Infectious Bronchitis Live Virus strain H52 (CVCC AV 1513)…….$\geq 10^{3.5} EID_{50}$
	Composition	Each dose contains: Newcastle Disease virus strain La Sota (CVCC AV1615)……..$\geq 10^{6.0}$ EID_{50} Infectious Bronchitis Live Virus strain H52 (CVCC AV 1513)…….$\geq 10^{3.5} EID_{50}$
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Live Viral Veterinary Vaccine
	Shelf life	12 months (2°C - 8°C)
	International availability	China
	Products already registered in Pakistan	BRONIPRA-ND-Hipra
	Demanded Price / Pack size	1000 Doses Vial / Decontrolled
	Certificates Submitted	**CoPP:** Legalized CoPP has been provided. **Valid until:** 2025-01-12 **Free sale:** Free sale of the product in exporting country.: Yes, confirmed from COPP **LOA:** Legalized LOA has been provided.
	Evaluator Remarks	During evaluation, following deficiencies have been observed in the application; • GMP of the foreign manufacturer has expired on 15-01-2023.

	Decision: **Keeping in view the legalized COPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;** • **GMP of the foreign manufacturer has expired on 15-01-2023.**	
46.	**Name of Applicant**	**M/s Orion Group,** 97 Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad.
	DSLdetails	DSLLicenseNo.06-331-0167-038556Dvalidup to22-01-2028.
	Nameof Manufacturer	***Company:*** Federal State Enterprise "Shchelkovo Biocombinat" **Address**: Biocombinat, Moscow oblast, 141142, Russian Federation,
	Brand Name+ Dosage Form+ Strength	**"Adsorbed Inactivated Vaccine against Foot-and-Mouth disease" containing SEROTYPES A, O, ASIA-I.**
	Composition	One Immunizing dose (2mL) for cattle contains: Inactivated FMD Serotype A ≥ 6 PD50/cattle Inactivated FMD Serotype O ≥ 6 PD50/cattle Inactivated FMD Serotype Asia-I ≥ 6 PD50/cattle
	Finished product specifications	Manufacturer's Specifications
	PharmacologicalGroup	Biologicals
	Shelf Life	18 Months(Store at2^{o}Cto8^{o}C)
	Internationalavailability	N/A
	Alternate Products Already registered in Pakistan	BrandName:Foot and Mouth Disease Vaccine Reg. No.052400 Marketby: M/s.MustafaBrothers
	Type of FormDy.No. Date of Application,Feesubmitted	Form 5-A Dy.No.30359(R&I) DRAP dated 13-11-2020. Fee of 100,000/- dated 06-11-2020.
	DemandedPrice Packsize	Decontrolled (50mL) 25 doses
	General documentation	Free Sale Certificate issued by The Ministry of Agriculture and Food of the Moscow Region, State-financed Veterinary Institution of the Moscow Region, Territorial Veterinary Authority, Russia.
	Evaluator Remarks	It is submitted that M/s. Orion has also applied for renaming of address of manufacturer from "***Biocombinat, Moscow oblast, 141142, Russian Federation***" to "***Biocombinat, Losino-*** ***Petrovsky, 141142, Russian Federation***" while site remains the same and submitted following documents: iii. Letter from Losino-Petrovsky City District Administration. (*In letter it is mentioned that legal address of FSE "Shchelkovo Biocombinat" has been changed* *from "**141142, Moscow Region, Shchelkovo District, Biocomibinate Township**" to "**141142,*** ***Moscow region, Losino-Petrovsky Urban District, Biocombinate Township**". FSE* *"Shchelkovo Biocombinat" has been operating at this address since 1924 and its actual location* *has not changed*).

		iv. Fee of Rupee 7500/- slip no. 0200108719.
	Decision: Registration Board deferred the case in 331st meeting for submission of the following: **i. Original legalized free sale certificate with updated address of manufacturer issued by concerned regulatory authority of country of origin.** **ii. Information about sub serotypes of applied FMD serotypes/vaccine.**	
	The firm has responded as under;	

Deficiency	**Response**
Original legalized free sale certificate with updated address of manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted Legalized FSC with updated address of manufacturer.
Information about sub serotypes of applied FMD serotypes/vaccine.	The firm has submitted letter from Manufacturer regarding serotypes and subtypes as under; Sertotype A (Iran-05) Serotype O (PanAsia-2) Serotype Asia-1 (Sindh-08)

	Decision: **Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	
47.	Name of Applicant	**M/s Orion Group,** 97 Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad.
	DSLdetails	DSL License No.06-331-0167-038556D valid up to 22-01-2028.
	Name of Manufacturer	***Company:*** Federal State Enterprise "Shchelkovo Biocombinat" **Address**: Biocombinat, Moscow oblast, 141142, Russian Federation,
	BrandName+DosageForm+ Strength	**Brucelvac** Lyophilizate for preparation of suspension for injection
	Composition	Each dose of vaccine contains: Live *Brucella abortus* strain RB -51 "SBC" …...10-34×109 CFU. Diluent Part: The diluent is an isotonic 0.85% sodium chloride solution in a 1/90 molar phosphate buffer solution with pH 6.8-7.2.
	Finished product specifications	Manufacturers Specifications
	Pharmacological Group	Immunobiological medicinal product.
	Shelf life	12 Months (Store at 2°C to 8°C)
	Internationalavailability	Russia, Spain
	Alternate Products Already registered in Pakistan	Brand Name: RB-51 CZV Reg. No.096847 Market by: M/s. Mustafa Brothers
	Type of Form Dy.No. Date of Application, Fee submitted	Form 5-A Dy.No.30358(R&I) DRAP dated 13-11-2020. Fee of 100,000/- dated 06-11-2020.
	Demanded Price Pack size	5 doses (10mL) Diluent; 20mL
	General documentation	Free Sale Certificate issued by The Ministry of Agriculture and Food of the Moscow Region, State-financed Veterinary Institution of the Moscow Region, Territorial Veterinary Authority, Russia.
	Evaluator Remarks	It is submitted that M/s. Orion has also applied for renaming of address of manufacturer from "***Biocombinat, Moscow oblast, 141142, Russian Federation***" to "***Biocombinat, Losino-***

		Petrovsky, 141142, Russian Federation" while site remains the same and submitted following documents: i. Letter from Losino-Petrovsky City District Administration. (*In letter it is mentioned that legal address of FSE "Shchelkovo Biocombinat" has been changed from "**141142, Moscow Region, Shchelkovo District, Biocomibinate Township**" to "**141142, Moscow region, Losino-Petrovsky Urban District, Biocombinate Township**". FSE "Shchelkovo Biocombinat" has been operating at this address since 1924 and its actual location has not changed*). ii. Fee of Rupee 7500/- slip no. 0200108719.
	Decision: Registration Board deferred the case for submission of the following by the firm in its meeting 331: i. Original legalized free sale certificate with updated address of manufacturer issued by concerned regulatory authority of country of origin.	
	The firm has responded as under; **Deficiency**: Original legalized free sale certificate with updated address of manufacturer issued by concerned regulatory authority of country of origin. **Response**: The firm has submitted Legalized FSC with updated address of manufacturer.	
	Decision: **Keeping in view the legalized CoPP indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**	
48.	**Name of Applicant**	**M/s Orion Group,** 97 Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad.
	DSL details	DSL License No.06-331-0167-038556D valid up to 22-01-2028.
	Name of Manufacturer	**DOLLVET BIYOTEKNOLOJI ANONIM SIRKETI** Address: Organize Sanayi Bölgesi Koçören OSB Mah. 106.Cadde No.6 Eyyübiye/Sanliurfa/TURKEY
	Brand Name+ Dosage Form+ Strength	**TAYLEDOLL** (Live attenuated Theileria Annulata vaccine against Theileria Annulata infection the cattle)
	Composition	Each dose (2.5 ml) contains: Vaccine: Lymphoid cell infected by living attenuated Theileria annulata macroschizoids….1x10^7 lymphoid cells/dose
	Finished product specifications	Manufacturer's Specifications
	Pharmacological Group	Vaccine
	Shelf life	36 months
	International availability	N/A
	Alternate Products Already registered in Pakistan	TEYLOVAC
	Type of Form Dy. No. Date of Application, Fee submitted	Form5-A Dy.No. 17000 (R&I) DRAP dated: 14-07-2020 Fee of Rs.100,000/-dated 10-07-2020
	Demanded Price Pack size	Decontrolled Vaccine: 5 Doses Diluent 10 ml
	General documentation	Free Sale Certificate, GMP issued by The Ministry of Agriculture and Forestry General Directorate of Food and Control Turkey has been provided

Decision by the Registration Board in its meeting No.324:

Registration Board deferred the case for the following:

i. Submit Stability studies of lyophilized part of product at appropriate time intervals 0,3,6,9, … for three batches.

ii. Apply for change in title of manufacturer as Title of firm on Submitted GMP and FSC are different then Form 5A.

iii. Submit evidence of required manufacturing facility i.e. protozoal vaccine section of manufacturer.

The firm has responded as under;

Deficiency	Response
Submit Stability studies of lyophilized part of product at appropriate time intervals 0,3,6,9, … for three batches.	The firm has submitted stability studies data of three batches.
Apply for change in title of manufacturer as Title of firm on Submitted GMP and FSC are different then Form 5A.	The firm has requested for renaming of the title & address of manufacturer as per GMP certificate.
Submit evidence of required manufacturing facility i.e. protozoal vaccine section of manufacturer.	The firm has submitted copy of GMP as evidence of manufacturing facility and the section, "Live parasite vaccines" has been mentioned in GMP certificate.

The firm has submitted GMP certificate with updated manufacturer name and address. However, FSC and LOA with updated address are awaited.

Decision:

Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and rectification of following deficiencies in the application;

- **FSC and LOA with updated address are required.**

b. **Registration of Locally Manufactured Veterinary Biological Products**

49.	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.1381Dated:15-11-2023 Rs.30,000/- Dated: 10-10-2023
	Brand Name +Dosage Form + Strength	**Extend Pro** Each liter contains; Dipotassium phosphate.$3H_2O$….12.7g Sodium glutamate…..8.67g Fructose….5g Sodium acetate.$3H_2O$…..4.3g TES (M-tris[hydroxymethyl)] methyl-2-aminoethane sulfonic acid)…1.95g Potassium Citrate….0.64g Monopotassium phosphate….0.65g Magnesium chloride.6H2O….0.34g Gentamycin Sulphate….1000-200mcg/ml Pasteurized Milk (optional)….10%V/V
	Composition	Each liter contains; Dipotassium phosphate.$3H_2O$….12.7g Sodium glutamate…..8.67g Fructose….5g Sodium acetate.$3H_2O$…..4.3g TES (M-tris[hydroxymethyl)] methyl-2-aminoethane sulfonic acid)…1.95g Potassium Citrate….0.64g

		Monopotassium phosphate….0.65g Magnesium chloride.6H2O….0.34g Gentamycin Sulphate….1000-200mcg/ml Pasteurized Milk (optional)….10%V/V
	Pharmacological Group	Semen Extender/Diluent
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life & Storage conditions	**12 Months (15-25 ºC)**
	Document Details	• **ML No. 00502; Renewed on 05-08-2022.** • **Inactivated Viral Vaccine Section approval 03rd April, 2023.**
	Pack size & Demanded Price	300ml, 500ml & 1000ml/De-Controlled
	Products Already registered in Pakistan	**Not Registered**
	Remarks of Evaluator	• The evidence of approval of the applied formulation (Local or international, is required. The formulation of the reference product submitted, does not match with the applied one. • Stability studies data supporting the proposed shelf life & storage conditions, is required. • As multiple pack sizes of the product have been proposed, the preferred pack size needs to be specified.
	Decision: **The Registration Board deferred the case for rectification of following deficiencies in the application;** • **The evidence of approval of the applied formulation (Local or international, is required. The formulation of the reference product submitted, does not match with the applied one.** • **Stability studies data supporting the proposed shelf life & storage conditions, is required.** • **As multiple pack sizes of the product have been proposed, the preferred pack size needs to be specified.** • **As applied product is a pharmaceutical formulation and not intended for any therapeutic use so submit justification for registration as a biological drug product.**	

Agenda Item No.6: <u>Personal Hearing-M/s Vigilant Lahore and M/s. Inuko, Lahore for the product of Immucox-5</u>

- The subject case is an FR/ complaint lodged by the M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore dated 15th January 2024, wherein they claimed that "the stated product had been already registered in their name, dated 19-10-1994 having registration number "015484". Therefore, the said product cannot be granted as registration to the M/s. Inuko, Lahore. In support of their case, Vigilant Veterinary claimed that the subject product is manufactured by the same manufacturer, i.e., "Ceva Animal Health Inc. Canada".
- The complaint was evaluated and two letters were served to M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore, dated 21-02-2024 and 02-09-2024 respectively that required the complainant to submit/provide sufficient information or documents to prove their claim of registration of the subject product, i.e., Immucox-5®. The firm submitted the following documents for their justification in support of the claim raised in the FR/ Complaint: -

Table:01

Sr. #.	Documents/ Clarification Required by the DRAP	Firm Submission
i.	Letter of Authorization/ Agreement between Market Authorization Holder and M/s Vigilant Veterinary Services for "Immucox Vaccine".	A photocopy of the document of 1st March 1993, as an evidence of agreement between M/s. Vetech Laboratories Ltd., Wellington, Province of Ontario, Canada and M/s. Vigilant Veterinary Services (Pvt) Limited, Chowk Chauburji, Lahore. The statement of term is as follows: - "The initial term of this agreement shall be from March 1, 1993, to and including February 29, 1996, but it is understood and agreed that if the $300,000.00 target set out in paragraph 2 hereof is met, the agreement shall automatically renew for a further three years to expire February 28, 1999. If the agreement is so renewed, the purchase price for Immucox purchased by Vigilant from Vetech shall be increased by such amount as Vetech and Vigilant may agree upon and a new target for purchase by Vigilant from Vetech during 1996 shall also be agreed upon. If the said target of $100,000.00 is not achieved in 1993, this agreement shall automatically terminate on the 28th day of February, 1994, unless Vetech and Vigilant agree in writing prior to March 1, 1994, to extend this term of the agreement."
ii.	Registration Letter of "Immucox vaccine" issued by DRAP.	Copy of Registration letter issued on 19-10-1994 alongwith copies of renewal submissions, dated as follows: - 28-08-2019; 24-09-2014; 30-09 2009; 29-09-2004; 25-10-1999.
iii.	Complete name of manufacturer and Market Authorization Holder of "Immucox Vaccine".	**-not provided-**
iv.	Any online link to verify registration status of "Immucox Vaccine" in Canada showing Market Authorization Holder or manufacturer also.	**-not provided-**
v.	The detail composition of "Immucox Vaccine" and similarity with "Immucox ® 5	Certificate of analysis of 2013 provided with composition of the product, i.e., 1. E. acervulina;

	Vaccine" as composition of both seems to be different.	2. E. maxima; 3. E. necatrix; 4. E. tenella,
vi.	The letter/permission of change of name of manufacturer from M/s Vetech Laboratories Ltd to M/s Ceva Sante Animale Canada (as stated in your letter).	**-not provided-**
vii.	Import record of "Immucox Vaccine".	Import invoices copies dated Dec. 2011 and Dec. 2013.

- The reply submitted by the firm did not suffice its claim that the same product was approved to the name of M/s. Inuko, Lahore. It is pertinent to mention here that the firm M/s. Inuko, Lahore was already in the court for issuance of Registration letter of the product Immucox-5®, that was approved in M-331 of the Registration Board. But its letter was not issued due to above mentioned complaint of M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore. The honourable high court in writ petition-51565 of 2024 has decided the case and directed the DRAP to dispose of the matter in first week of October, 2024, positively.
- The comparison of documents/information submitted by both the parties, is as under;

Table:02

Sr. #.	**Documents provided as an evidence.**	**M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore.**	**M/s. Inuko, Lahore**
i.	**Product Details**	Immucox Vaccine **Each dose of vaccine contains:** **E. acervulina… not provided-** **E. maxima……..not provided-** **E. necatrix not provided-** **E. tenella… not provided-**	Immucox ® 5 Each dose of vaccine contains: Eimeria acervulina.at least…… 151 oocysts/dose Eimeria brunetti…….at least 40 oocysts/dose Eimeria maxima…….at least 50 oocysts/dose Eimeria necartrix……..….at least 51 oocysts/dose Eimeria tenella……..….at least 25 oocysts/dose
ii.	Complete name of manufacturer and Market Authorization Holder of "Immucox-5 Vaccine". As of today.	-no evidence provided for agreement bw M/s. Ceva Sante Animale, Canada,	Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore provided, i.e., valid till 31st December, 2024.
iii.	Letter of Authorization/ Agreement	A photocopy of the document of 1st March 1993.	Original, Legalized and valid Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore, as an exclusive distributor of Immucox ®

			5 provided, i.e., valid till 31st December, 2024.
iv.	Complete name of manufacturer and Market Authorization Holder of "Immucox Vaccine".	**-not provided-**	
v.	Any online link to verify registration status of "Immucox Vaccine" in Canada showing Market Authorization Holder or manufacturer also.	**-not provided-**	Online justification provided by the firm that the subject product is registered with M/s. Ceva Sante Animale, Canada and on free sale in the country of origin.
vi.	The detail composition of "Immucox Vaccine" and similarity with "Immucox ® 5 Vaccine" as composition of both seems to be different.	Certificate of analysis of 2013 provided with composition of the product, i.e., 1. E. acervulina; 2. E. maxima; 3. E. necatrix; 4. E. tenella,	Each dose of vaccine contains: Eimeria acervulina.at least…… 151 oocysts/dose Eimeria brunetti…….at least 40 oocysts/dose Eimeria maxima…….at least 50 oocysts/dose Eimeria necartrix……..….at least 51 oocysts/dose Eimeria tenella…….….at least 25 oocysts/dose
vii.	The letter/permission of change of name of manufacturer from M/s Vetech Laboratories Ltd to M/s Ceva Sante Animale Canada (as stated in your letter).	**-not provided-**	Original, Legalized and valid Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore, as an exclusive distributor of Immucox 5® provided, i.e., valid till 31st December, 2024.
viii.	Import record of "Immucox Vaccine".	Import invoices copies dated Dec. 2011 and Dec. 2013.	----------

- In accordance to above case history, both parties were called for personal hearing for defense of their case in 340th meeting of the Board.

Proceeding of the Board in its 340th meeting:

In compliance to letter for personal hearing, Ms. Irum Advocate from M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore requested for an adjournment however, Mr. Umar Hameed Khan being counsel of M/s. Inuko, Lahore presented the case and ensure that all the legal liabilities on M/s. Inuko, Lahore for the grant of registration has been complied, and requested for grant of registration.

Decision of the Registration Board in its 340th meeting:

The Registration Board deliberated the case and acceded the request of M/s. Vigilant Veterinary Services (Pvt.) Limited, Lahore for adjournment along with the direction to appear in the next meeting otherwise case shall be decided, ex-parte.

In light of above decision of the Registration Board, M/s. Vigilant Veterinary Services (Pvt.) Limited, Lahore, was called for personal hearing in 343rd meeting of the Registration Board.

Proceeding of 343rd meeting of the Registration Board:

In compliance to the letter of personal hearing, Ms. Irum Advocate and Dr. Muhammad Azam Chohan, Chief Executive, Vigilant Veterinary Services (Pvt.) Limited, Lahore, appeared before the Board and submitted as under;

"That Vigilant Veterinary Services (Pvt.) Ltd. is a renowned firm which is offering its services in Pakistan for more than 2 decades. It is pertinent to mention here that the said firm entered in an agreement with VETECH LABORATORIES INC. of 131 Malcolm Road, Guelph, Ontario, Canada N1K 1A8 dated on 01-03-1993.

That vide agreement dated 01-03-1993, Vigilant Veterinary Services (Pvt.) Ltd. were delegated the exclusive rights to sell IMMUCOX vaccine directly or through third party agents throughout Pakistan.

That thereafter, Vigilant Veterinary Services (Pvt.) Ltd. applied for the registration of IMMUCOX vaccine under section 7 of the Drugs Act, 1976 and Rule 30 of the Drugs (registration and advertising) Rules 1976.

That the drug was registered vide Document No. 3-4/94- Reg-I(M-109) bearing Registration No. 015484 dated 19- 10-1994. After registration of IMMUCOX vaccine, Vigilant Veterinary Services (Pvt.) Ltd. imports and sales the said vaccine in Pakistan.

That thereafter VETECH merged with Ceva Animal Health in a new firm named Ceva Animal Health Canada. After merger all the ongoing business of VETECH LABORATORIES INC. was shifted to Ceva Animal Health Canada located at the same premises 131 Malcolm Road, Guelph, Ontario, Canada N1K 1A8. Ceva Animal Health Canada continued to sell the IMMUCOX vaccine to Vigilant Veterinary Services (Pvt.) Ltd. without any objection or any hindrance from any quarter whatsoever. The invoices issued by Ceva Animal Health Canada are also available.

That till today Vigilant Veterinary Services (Pvt.) Ltd. is holding the drug registration and thereby the brand name, intellectual and propriety rights are in its name since 1994 without objection or interference either by CEVA ANIMAL HEALTH OR ANY OTHER AGENCY. It will be not out of place to mention here that the IMMUCOX vaccine is a renowned name in Pakistan due to the 20+ years of effort, cost and risk taken by Vigilant Veterinary Services (Pvt.) Ltd. and now IMMUCOX vaccine is an ICON of Vigilant Veterinary Services (Pvt.) Ltd. And both are recognized as a part and parcel of each other.

That now it comes to the knowledge of Vigilant Veterinary Services (Pvt.) Ltd. that another firm has applied for the same name with a minor change i.e IMMUCOX 5 instead of IMMUCOX for registration, which is against the law and facts available on record.

That we immediately applied for cancellation of registration of Immucox 5. The request of Vigilant Veterinary Services (Pvt.) Ltd. was considered by the Registration Board and they offered an opportunity of hearing.

That the matter under consideration is that IMMUCOX® vaccine is registered in the name of Vigilant Veterinary Services (Pvt.) Ltd. and as per clause 2 of Form No. 5 that design/colour, graphic of label/carton is not copy /counterfeit of any other drug. If we observe the script of IMMUCOX 5 it is similar to IMMUCOX which could not be differentiated by a layman and he could easily be deceived. Even otherwise it is also against the established law. That Inouko Animal Health (Private) Limited. is trying to get IMMUCOX 5 registered, which should not be issued to them BECAUSE IT COULD BE USED IN DECEPTIVE MANNER to grab the market share of IMMUCOX which is established in Pakistan by Vigilant Veterinary Services (Pvt.) Ltd. with 20+ years of effort, cost and risk. It is worth mentioning here that the registration of IMMUCOX vaccine still exists in the name of Vigilant Veterinary Services (Pvt.) Ltd. since 1994 and same has been renewed as per law regularly.

That there is no such data available on net uploaded by Ceva Animal Health. However, names of countries are mentioned at their site with whom they are doing business.

That has already been mentioned that after the merger Ceva Animal Health has accommodated all the clients of VETECH LABORATORIES INC. The agreement was never rescinded or amended in any manner till today and both the parties are abiding terms and conditions till today."

During the hearing, the Board was apprised by Ms. Irum Advocate and Dr. Muhammad Azam Chohan, Chief Executive, Vigilant Veterinary Services (Pvt) Limited, Lahore that the last shipment of the Immucox Vaccine was imported in 2014 and after merger of the VETECH LABORATORIES INC. Canada with Ceva Animal Health, Canada, old distribution agreement dated 01-03-1993 with VETECH LABORATORIES INC. Canada was never revised and submitted to DRAP.

The Board was further apprised by the Division of BE&R that drug registered in the name of M/s Vigilant Veterinary Services (Pvt) Limited, Lahore i.e Immucox Vaccine is tetravalent vaccine while the drug applied for registration by M/s Inouko Animal Health (Private) Limited i.e. Immucox 5 Vaccine, is pentavalent vaccine.

Decision of 343rd meeting of the Registration Board:

The Board after hearing M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore and going through the facts, decided to defer the case and directed the Division of Biological Evaluation and Research to write an email to Ceva Animal Health, Canada for confirmation of following information/facts;

i. Registration/Marketing Authorization status of Immucox Vaccine.

ii. Validity/existence of distribution agreement for Pakistan pertaining to Immucox Vaccine & Immucox 5 Vaccine with M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore or M/s Inouko Animal Health (Private) Limited, Lahore.

Updated Status of the Case:

Email dated 04-12-2024 from Lucas Figueiredo, Campus Director, Ceva Animal Health – Canada (lucas.figueiredo@ceva.com):

This is Lucas Figueiredo from Ceva Animal Health Inc Canada. Our company Ceva Animal Health inc is located at 131 Malcolm Road Guelph, Ontaria, Canada and it is a subsidiary of Ceva Sante Animale S.A. having office at 10 Avenue, de la Ballastiere 33500, Libourne, France.

Ceva Canada is the manufacturer of a drug by the named "Eimeria Acervulina-Brunetti-Maxima-Necatrix –Tenella Vaccine, Live oocysts Immucox ® 5" ("Immucox 5"). The registration of the said drug was approved in the favor of "Inouko Animal Health (Private) Limited" which is subsidiary of Ceva Sante Animale S.A. France by the Registration Board in 330th Meeting held on 24th to the 26th of July, 2023. The Sole Agency Agreement regarding the said drug had also been entered by Ceva in the favor of Inouko Animal Health (Private) Limited.

It has come into the knowledge of Ceva Animal Health inc that a company by the name of Vigilant Veterinary Services (Pvt) Limited has filed a Complaint alleging that that "the stated product had been already registered in their name, dated 19-10-1994 having registration number "015484". The instant letter attached seeks to clarify the wrong and false assertions/ accusations made by Vigilant Veterinary Services (Pvt) Limited.

The product registered in favor of Vigilant Pharma namely Immucox for Chickens I (Registration No. 015484) was officially discontinued by Ceva Animal in 2019 and its license was withdrawn from Canadian Food Inspection Agency (CFIA) – Canadian Centre for Veterinary Biologics (CCVB) by Ceva Animal. A letter from CFIA-CCVB dated 03-06-2019 confirming this discontinuation is attached as Annexure 'B' for your reference. It has been falsely claimed by Vigilant Pharma that Immucox for Chickens I (Registration No. 015484) is manufactured by Ceva Animal since it has been discontinued in 2019.

Immucox 5, licensed by Canadian Food Inspection Agency (CFIA) – Canadian Centre for Veterinary Biologics (CCVB) in January 2017 and it is a new product with different to meet updated regulatory and efficacy standards, and it has significantly different formulations from **Immucox for Chickens I** (Registration No. 015484).

Immucox 5 is entirely separate and distinct from the discontinued **Immucox for Chickens I (Registration No. 015484)**, which was discontinued in 2019. It is also evident from Annexure 'A' of this letter and also noted by the Registration Board in the Minutes of its 340th Meeting.

NOTE: Please be noted that Ceva Canada is currently manufacturing different range of Immucox vaccine (Immucox 3, Immucox 5 and Immucox T) and each one has its own specification and composition.

Considering the foregoing, it is most respectfully and humbly prayed that the claim of Vigilant Pharma is false and frivolous and liable to be dismissed, and Registration Letter for Immucox 5 should be issued in the favor of Inouko Animal Health (Private) Limited.

Email dated 20-12-2024 from Kelly Groskopf, Regulatory Affairs Specialist, Ceva Animal Health – Canada:

This is Kelly Groskopf from Ceva Animal Health Inc Canada. Our company Ceva Animal Health inc is located at 131 Malcolm Road Guelph, Ontaria, Canada and it is a subsidiary of Ceva Sante Animale S.A. having office at 10 Avenue, de la Ballastiere 33500, Libourne, France.

Ceva Canada is the manufacturer of a drug by the named "Eimeria Acervulina-Brunetti-Maxima-Necatrix –Tenella Vaccine, Live oocysts Immucox ® 5" ("Immucox 5"). The registration of the said drug was approved in the favor of "Inouko Animal Health (Private) Limited" which is subsidiary of Ceva Sante Animale S.A. France by the Registration Board in 330th Meeting held on 24th to the 26th of July, 2023. The Sole Agency Agreement regarding the said drug had also been entered by Ceva in the favor of Inouko Animal Health (Private) Limited.

It has come into the knowledge of Ceva Animal Health inc that a company by the name of Vigilant Veterinary Services (Pvt) Limited has filed a Complaint alleging that that "the stated product had been already registered in their name, dated 19-10-1994 having registration number "015484". The instant letter attached seeks to clarify the wrong and false assertions/ accusations made by Vigilant Veterinary Services (Pvt) Limited.

The product registered in favor of Vigilant Pharma namely Immucox for Chickens I (Registration No. 015484) was officially discontinued by Ceva Animal in 2019 and its license was withdrawn from Canadian Food Inspection Agency (CFIA) – Canadian Centre for Veterinary Biologics (CCVB) by Ceva Animal. A letter from CFIA-CCVB dated 03-06-2019 confirming this discontinuation is attached as Annexure 'B' for your reference. It has been falsely claimed by Vigilant Pharma that Immucox for Chickens I (Registration No. 015484) is manufactured by Ceva Animal since it has been discontinued in 2019.

Immucox 5, licensed by Canadian Food Inspection Agency (CFIA) – Canadian Centre for Veterinary Biologics (CCVB) in January 2017 and it is a new product with different to meet updated regulatory and efficacy standards, and it has significantly different formulations from Immucox for Chickens I (Registration No. 015484).

Immucox 5 is entirely separate and distinct from the discontinued Immucox for Chickens I (Registration No. 015484), which was discontinued in 2019. It is also evident from Annexure 'A' of this letter and also noted by the Registration Board in the Minutes of its 340th Meeting.

NOTE: Please be noted that Ceva Canada is currently manufacturing different range of Immucox vaccine (Immucox 3, Immucox 5 and Immucox T) and each one has its own specification and composition.

NOTE: It is clarified that Ceva Animal Health Inc Canada has no relationship whatsoever with Vigilant Pharma.

Considering the foregoing, it is most respectfully and humbly prayed that the claim of Vigilant Pharma is false and frivolous and liable to be dismissed, and Registration Letter for Immucox 5 should be issued in the favor of Inouko Animal Health (Private) Limited.

Letter from Ms. Irum Advocate from M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore

I am writing this letter in exercise of authority given to me by M/s Vigilant Veterinary Services (Pvt.) Ltd. to follow up on my previous communication dated 03-12-2024, and personal hearing before the Honorable Registration Board meeting No. 341 dated 5-12-2024 regarding the registration of the brand name IMMUCOX for our company, Vigilant Veterinary Services (Pvt.) Ltd.

As highlighted in my earlier correspondence, and personal hearing before the Honorable Registration Board it is crucial for our company to retain exclusive rights to the brand name IMMUCOX to prevent financial losses and avoid potential confusion in the market due to the use of the same or similar names by other entities. Our marketing strategies, branding efforts and customer recognition are all tied to this name, making its protection essential for the continuity of our business operations.

To further strengthen our case and clarify any concerns, I respectfully have requested an in-person hearing before the Registration Board. I am thankful to the Registration Board who has provided an opportunity to present additional evidence and arguments supporting our claim and to address questions the honorable board had.

I kindly urge your office to keep in view the '**Look-Alike Sound-Alike** (LASA, ORTHOGRAPHIC and PHONETIC)' resemblance before granting a similar brand name to any other company. I am confident that this step will help resolve the matter efficiently and ensure a fair outcome for all stakeholders involved.

Decision:

Keeping in view the email received from Lucas Figueiredo, Campus Director & Kelly Groskopf, Regulatory Affairs Specialist, Ceva Animal Health – Canada, the Board decided to regret the complaint lodged by M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore, with the following directions;

i. **The Board directed the Division of Biological Evaluation & Research to issue registration letter of Immucox-5 Vaccine already approved in 331st meeting of the Board in the name of M/s Inouko Animal Health (Private) Limited, Lahore.**
ii. **The Board further directed the Division of Biological Evaluation & Research to issue show-cause notice and letter of personal hearing to M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore as to why the registration of their product Immucox Vaccine (Reg. No. 015484) may not be cancelled?**

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

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Item No. V. Applications submitted on e-App

Registration Board 344 Meeting Minutes:

Sr. No	Title	Description
1	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(1HL-QGQ-4SQ6, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**Q TRON 8MG TABLET**
	Label Claim	Each Film coated Tablet contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron .... 8 mg
	Pharmacotherapeutic Group of (API)	Anti emetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020103s035_020605s019_020781s019lbl.pdf
	For generic drugs (me-too Status)	Zofran mg 8 Tablet (Novartis Pharma (Pakistan) Limited)
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Zofran tablet
	Detail of stability batches of drug product	2 batches of 5000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer • BMRs of stability batches shall be submitted • Documents of procurement of drug substance shall be submitted Firm has provided following: GMP certificate of drug substance manufacturer Commercial invoice attested by I&E DRAP BMrs
	Shortcoming	
	Decision	Approved Registration letter shall be issued after verification of loan letter.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>2</td><td>Name, address of Manufacturing site.</td><td>shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore(000577)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(B76-BHQ-XLL7, 2024-08-21)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-08-15,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cinzit dry oral suspension 200mg/5ml</td></tr>
<tr><td></td><td>Label Claim</td><td>Each 5 ml reconstituted suspension contains Azithromycin 200 mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Macrolide antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>British Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>MHRA</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>AGP Pharmaceuticals</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>15ml-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 15-12-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>--</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Nexchem pharmaceuticals co.,ltd</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Nexchem pharmaceuticals Co.,Ltd. China</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Azomax Suspension</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 150 bottles each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>--</td></tr>
<tr><td></td><td>Evaluation</td><td>instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Valid DML/GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin.</td><td>Valid copy of DML submitted</td></tr>
<tr><td>Evidence of approval of required manufacturing facility i.e., Dy powder suspension section (general), as a new section from CLB shall be submitted.</td><td>Additional section of "Dry powder suspension (general) granted dated 14-02-2024</td></tr>
<tr><td>Drug substance stability data as per Zone IV conditions shall be submitted</td><td>Submitted</td></tr>
<tr><td>Clarification shall be submitted regarding hydrate form of drug substance.</td><td>Azithromycin dihydrate</td></tr>
<tr><td>Dissolution tests has not been performed during Pharmaceutical equivalence studies.</td><td>We have adopted BP specifications for Azithromycin Oral Suspension and all the parameters are tested according to BP specifications (BP 2024). The dissolution test in not mention in BP monogrpah so we are not included and perfomed dissolution test in Pharmaceutical equivalence studies</td></tr>
<tr><td>Comparative Dissolution Profile of applied drug product against the reference/comparator product shall be submitted</td><td>We have adopted BP specifications for Azithromycin Oral Suspension and all the parameters are tested according to BP specifications (BP 2024). The dissolution test in not mention in BP monogrpah so we are not perfomed Comparative Dissolution Profile of applied drug product. Also, Comparative Dissolution Profile is mandatory for Capsule and Tablet dosage form and for dry powder suspension Comparative Dissolution Profile is mandatory if dissolution test mentioned in relevant monograph.</td></tr>
<tr><td>Section 1.5.6 refers to BP monograph for drug product specifications, while section 3.2.P.5.1 claims USP specifications. Clarification shall be submitted in this regard.</td><td>The prodcut Cinzit (Azithromycin) dry suspension are tested according to BP monograph of Drug product specifications. Section 1.5.6 refers to BP monograph for drug product specifications are corrected while it is mistakenly written USP in section 3.2.P.5.1.</td></tr>
<tr><td>Dissolution test has not been included in the drug product specifications.</td><td>We have adopted BP specifications for Azithromycin Oral Suspension and all the parameters are tested according to BP specifications (BP 2024). The dissolution test in not mention in BP monogrpah so we are not included dissolution test in drug product specifications.</td></tr>
<tr><td>Documents confirming import of the drug substance, issued by DRAP I&E office, shall be submitted</td><td>Copy of commercial invoice attested by DRAP I&E Office is submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for change of specifications as per SRO1324 (I)/2024 dated 30-08-2024</td></tr>
</table>

Sr. No	Title	Description
3	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(2PG-L7A-59R6, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	**Linus Solution for Infusion 2 mg/ml; 300 ml**
	Label Claim	Each 300ml ContainsLinezolid 600mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Zyvox ® 2 mg/ml is Approved in USFDA
	For generic drugs (me-too Status)	Linzolet Solution for Infusion 2 mg/ml; 300 ml Solution for Infusion by Winlet Pharmaceuticals (Pvt) Ltd. is DRAP Approved.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection LVP (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	M/s Optimus Drugs Private Limited.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against i.e., Linzolet infusion of LCI.
	Detail of stability batches of drug product	2 batches of 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 12-12-2020
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations • Batch manufacturing record of stability batches shall be submitted • Reply: Firm has submitted BMRs of two stability batches.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
4	Name, address of Manufacturing site.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan**(000578)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(2XN-NGV-YELE, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	**DEXOJIN 30MG**
	Label Claim	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w Equivalent to Dexlansoprazole.....30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 30 mg CAPSULES by USFDA Approved
	For generic drugs (me-too Status)	Razodex 30mg Capsule Getz Pharma Pakistan
	Proposed Pack Size	30`S-De-Controlled
	GMP status of the firm	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021
	Evidence of approval of manufacturing facility	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021
	Name & address of API manufacturer	VISION PHARMACEUTICALS PVT LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against Razodex capsule of M/s Getz
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Following shall be submitted: · BMR of drug product stability batches. Reply: Submitted
	Shortcoming	
	Decision	Deferred Registration Board referred to its following decision of 286th meeting: "Registration Board after thorough deliberation and considering the decision of 14th meeting of Policy Board decided to grant 10 products per section for all the firms for which section approval was granted by Central Licensing Board before 14th meeting of Policy Board of DRAP held on10th & 11th of Sep, 2015. However, only those firms shall be considered for grant of registration of ten products per section, whose registered products as of today are less than ten products per section." While referring to the above cited decision it was noted that as per available record M/s Jinnah Pharmaceuticals has already availed registration of more than 10 products in the "Capsule general" section, hence the Board deferred the instant application for consideration on its turn.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>5</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(D4U-PMV-L9ML, 2024-12-16)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>75000.0,
2024-10-18,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Menaquin K2 180mcg soft gelatin capsule</td></tr>
<tr><td></td><td>Label Claim</td><td>Each soft gelatin capsule contains: Menaquinone-7 (vitamin K2) ..... 180mcg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Vitamin K analogue</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>TGA - Therapeutic Goods Administration</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Nil</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>20's-As per SRO,30's-As per SRO,60's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Anthem Biosciences Pvt. Ltd, Unit-IV. & Address: Plot No. 276-P, 277-P, Sy No. 20, Bannikuppe Road Harohalli Industrial area, phase-II, Kanakapura Taluk, Ramanagara District.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Anthem Biosciences , India</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence & CDP performed against reference product Vitamin K2 Max of Herbs of Gold</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 600 capsules each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 14-04-2023</td></tr>
<tr><td></td><td>Evaluation</td><td>instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Justification shall be submitted for the n-house standard of drug substance, while the USP monograph is available for the drug substance.</td><td>We have received working standard from the manufacturer with the shipment of API sample. During the initial product testing and subsequent stability testing we have used the same working standard. We hereby assure that we shall procure and use USP working standard at the time of manufacturing of commercial batches</td></tr>
<tr><td>Justification shall be submitted for using microencapsulated drug substance for the formulation of drug product.</td><td>Pure form of API is only available in microencapsulated form. This encapsulated form is completely soluble in soyabean oil which is the solvent of the formulation</td></tr>
<tr><td>Disintegration test has not been performed in Pharmaceutical equivalence studies.</td><td>Disintegration test results is included in the pharmaceutical equivalence studies</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>copy of commercial invoice submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Deferred
for following:
Clarification regarding the status of applied formulation in reference regulatory authorities whether as a drug or otherwise.
Documents of procurement of drug substance with approval of DRAP I&E office</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>6</td><td>Name, address of Manufacturing site.</td><td>STARWAYS PHARMACEUTICALS Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan(000999)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(2MP-MUQ-TADR, 2024-12-13)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>37000.0,
2024-12-04,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Montestar 10mg Tablet</td></tr>
<tr><td></td><td>Label Claim</td><td>Each Film Coated Tablet Contains:Montelukast as sodium .....10mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Leukotriene receptor antagonists</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>usfda approved</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>MONTELUKAST 10MG TABLET BY FEROZSONS LABORATORIES PRIVATE LIMITED</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>14's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.3-1/2021-Lic issued by Secretary CLB dated 2-12-2024 approved in 307 meeting of CLB held on 20-11-2024, based upon inspection conducted on 12-08-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.3-1/2021-Lic issued by Secretary CLB dated 2-12-2024 approved in 307 meeting of CLB held on 20-11-2024, based upon inspection conducted on 12-08-2024.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>MOREPEN LABORATORIES LIMITED</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has submitted loan letter form M/s Medicraft</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>2 batches of 5000 tablets each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan letter from M/s Medicraft Pharmaceuticals, Risalpur, Pakistan</td></tr>
<tr><td></td><td>Evaluation</td><td>instant application has been evaluated and found deficient for following observations:
Observations
<table><tr><th>Observations</th><th>Response</th></tr><tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td></td></tr><tr><td>Pharmaceutical Equivalence and CDP studies of applied product against the reference/comparator product shall be submitted.</td><td>Submitted</td></tr><tr><td>Documents confirming import of the drug substance, issued by the DRAP I&E office in name of frim form which drug substance has been borrowed,, shall be submitted</td><td>Submitted</td></tr><tr><td>BMRs of drug product stability batches shall be submitted.</td><td></td></tr></table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Registration letter will be issued upon submission of following:
• Valid DML/GMP certificate of drug substance manufacturer
• BMRs of drug product stability batches
• Verification of loan letter.</td></tr>
</table>

Sr. No	Title	Description
7	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(35T-U13-L9T9, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Ceframit 250mg Capsule**
	Label Claim	Each Capsule contains:Cephradine.....250mg
	Pharmacotherapeutic Group of (API)	First generation cephalosporin, ATC code: J01DB09
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Cephradine 250mg capsule of M/s ACS Dobfar S.p.A, Via Laurentina Km 24, 730 – 00071 Pomezia, Roma, Italy (MHRA Approved)
	For generic drugs (me-too Status)	Velosef 250mg Capsule of M/s GSK Pakistan
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted new section of “Capsule (Cephalosporinl)” vide letter no. F.1-10/2012-Lic issued by Secretary CLB dated 07-06-2022.
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CD submitted against Cefaclor capsule
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Dr. Raza Pharma along with invoice and delivery challan.
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
8	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(3RW-BNE-ESTG, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Lubiprostin 8mcg Soft Gelatin Capsule**
	Label Claim	Each soft gelatin capsule contains Lubiprostone 8mcg
	Pharmacotherapeutic Group of (API)	A06AX : Other drugs for constipation
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	US Food & Drug Administration (FDA)
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	10's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	Shandong Kehui Phar- maceutical Co., Ltd..Address:No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shan- dong Province., China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Shandong Kehui Pharmaceutical Co., Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against reference product Amitiza capsule
	Detail of stability batches of drug product	3 batches of 5000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 28-12-2022
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Dissolution test has not been performed in Pharmaceutical equivalence studies. Reply: Firm has submitted Pharmaceutical equivalence studies including dissolution test. Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted. Reply: Firm has submitted commercial invoice and Airway Bill.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
9	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(3Z3-18E-JL45, 2024-12-11)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Zonas**
	Label Claim	Each mL contains 20 mgof zonisamide
	Pharmacotherapeutic Group of (API)	Other antiepileptics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP inspection dated 27-08-2024 conculdes satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB base dupon approval in 296 meeting of CLB
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Maithri Drugs Private Limited,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Zonisade suspension
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued by DRAP I&E Office.
	Evaluation	instant application has been evaluated and found deficient for following observations: • Evidence of the availability of USP monograph for the applied formulation shall be submitted as claimed in section 1.5.6. Reply: We will claim innovator 's specification while te ting method has been adopted as per USP monograph of compounded oral suspension of zonisamide all testing parameters already submitted in the mentioned. section. However, fees for change of specifica ions from USP to Innovator's Specifications has Been paid. • Valid DML/GMP certificate of drug substance manufacturer shall be submitted. Firm has submitted valid GMP certificate issued by DCA Telangana • Drug product stability data of 6th month time point shall be submitted. **6th month time point stability data of drug product has been submitted.**
	Shortcoming	
	Decision	Approved With Innovator's specifications

Sr. No	Title	Description
10	Name, address of Manufacturing site.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad**(000778)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(4H1-2YZ-U4A3, 2024-12-26)
	Detail of Fee Submitted	37000.0, 2024-11-29,
	The proposed proprietary name / brand name	**Ferium**
	Label Claim	Each 10ml vial contains: Ferric Carboxymaltose Complex Equivalent to iron...500mg
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Ferinject ® Dispersion for Injection/Infusion is approved in USFDA
	For generic drugs (me-too Status)	Fercari Dispersion for Injection/Infusion 50 mg Iron/ml by Hilton Pharma
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	Firm has been granted additional section of “Liquid Injection Vial (General)” section vide letter no. F.1-54/2009-Lic (Vol-I) issued by Secretary CLB dated 22-03-2024.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection Vial (General)” section vide letter no. F.1-54/2009-Lic (Vol-I) issued by Secretary CLB dated 22-03-2024.
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co. Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IVb conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against Ferinject injection
	Detail of stability batches of drug product	3 batches of 1000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name o M/s Cunningham Pharma dated 2-09-2022
	Evaluation	Following shall be submitted: · Valid DML/GMP certificate of drug substance manufacturer Reply: Submitted. · Loan letter from M.s Cunningham Pharma for the borrowed drug substance. Firm has submitted loan letter from M/s Cunningham
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>11</td><td>Name, address of Manufacturing site.</td><td>Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad(000892)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(4JM-PU9-XQ61, 2024-12-16)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>37000.0,
2024-10-01,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>C-Bact dry powder for injection</td></tr>
<tr><td></td><td>Label Claim</td><td>Each Vial Contains: Cefoperazone Sodium eq to Cefoperazone...1000 mgSulbactam Sodium eq to Sulbactam.....1000 mg (JP Specifications)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Any Other</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Sulperazon for IV Injection manufactured by Pfizer Japan</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>2SUM 2 g Injection</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>1 Vial-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 17-08-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Dry Powder Injection (Cephalosporin)” vide letter no. F.1-37/2016-Lic (Vol-I) issued by Secretary CLB dated 18-02-2020.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co ., Ltd. Address: West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi City,Shandong Province, P._R.China. Tel:+865398241531 Email:export@luoxin.cn</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co ., Ltd.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against 2Sum injection of M/s Sami</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 2272 packs each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 5 (License to import Drugs) issued by AD DRAP I&E Office, Islamabad dated 22-10-2021</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
<table>
<tr><th>Observations</th><th>Firm's response</th></tr>
<tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Firm has submitted copy of valid DML of drug substance manufacturer</td></tr>
<tr><td>Justification shall be submitted for the declaration of water content in drug product analysis as below 1%, while batch release certificate of the drug substance used for manufacturing of drug product batches has declared water content as greater than 2%.</td><td>Firm while referring to the decision of 329th meeting of Registration Board has requested to consider the instant product with Innovator's specifications. Water content of finish product was checked and it was less than 1% at that time. We have checked it again and results complies with API water content results.</td></tr>
<tr><td>Reconciliation of the imported quantity of drug substance shall be submitted against the batch sizes of drug product stability batches manufactured.</td><td>This is a typographical mistake and batch sizes were written wrong. We are thankful that you have checked the files so thoroughly and pointed out the mistake for correction. Correct batch sizes are 454 vials for 1gm and 227 vials for 2g dossier. it will not happen again and we will be careful in future.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
With Innovator specifications. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for change of specifications as per SRO1324 (I)/2024 dated 30-08-2024</td></tr>
</table>

Sr. No	Title	Description
12	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(4ME-MJW-2L77, 2024-10-29)
	Detail of Fee Submitted	75000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Urotone 10mg Tablet**
	Label Claim	Each Tablet contains:Bethanechol Chloride.....10mg
	Pharmacotherapeutic Group of (API)	Coline esters N07AB
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Bethanechol Chloride Tablet, USP 10mg of M/s Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 (USFDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Nanyang Libang Pharmaceutical Co., Ltd Add: Kuiying, Waidan, Wancheng District, Nanyang City, Henan, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against Bethanecol tablet
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted MOU and loan letter M/s Medisure Laboratories along with clearance certificate issued by AD DRAP I&E Karachi dated 24-08-2023 in name of M/s Medisure
	Evaluation	Firm has requested vide letter no. Nil dated 17-2-2024 to consider the instant application against priority quota of their additional section of Tablet general granted vide vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024. Following shall be submitted: • BMR of drug product stability batches. Reply: Submitted • GMP/DML of drug substance manufacturer Submitted Evidence of availability of HPLC equipped with Electro conductivity detector. Firm has submitted for commercial invoice for HPLC equipped with The Electro chemical detector • Name of the manufacturer of reference product used for CDP studies. Bethanechol Chloride Tablet, USP 10mg of Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
13	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(5YH-M9G-AHAW, 2024-11-21)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	**Q MONT SACHET**
	Label Claim	Each sachet contains:Montelukast as Sodium .....4 mg.
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Merck Research Laboratories. Singulair ® 4 mg.
	For generic drugs (me-too Status)	AGP Limited Lucast ® 4mg sachet
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Sachet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Sachet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	NA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Lukast sachet of M/s AGP
	Detail of stability batches of drug product	2 batches of 5000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E Office dated 26-09-2022 in name of M/s Bio Mark has been submitted
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer • BMRs of stability batches shall be submitted Firm has submitted trial forms for the drug product stability batches.
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter.

Sr. No	Title	Description
14	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(6QU-Q6E-32YL, 2024-09-16)
	Detail of Fee Submitted	30000.0, 2024-05-22,
	The proposed proprietary name / brand name	**TRACKCIN**
	Label Claim	Each Tablet contains Ciprofloxacin (as Hydrochloride) 750mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too Status)	CIPROSAFE
	Proposed Pack Size	10's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	carryfor Pharmaceutical Pvt Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Ciprosafe 750mg tablet of M/s Safe Pharmaceuticals
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application has been processed against new DML Priority. Observations: Following shall be submitted: Analytical method verification studies of drug substance performed by M/s Q. Track. Firm reply: AMV studies submitted by M/s Q. Track BMR of drug product stability batches Reply: Firm has submitted trial forms of drug product stability batches Differential fee of Rs. ,7000/- as per S.R.O. 1324(I)/2024 dated 30-08-2024
	Shortcoming	
	Decision	Approved Firm shall submit differential fee of Rs. ,7000/- as per S.R.O. 1324(I)/2024 dated 30-08-2024 before issuance of registration letter

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>15</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(79J-WWX-P1WT, 2024-08-26)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-23,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Dercutane 40mg Soft Gelatin Capsules</td></tr>
<tr><td></td><td>Label Claim</td><td>Each soft gelatin capsule contains: Isotretinoin ..... 40mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Retinoids ATC code: D10BA01</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Food & Drug Administration (FDA)</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Maxinoin Capsule 40mg</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-As per SRO,20's-As per SRO,30's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Chongqing Huapont Pharmaceutical Co., Ltd. No. 69 Xingguang Avenue Renhe Town, Yubei District, Chongqing, P.R. China</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Chongqing Huapont Pharmaceutical Co., Ltd.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Myorisan soft gelatin capsule</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 3000 capsules each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 01-3-2023.</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table><tr><th>Observations</th><th>Reply</th></tr><tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Valid DML of drug substance manufacturer submitted</td></tr><tr><td>Evidence of previously registered me-too produict for applied formulation shall be submitted along with registration number or else submit differential fee for new product as per SRO1324 (I)/2024 dated 30-08-2024</td><td>Firm has referred to Maxinoin capsule of Maxitech with Reg. #108920</td></tr><tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Firm has submitted copy of invoice, packing list and DHL receipt</td></tr></table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
16	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(7WS-QXM-GVJ3, 2024-12-13)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**Montestar 5mg Tablet**
	Label Claim	Each chewable Tablet Contains:Montelukast as sodium 5mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	usfda approved
	For generic drugs (me-too Status)	MONTEKAST 5MG TABLET BY FEROZSONS LABORATORIES PRIVATE LIMITED
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.3-1/2021-Lic issued by Secretary CLB dated 2-12-2024 approved in 307 meeting of CLB held on 20-11-2024, based upon inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.3-1/2021-Lic issued by Secretary CLB dated 2-12-2024 approved in 307 meeting of CLB held on 20-11-2024, based upon inspection conducted on 12-08-2024.
	Name & address of API manufacturer	MOREPEN LABORATORIES LIMITED
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Montiget 5mg tablet of Getz pharma
	Detail of stability batches of drug product	2 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Medicraft Pharmaceuticals, Risalpur, Pakistan
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Documents of procurement of drug substance shall be submitted Reply: Firm has submitted commercial invoice attested by DRAP I&E Office Peshawar, in name of M/s Medicraft
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter.

Sr. No	Title	Description
17	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(7Z7-57S-X7RN, 2024-10-25)
	Detail of Fee Submitted	37000.0, 2024-09-30,
	The proposed proprietary name / brand name	**Exlanso 60 mg Capsule**
	Label Claim	Exlanso 60mg Capsule Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent to Dexlansoprazole 60mg (Innovator's Specification).
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 60 mg CAPSULES by USFDA Approved
	For generic drugs (me-too Status)	Razodex 60mg Capsule by Getz Pharma Pakistan (Pvt.) Ltd 29-30/27,Korangi Industrial Area,Karachi
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Delanso DR capsule of M/s Sami
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Case has been processed against New DML priority
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
18	Name, address of Manufacturing site.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT**(000941)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(87N-TM8-Z6L6, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-09-30,
	The proposed proprietary name / brand name	**Sewpram 10mg Tablet**
	Label Claim	Each film coated tablet contains:Escitalopram oxalate equivalent toEscitalopram ..... 10mg(Product Specs: USP Specs.)
	Pharmacotherapeutic Group of (API)	PErformed against Citanew tablet 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	www.accessdata.fda.gov
	For generic drugs (me-too Status)	Citanew 10mg tablet Manufacturer :Hilton Pharma Karachi
	Proposed Pack Size	as per SRO's-Controlled
	GMP status of the firm	Firm has been granted additional section of “STablet capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “STablet capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	Smilax Laboratories Limited Address: Plot No: 12/A, Phase – III, IDA Jeedimetla, Hyderabad – 500 055, Telangana state, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against
	Detail of stability batches of drug product	3 batched of 1000 nits each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Documents of procurement of drug substance shall be submitted Reply: Firm has submitted copy of airway bill, packing list and invoice, while clearance certificate issued by DRAP I&E office not attested by DRAP I&E office Islamabad dated 12-05-2022 in the application of Escitalopram 20mg strength vide tracking ID no. ZHG-5XY-B2ET
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
19	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(8J8-ZDP-ZT6G, 2024-12-26)
	Detail of Fee Submitted	75000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Ninteda 100mg soft gelatin capsule**
	Label Claim	Each capsule contains:100mg nintedanib equivalent to 120.40mg nintedanib ethanesulfonate
	Pharmacotherapeutic Group of (API)	Anticancer (L01EX09)
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Therapeutic Goods Administration (TGA)
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	30's-As per SRO,60's-As per SRO
	GMP status of the firm	GMP inspection dated 20-11-2024 concludes satisfactory GMP compliance
	Evidence of approval of manufacturing facility	Soft gelatin capsule (Cytotoxic) new section granted dated 10-05-2024
	Name & address of API manufacturer	Glenmark Life Sciences Limited Address GLENMARK LIFE SCIENCES LTD.PLOT NO Z-103/l,DAHEJ SEZ ,PHASE-II, CITY.- DAHEJ, ,DIST.- BHARUCH GUJARAT STATE, INDIAA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Ofev 100mg soft gelatin capsule of M. Bohreinger
	Detail of stability batches of drug product	3 batches of 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	License to import issued by DRAP I&E office, Karachi dated 15-12-2023
	Evaluation	The case has been processed against the New section priority. Nintedanib is a kinase inhibitor indicated in adults for: • Treatment of idiopathic pulmonary fibrosis (IPF) (1.1) • Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (1.2) • Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) (1.3) Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer Reply: Valid GMP submitted issued by F&DCA Gujarat
	Shortcoming	
	Decision	Approved

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td rowspan="19">20</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(91N-VV4-8U6W, 2024-09-10)</td></tr>
<tr><td>Detail of Fee Submitted</td><td>75000.0,
2024-07-23,</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Dercutane 5mg Soft Gelatin Capsules</td></tr>
<tr><td>Label Claim</td><td>Each soft gelatin capsule contains: Isotretinoin ..... 5mg</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Retinoids ATC code: D10BA01</td></tr>
<tr><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Approved by MHRA of UK</td></tr>
<tr><td>For generic drugs (me-too Status)</td><td>None</td></tr>
<tr><td>Proposed Pack Size</td><td>15's-As per SRO,30's-As per SRO,60's-As per SRO,90's-As per SRO</td></tr>
<tr><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td>Name & address of API manufacturer</td><td>Chongqing Huapont Pharmaceutical Co., Ltd. No. 69 Xingguang Avenue Renhe Town, Yubei District, Chongqing, P.R. China</td></tr>
<tr><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Chongqing Huapont Pharmaceutical Co., Ltd.</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Isotretinoin Ascent 5mg soft gelatin capsule of M/s Douglas Pharma</td></tr>
<tr><td>Detail of stability batches of drug product</td><td>3 batches of 3000 capsules each</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 01-3-2023.</td></tr>
<tr><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Valid DML of drug substance manufacturer submitted</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Firm has submitted copy of invoice, packing list and DHL receipt</td></tr>
</table></td></tr>
<tr><td>Shortcoming</td><td></td></tr>
<tr><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
21	Name, address of Manufacturing site.	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan**(000980)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(976-8DL-XDU9, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	**G-OMOZOL**
	Label Claim	Each Capsule contain: Enteric Coated Pellets of Omeprazole eq. to 20 mg Omeprazole
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Approved b US FDA
	For generic drugs (me-too Status)	Risek 20mg Capsule
	Proposed Pack Size	21's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	Vision pharmaceutical ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Risek capsule 20mg
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice from M/s Vision Pharma
	Evaluation	The case has been processed as against new DML priority: Obsevations: Submit following: Drug substance COA, specifications and analytical method verification from M/s Gelcap. Justification shall be submitted for the Chromatographic conditions applied for Assay test with reference to those recommended b USP monograph. Reply: We didn't found any peak after 10 minutes in verification of Assay testing method of Omeprazole 20mg . Due to this we finalized 8.00 minutes for our chromatograms stop time. As well as verification of Assay testing method of omeprazole 20mg already submitted with chromatograms in Module -III.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
22	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ANX-T7R-UJ1L, 2024-10-25)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Calcidiol 0.266mg soft gelatin Ca**
	Label Claim	Each soft gelatin capsule contains: Calcifediol monohydrate.....0.266mg
	Pharmacotherapeutic Group of (API)	Vitamin D and analogues, ATC code: A11CC06
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	10's-As per SRO,5's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	CARBOGEN AMCIS B.V. Address Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from CARBOGEN AMCIS B.V , Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product Hidroferol soft gelatin capsule
	Detail of stability batches of drug product	3 batches of 700 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 02-09-2022.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Evidence of approval of “Soft gelatin capsule (General)” as new/additional section from CLB, shall be submitted. Reply: Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021 Performance of Dissolution test, as recommended by USP monograph, shall be submitted in Pharmaceutical equivalence studies. Reply: Firm has submitted Pharmaceutical equivalence studies including dissolution test performance as per USP monograph
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
23	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(DGS-9JA-N2A4, 2024-11-21)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	**QMONT TABLET 10MG**
	Label Claim	Each Film coated IR Tablet contains:Montelukast as Sodium..... 10 mg.
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Singulair ® 10 mg (Merck Research Laboratories) USFDA
	For generic drugs (me-too Status)	Lukast 10 mg Tablet by AGP
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Lukast tablet of M/s AGP
	Detail of stability batches of drug product	2 batches of 5000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E Office dated 26-09-2022 in name of M/s Bio Mark has been submitted
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer
	Shortcoming	
	Decision	Approved Firm shall submit valid DML/GMP certificate of drug substance manufacturer before issuance of registration letter.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>24</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(DA2-9JA-LVMP, 2024-12-09)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>75000.0,
2024-09-24,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Invital-D 10000IU Soft Gelatin Capsule</td></tr>
<tr><td></td><td>Label Claim</td><td>Each soft gelatin capsule contains:10,000 IU of Cholecalciferol which is equivalent to 0.25mg of Cholecalciferol</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Vitamin-D Analog</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>AIFA - Italian Medicines Agency</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Nil</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>M/s Fermenta Biotech Ltd. & Address: Plot NOs. Z109 B&C, Dahej SEZ II, Village-Dahej, Taluka-Vagara, Dist- Bharuch 392130, Gujarat, India</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from FERMENTA BIOTECH LIMITED India.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Nodigap capsule</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 10000 capsules each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 14-10-2022</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Disintegration test has not been performed in Pharmaceutical equivalence studies.</td><td>Pharmaceutical equivalence studies with performance of disintegration test submitted</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Copy of invoice along with DHL receipt submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>25</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(DL9-567-74TX, 2024-12-09)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>75000.0,
2024-09-24,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Invital-D 3200IU Soft Gelatin Capsule</td></tr>
<tr><td></td><td>Label Claim</td><td>Each soft gelatin capsule contains: 3200IU of Cholecalciferol which is equivalent 0.08mg of Cholecalciferol</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Vitamin-D Analog</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Approved by MHRA of UK of Internis Pharmaceuticals Ltd</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>None</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>M/s Fermenta Biotech Ltd. & Address: Plot NOs. Z109 B&C, Dahej SEZ II, Village-Dahej, Taluka-Vagara, Dist- Bharuch 392130, Gujarat, India</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from FERMENTA BIOTECH LIMITED India.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product STRIVIT-D3 3200 IU Capsules of M/s Strides Pharma UK Ltd</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 10000 capsules each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 14-10-2022</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Disintegration test has not been performed in Pharmaceutical equivalence studies.</td><td>Pharmaceutical equivalence studies with performance of disintegration test submitted</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Copy of invoice along with DHL receipt submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
26	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(DZV-YLB-3AN6, 2024-10-08)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Ceframit 250mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml contains:Cephradine.....250mg
	Pharmacotherapeutic Group of (API)	First generation cephalosporin, ATC code: J01DB09
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml M/S Strides Pharma UK Ltd Unit 4 Metro Centre Tolpits Lane Watford Hertfordshire WD18 9SS Trading as: Co-pharma MHRA Approved
	For generic drugs (me-too Status)	Velosef 250mg/5ml for Oral suspension of M/s GSK
	Proposed Pack Size	1x1's,As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted new section of "Dry powder suspension (Cephalosporinl)" vide letter no. F.1-10/2012-Lic issued by Secretary CLB dated 07-06-2022.
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence submitted
	Detail of stability batches of drug product	3 batches of 250 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Dr. Raza Pharma along with invoice and delivery challan.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations BMRs of drug product stability batches shall be submitted. Reply: Firm has submitted BMRs Details of the reference product against which Pharmaceutical equivalence has been performed, shall be submitted Reply Brand Name: Velosef 250mg/5ml for Oral suspension Manufacturer Name/Registration holder: M/S GSK(Glaxosmithkline Pakistan Limited)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
27	Name, address of Manufacturing site.	**Sayyed Pharmaceutical (pvt) Ltd** plot 67/2 , phase 3, industrial Estat Hattar**(000697)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ESE-VBG-JXWE, 2024-10-03)
	Detail of Fee Submitted	30000.0, 2024-08-30,
	The proposed proprietary name / brand name	**AQUA-SYD 5ml**
	Label Claim	Each ampoule contains: Sterile Water for Injection....5ml
	Pharmacotherapeutic Group of (API)	Solvent
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Approved by MHRA
	For generic drugs (me-too Status)	Water for injection (Healthtek Pharma)
	Proposed Pack Size	1 x100 Ampoule-As per SRO
	GMP status of the firm	Firm has been granted additional section of “Liquid Injectable ampoule (General)” vide letter no. F.3-6/2006-Lic (Vol-I) issued by Secretary CLB dated 24-04-2024
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injectable ampoule (General)” vide letter no. F.3-6/2006-Lic (Vol-I) issued by Secretary CLB dated 24-04-2024
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against WFI of M/s Healthtek
	Detail of stability batches of drug product	2 batches of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	N/A
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Submit drug product stability data of 6th month time point Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
28	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(G71-JSQ-S16M, 2024-12-11)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Trony Oral Solution**
	Label Claim	Each ml contains : Risperidone 1mg
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Approved in HPRA of Ireland- https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=RISPERDAL+1+mg%2fml+oral+solution&field=TRADENAMES
	For generic drugs (me-too Status)	Brand Name:Espidone oral solution of M/s Nabiqasim
	Proposed Pack Size	30ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Risperdal oral solution
	Detail of stability batches of drug product	3 batches of 200 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted license to import issued by DRAP I&E office dated 12-10-2020.
	Evaluation	instant application has been evaluated and found deficient for following observations: • Valid DML/GMP certificate of drug substance manufacturer shall be submitted. Firm has submitted valid GMP certificate issued by DCA Andhra Pradesh • Drug substance analytical method verification studies form drug product manufacturer shall be submitted. Firm has submitted drug substance analytical method verification studies performed by M/s A’raf pharma • Drug product specifications and analytical procedure shall be submitted. Firm has submitted Drug product specifications and analytical procedure as per USP monograph • Drug product stability data of 6th month time point shall be submitted. Drug product stability data at both accelerated and long term conditions submitted for 6th month time point.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
29	Name, address of Manufacturing site.	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan**(000980)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(G8B-PTL-SZXN, 2024-10-08)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	**G-Esomol 20mg Capsule**
	Label Claim	Esomeprazole 22.5% (As Mg.3H2O Enteric Coated Pellets) equivalent to Esomeprazole 20mg
	Pharmacotherapeutic Group of (API)	Proton Pump inhibitor
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ASTRAZENECA
	For generic drugs (me-too Status)	NEXIUM 20MG CAPSULE
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	Saakh Pharma (Pvt) Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Nexum capsule
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice form M/s Saakh Pharma
	Evaluation	The case has been processed against the New DML priority. Observations: Submit drug substance (Esomeprazole Enteric coated pellets) stability data form M/s Saakh Pharma till claimed shelf life. Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
30	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(GWY-JJG-ZVRH, 2024-09-10)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	**Zetrozen 500 mg Tablet**
	Label Claim	Each film coated Tablet Contains:Azithromycin as dihydrate eq.to Azithromycin.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered by US – FDA
	For generic drugs (me-too Status)	Azitma 500mg Tablets by Sami Pharmaceuticals (Reg.No.....074900)
	Proposed Pack Size	1x6's Tablets -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD. (abbreviated as ZJGB) . Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P. R. China. Manufacturing S
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Azitma tablet of M/s Sami
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Documents of procurement of drug substance shall be submitted Firm's reply: Firm has submitted loan letter from M/s Stanley Pharma along with clearance certificate issued in name of M/s Stanley Pharma • Differential fee as per SRO 1324 (I)/2024 dated 30-08-2024, since application has qualified screening after 30-08-2024. Not submitted
	Shortcoming	
	Decision	Approved Registration letter will be issued upon submission of following: Differential fee as per SRO 1324 (I)/2024 dated 30-08-2024, since application has qualified screening after 30-08-2024 Verification of loan letter

Sr. No	Title	Description
31	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(H9X-6VQ-MQP5, 2024-12-26)
	Detail of Fee Submitted	75000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Ninteda 150mg soft gelatin capsule**
	Label Claim	Each capsule contains: 150mg nintedanib equivalent to 180.60mg nintedanib ethanesulfonate.
	Pharmacotherapeutic Group of (API)	Protein Kinase Inhibitor (L01EX)
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Food and Drug Administration (FDA) USA
	For generic drugs (me-too Status)	None
	Proposed Pack Size	30's-As per SRO,60's-As per SRO
	GMP status of the firm	Firm has been granted additional section of “Soft Gelatin Capsule Cytotoxic” section in 296th meeting of CLB issued by Secretary CLB dated 10-05-2024
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft Gelatin Capsule Cytotoxic” section in 296th meeting of CLB issued by Secretary CLB dated 10-05-2024
	Name & address of API manufacturer	GLENMARK LIFE SCIENCES LTD.PLOT NO Z-103/l,DAHEJ SEZ ,PHASE-II, CITY.- DAHEJ, ,DIST.- BHARUCH GUJARAT STATE, INDIAA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against reference product of Ofev SG Cap 150mg of M/s Boehringer Ingelheim
	Detail of stability batches of drug product	3 batches of 1000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted license to import issued by DRAP I&E Office, Karachi dated 15-12-2023
	Evaluation	The case has been processed against the New section priority. Nintedanib is a kinase inhibitor indicated in adults for: • Treatment of idiopathic pulmonary fibrosis (IPF) (1.1) • Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (1.2) • Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) (1.3) Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
32	Name, address of Manufacturing site.	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan**(000980)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(HMR-SAX-JNPA, 2024-10-16)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	**G-LANSO 30MG CAPSULE**
	Label Claim	Lansoprazole (As enteric coated pellets) 30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too Status)	Agopton capsule 30mg of M/s Helix
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	Saakh Pharma (Pvt) Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Qpro capsule of M/s Bosch
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice from M/s Saakh Pharma
	Evaluation	The case has been processed against the new DML priority.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
33	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(L1Z-BS1-MHUA, 2024-11-01)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Calcidiol 30mcg extended release soft gelatin capsule**
	Label Claim	Each extended release soft gelatin capsule contains: Calcifediol monohydrate.....30mcg
	Pharmacotherapeutic Group of (API)	Vitamin D and analogues, ATC code: A11CC06
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Rayaldee approved by Food and Drug Administration - USFDA
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	15's-As per SRO,30's-As per SRO,60's-As per SRO,90's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	4. Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	CARBOGEN AMCIS B.V. & Address: Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from CARBOGEN AMCIS B.V , Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product RayAldee 30mcg soft gelatin capsule
	Detail of stability batches of drug product	3 batches of 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 02-09-2022.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Evidence of approval of “Soft gelatin capsule (General)” as new/additional section from CLB, shall be submitted. Response: Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021 Clarification shall be submitted regarding the formulation ingredient responsible for the extended release profile of the applied dosage form. Response: Calcifediol is highly lipophilic and exhibits poor water solubility. In this formulation, we have incorporated paraffin wax and Hypromellose K100M as controlled-release agents. Paraffin wax forms a matrix that releasably binds with the drug, effectively preventing the immediate release of calcifediol. Meanwhile, Hypromellose K100M generates hydrophilic matrices, facilitating the extended release of the drug through gel layer formation. This combination ensures a controlled and sustained drug release profile.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
34	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(LR6-1D4-XLPN, 2024-12-19)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Zitrigine Oral Suspension**
	Label Claim	Each ml contains: Lamotrigine ... 5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors (SSRIs)
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	HPRA Approved ; https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results/item?pano=PA22697/018/001&t=Lamotrigine%20SyriMed%205mg/ml%20O ral%20Suspension
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	60ml-Controlled
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence submitted against Lamotrigine oral suspension
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 08-11-2023.
	Evaluation	Your instant application has been evaluated and found deficient for following observations: Observations Justification shall be submitted for referring to USP monograph for drug product specifications since the available USP monograph is for Compounded Oral suspension Reply: We will claim innovator specification while testing method has been adopted as per USP monograph of compounded oral suspension of Lamotrigine, all testing parameter already submitted in the mentioned However, fee for change of specifications from USP to lnnovator specification has been paid. · Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. Reply: Drug substance specifications, analytical procedure and analytical method verification studies has been submitted from drug product manufacturer · Readable copies of drug substance stability studies shall be submitted. Submitted for both accelerated and long term · Name of the manufacturer of the reference product used for Pharmaceutical equivalence shall be submitted Reply : Details have been submitted for Syri Pharma UK. Drug product stability data of 6th month time point shall be submitted. Reply: Submitted for both accelerated and long term
	Shortcoming	
	Decision	Approved with innovator's specifications

Sr. No	Title	Description
35	Name, address of Manufacturing site.	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore**(000577)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(MP2-WRT-YV8W, 2024-10-08)
	Detail of Fee Submitted	30000.0, 2024-09-02,
	The proposed proprietary name / brand name	**M.cip dry oral suspension 250mg/5ml**
	Label Claim	Each 5ml reconstituted Suspension contains Ciprofloxacin 250mg
	Pharmacotherapeutic Group of (API)	Flouroquinolone antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too Status)	Novidat suspension of SAMI Pharmaceuticals
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP certificate issued dated 15-12-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Dry Powder suspension (General)” vide letter no. F.1-29/2001-Lic (Vol-III) issued by Secretary CLB dated 14-02-2024
	Name & address of API manufacturer	Citi.pharma (Pvt) Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Novidat Suspension
	Detail of stability batches of drug product	3 batches of 150 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	--
	Evaluation	Instant application has been evaluated and found deficient for following observations: Observations Clarification shall be submitted regarding salt form of drug substance, whether its Ciprofloxacin or Ciprofloxacin HCl. Dissolution tests has not been performed during Pharmaceutical equivalence studies. Comparative Dissolution Profile of applied drug product against the reference/comparator product shall be submitted Dissolution test has not been included in the drug product specifications. Documents confirming procurement of the drug substance, , shall be submitted
	Shortcoming	
	Decision	Deferred For further deliberation regarding the salt form of drug substance and requirements of diluent for applied formulation

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>36</td><td>Name, address of Manufacturing site.</td><td>Invictus Pharmaceuticals Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad(000892)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(MPW-EG2-BXV5, 2024-11-11)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>37000.0,
2024-10-01,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>C-Bact dry powder for injection</td></tr>
<tr><td></td><td>Label Claim</td><td>Each Vial Contains: Cefoperazone Sodium eq to Cefoperazone...500 mgSulbactam Sodium eq to Sulbactam.....500 mg (JP Specifications)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Any Other</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Sulperazon for IV Injection manufactured by Pfizer Japan</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>2SUM 1 g Injection</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>1 Vial-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 17-08-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Dry Powder Injection (Cephalosporin)” vide letter no. F.1-37/2016-Lic (Vol-I) issued by Secretary CLB dated 18-02-2020.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co ., Ltd. Address: West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi City,Shandong Province, P._R.China. Tel:+865398241531 Email:export@luoxin.cn</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co ., Ltd.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against 2Sum injection of M/s Sami</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batches of 5454 packs each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 5 (License to import Drugs) issued by AD DRAP I&E Office, Islamabad dated 22-10-2021</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table><tr><th>Observations</th><th>Firm's response</th></tr><tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Firm has submitted copy of valid DML of drug substance manufacturer</td></tr><tr><td>Justification shall be submitted for the declaration of water content in drug product analysis as below 1%, while batch release certificate of the drug substance used for manufacturing of drug product batches has declared water content as greater than 2%.</td><td>Firm while referring to the decision of 329th meeting of Registration Board has requested to consider the instant product with Innovator's specifications. Water content of finish product was checked and it was less than 1% at that time. We have checked it again and results complies with API water content results.</td></tr><tr><td>Reconciliation of the imported quantity of drug substance shall be submitted against the batch sizes of drug product stability batches manufactured.</td><td>This is a typographical mistake and batch sizes were written wrong. We are thankful that you have checked the files so thoroughly and pointed out the mistake for correction. Correct batch sizes are 454 vials for 1gm and 227 vials for 2g dossier. it will not happen again and we will be careful in future.</td></tr></table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
With Innovator specifications. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for change of specifications as per SRO1324 (I)/2024 dated 30-08-2024</td></tr>
</table>

Sr. No	Title	Description
37	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(NWL-2ZM-D3XQ, 2024-10-29)
	Detail of Fee Submitted	75000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Urotone 25mg Tablet**
	Label Claim	Each Tablet contains:Bethanechol Chloride.....25mg
	Pharmacotherapeutic Group of (API)	Coline esters N07AB
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Bethanechol Chloride Tablet, USP 25mg of M/s Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 (USFDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Nanyang Libang Pharmaceutical Co., Ltd Add: Kuiying, Waidan, Wancheng District, Nanyang City, Henan, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against Bethanecol tablet
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted MOU and loan letter M/s Medisure Laboratories along with clearance certificate issued by AD DRAP I&E Karachi dated 24-08-2023 in name of M/s Medisure
	Evaluation	Firm ide its letter no. nil dated 17-12-024 has requested to consider its instant application priority quota of their additional section of Tablet general granted vide vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024 Bethanechol Chloride Tablets, USP are indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention • BMR of drug product stability batches. Reply: Submitted • GMP/DML of drug substance manufacturer Submitted Evidence of availability of HPLC equipped with Electro conductivity detector. Firm has submitted for commercial invoice for HPLC equipped with The Electro chemical detector • Name of the manufacturer of reference product used for CDP studies. Bethanechol Chloride Tablet, USP 25mg of Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
38	Name, address of Manufacturing site.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.**(000644)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(P4J-93L-AUTZ, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Prostone 100mg Tablet**
	Label Claim	Each Uncoated Tablet contains:Progesterone (USP).....100MG(Product Complies Innovator's Specs)
	Pharmacotherapeutic Group of (API)	Progestins
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted additional section of "Tablet section Steroid (Hormone)" section vide letter no. F.3-6/2007-Lic (Vol-I) issued by Secretary CLB dated 27-0-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of "Tablet section Steroid (Hormone)" section vide letter no. F.3-6/2007-Lic (Vol-I) issued by Secretary CLB dated 27-0-2019.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IVb conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against refernce product of Lutigest tablet
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted license to import issued by DRAP I&E Office, Peshawar dated 20-12-2022 along with Form 3, Form 7 and invoice
	Evaluation	Following shall be submitted: • Valid DML/GMP certificate of drug substance manufacturer Copy of DML valid till 22nd October, 2025 is submitted • Justification for not including dissolution test I drug product specifications. Reply: As this is a vaginal tablet, Dissolution Tests cannot be performed and are therefore not applicable.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
39	Name, address of Manufacturing site.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad**(000778)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(PPT-GBA-P6QG, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-11-29,
	The proposed proprietary name / brand name	**Ferium**
	Label Claim	Each ml contains: Ferric Carboxymaltose complex equivalent to Iron....50mg
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Ferinject ® Dispersion for Injection/Infusion is approved in USFDA
	For generic drugs (me-too Status)	Fercari Dispersion for Injection/Infusion 50 mg Iron/ml by Hilton Pharma
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	Firm has been granted additional section of “Liquid Injection ampoule (General)” section vide letter no. F.1-54/2009-Lic (Vol-I) issued by Secretary CLB dated 22-03-2024.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection ampoule (General)” section vide letter no. F.1-54/2009-Lic (Vol-I) issued by Secretary CLB dated 22-03-2024.
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co. Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IVb conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against Ferinject injection
	Detail of stability batches of drug product	3 batches of 1000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Cunningham Pharma dated 2-09-2022
	Evaluation	Loan letter from M/s Cunningham Pharmaceuticals for the borrowed drug substance shall be submitted.
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter.

Sr. No	Title	Description
40	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(PTE-PBE-WNT9, 2024-12-11)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Zeetam Oral Solution**
	Label Claim	Each ml contains:Levetiracetam..... 100mg
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved - https://products.mhra.gov.uk/product/?product=KEPPRA%20100%20MG%2FML%20ORAL %20SOLUTION
	For generic drugs (me-too Status)	Registration Number 063168 Brand Name Lumark oral solutionn 100mg/5ml Dosage Form Oral solution Registration Date 4/6/2010 Market Authorisation Holder The Searle Company Limited
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Keppra oral solution
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 14-03-2024.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations · Drug substance analytical method verification studies form drug product manufacturer shall be submitted. Response: Firm ha submitted analytical method verification studies form drug product manufacturer Stability data summary sheets shall be submitted. Drug product stability data of 6th month time point shall be submitted. Submitted for both accelerated and long term
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
41	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(PU6-TGT-VP91, 2024-12-19)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Ziapine Oral Suspension**
	Label Claim	Each ml contains Quetiapine as Fumarate..... 20mg
	Pharmacotherapeutic Group of (API)	other antiepileptics, ATC code: N03AX09
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	https://products.mhra.gov.uk/product/?product=QUETIAPINE%20ROSEMONT%2020%20M G%2FML%20ORAL%20SUSPENSION - MHRA Approved
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	100ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Queitapine oral suspension
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 14-03-2024
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Firm has submitted valid GMP certificate issued by FDCA Gujarat in name of M/s Cohance Lifesciences (Former ZCL Chemicals) • Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. • Firm has submitted specifications, analytical procedure and analytical method verification studies from M/s A’raf. • Name of the manufacturer of the reference product used for Pharmaceutical equivalence shall be submitted • Firm has submitted details as of M/s Rosemont Pharmaceuticals Ltd. UK Drug product stability data of 6th month time point shall be submitted. Submitted for both accelerated and long term conditions
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
42	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(QG2-LMM-P7LT, 2024-11-04)
	Detail of Fee Submitted	37000.0, 2024-09-25,
	The proposed proprietary name / brand name	**Destrack 5 mg Tablet**
	Label Claim	Each Film coated tablet containing:Desloratadine.....5 mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021312s006lbl.pdf
	For generic drugs (me-too Status)	Sami Pharma (Neo-Antial 5mg tablet)
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	Morepen Laboratories
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Neo-antial tablet
	Detail of stability batches of drug product	2 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice attested by DRAP I&E office issued in name of M/s Bio Mark has been submitted
	Evaluation	Following shall be submitted: • Analytical method verification studies of drug substance from M/s Q. Track • Loan letter from M/s Bio Mark pharmaceuticals Reply: Firm has submitted loan letter from M/s Bio-Mark
	Shortcoming	
	Decision	Approved Following shall be submitted before issuance of registration letter: Verification of loan letter. Analytical method verification studies of drug substance from M/s Q. Track

Sr. No	Title	Description
43	Name, address of Manufacturing site.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road**(000455)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(R11-E3B-T2SZ, 2024-09-30)
	Detail of Fee Submitted	30000.0, 2023-09-22,
	The proposed proprietary name / brand name	**Azithrolite**
	Label Claim	Azithromycin USP 200mg/ 5ml after reconstitution
	Pharmacotherapeutic Group of (API)	Macrolide antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA-UK
	For generic drugs (me-too Status)	Sami Pharmaceuticals
	Proposed Pack Size	1 Bottle/ Pack -As per SRO
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Dry Powder suspension (General)” vide letter no. F.1-5/95-Lic (Vol-III) issued by Secretary CLB dated 08-11-2022.
	Name & address of API manufacturer	Unichem Pharmaceutical Pakistan (Pvt) Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Unichem Pharmaceuticals Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Azitma suspension of M/s Sami
	Detail of stability batches of drug product	3 batches of 60 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	Your instant application has been evaluated and found deficient for following observations: Observations Dissolution test has not been performed in Pharmaceutical equivalence studies. Comparative dissolution profile has not been submitted Justification shall be submitted for not including dissolution test in drug product specifications, as recommended by USP monograph of Azithromycin oral suspension. As evident from submitted chromatograms, Assay test has been performed at wavelength of 230nm while the USP monograph of Azithromycin oral suspension has recommended wavelength of 210m. Justification shall be submitted in this regard. • Batch manufacturing record of stability batches shall be submitted • Documents confirming procurement of drug substance shall be submitted You are therefore advised to submit response to above cited observations at earliest for further processing of the case.
	Shortcoming	
	Decision	Deferred for submission of reply to above cited shortcomings

Sr. No	Title	Description
44	Name, address of Manufacturing site.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan**(000578)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(RAW-3AL-Y7XZ, 2024-12-27)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	**DEXOJIN 60MG**
	Label Claim	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w Equivalent to Dexlansoprazole.....60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 60 mg CAPSULES by USFDA Approved
	For generic drugs (me-too Status)	Razodex 60mg Capsule (GETZ PHARMA PAKISTAN)
	Proposed Pack Size	30`S-De-Controlled
	GMP status of the firm	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021
	Evidence of approval of manufacturing facility	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021
	Name & address of API manufacturer	VISION PHARMACEUTICALS PVT LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against Razodex capsule of M/s Getz
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	BMR of drug product stability batches shall be submitted Reply: Submitted
	Shortcoming	
	Decision	Deferred Registration Board referred to its following decision of 286th meeting: "Registration Board after thorough deliberation and considering the decision of 14th meeting of Policy Board decided to grant 10 products per section for all the firms for which section approval was granted by Central Licensing Board before 14th meeting of Policy Board of DRAP held on10th & 11th of Sep, 2015. However, only those firms shall be considered for grant of registration of ten products per section, whose registered products as of today are less than ten products per section." While referring to the above cited decision it was noted that as per available record M/s Jinnah Pharmaceuticals has already availed registration of more than 10 products in the "Capsule general" section, hence the Board deferred the instant application for consideration on its turn.

Sr. No	Title	Description
45	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(RDM-HTD-S77S, 2024-10-24)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Lubiprostin 24mcg Soft Gelatin Capsule**
	Label Claim	Each soft gelatin capsule contains: Lubiprostone 24mcg
	Pharmacotherapeutic Group of (API)	A06AX : Other drugs for constipation
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Food and Drug Administration - USFDA
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	10's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	Shandong Kehui Phar- maceutical Co., Ltd..Address:No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shan- dong Province., China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Shandong Kehui Pharmaceutical Co., Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against reference product Amitiza capsule
	Detail of stability batches of drug product	3 batches of 5000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 28-12-2022
	Evaluation	It is a chloride channel activator indicated for the treatment of: • chronic idiopathic constipation (CIC) in adults. (1.1) • opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation Instant application has been evaluated and found deficient for following observations: Observations Dissolution test has not been performed in Pharmaceutical equivalence studies. Reply: Firm has submitted Pharmaceutical equivalence studies including performance of dissolution test Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted Reply: firm has submitted copy of invoice along with Airway bill
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
46	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(RJX-7QZ-29AZ, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Ceframit 125mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml contains:Cephradine.....125mg
	Pharmacotherapeutic Group of (API)	First generation cephalosporin, ATC code: J01DB09
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Nicef Syrup 125mg/5ml M/S Strides Pharma UK Ltd Unit 4 Metro Centre Tolpits Lane Watford Hertfordshire WD18 9SS Trading as: Co-pharma MHRA Approved
	For generic drugs (me-too Status)	Velosef 125mg/5ml for Oral suspension of M/s GSK
	Proposed Pack Size	1x1's,As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted new section of "Dry powder suspension (Cephalosporinl)" vide letter no. F.1-10/2012-Lic issued by Secretary CLB dated 07-06-2022.
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence submitted
	Detail of stability batches of drug product	3 batches of 250 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Dr. Raza Pharma along with invoice and delivery challan.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations BMRs of drug product stability batches shall be submitted. Submitted Details of the reference product against which Pharmaceutical equivalence has been performed, shall be submitted Brand Name: Velosef 125mg/5ml for Oral suspension Manufacturer Name/Registration holder: M/S GSK(Glaxosmithkline Pakistan Limited)
	Shortcoming	
	Decision	Deferred for evidence of approval of applied formulation in any of the reference regulatory athorities adopted by Registration Board in its 275th meeting

Sr. No	Title	Description
47	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(RW5-M7Z-LUT5, 2024-12-20)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Lubiprostin 12mcg Soft Gelatin Capsule**
	Label Claim	Each soft gelatin capsule contains: Lubiprostone 12mcg
	Pharmacotherapeutic Group of (API)	A06AX : Other drugs for constipation
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
	For generic drugs (me-too Status)	Nil
	Proposed Pack Size	10's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	Shandong Kehui Phar- maceutical Co., Ltd.. Address :No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shan- dong Province., China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Shandong Kehui Pharmaceutical Co., Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against reference product Amitiza capsule
	Detail of stability batches of drug product	3 batches of 5000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 28-12-2022
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Dissolution test has not been performed in Pharmaceutical equivalence studies. Reply: Firm has submitted Pharmaceutical equivalence studies including performance of dissolution test Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted Reply: firm has submitted copy of invoice along with Airway bill
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
48	Name, address of Manufacturing site.	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan.**(000982)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(S89-THM-G5NW, 2024-09-25)
	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	**QMERENE-MR**
	Label Claim	Each Modified release Capsule contains Mebeverine hydrochloride as extended release pellets equivalent to mebeverine hydrochloride BP.....200mg
	Pharmacotherapeutic Group of (API)	Synthetic anticholinergics
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too Status)	MEBEVER- MR 200 of M/s Getz Pharma
	Proposed Pack Size	Alu Alu Blister 10's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.2-6/2019-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	VISION PHARMACEUTICAL
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Mebever-M Capsuel of M/s Getz
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Differential fee of Rs. 7,000- as per as per SRO1324 (I)/2024 dated 30-08-2024, since application qualified screening after 30-08-2024. • Analytical method verification studies of drug substance from M/s Q. Track shall be submitted. • Batch manufacturing record of drug product stability batches shall be submitted
	Shortcoming	
	Decision	Deferred for submission of reply to above cited shortcomings

Sr. No	Title	Description
49	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(SHG-ENA-NPZE, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**MIZRAF**
	Label Claim	Each ml contains Rivastigmine as Tartrate.....2mg
	Pharmacotherapeutic Group of (API)	psychoanaleptics, anticholinesterases, ATC code: N06DA03
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	RIVASTIGMINE by M/S ROSEMONT MHRA Approved
	For generic drugs (me-too Status)	Rivastigmine Sandoz by M/S Sandoz Pharma Sandoz
	Proposed Pack Size	120 ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Rivastigmine oral solution of M/s Rosemont
	Detail of stability batches of drug product	3 batches of 50 bottles each (120ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 19-09-2023
	Evaluation	instant application has been evaluated and found deficient for following observations: **Observations** • Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. • Firm has submitted Drug substance specifications, analytical procedure and analytical method verification studies from Ms A’raf • Drug substance stability studies shall be submitted from drug substance manufacturer i.e., M/s Shodhana Laboratories Private Limited Drug substance stability studies at accelerated and controlled room temperature has been submitted from drug substance manufacturer i.e., M/s Shodhana Laboratories Private Limited
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
50	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(SPN-YYR-5YVP, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-29,
	The proposed proprietary name / brand name	**BIOPAT DS EYE DROP (Olopatadine HCl 0.2 % ophthalmic solution)**
	Label Claim	Each ml contains:Olopatadine HCl (USP) equivalent Olopatadine ..... 2 mg
	Pharmacotherapeutic Group of (API)	Antiallergic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ALCON LABORATORIES, INC FORWORTH USA is available/approved in US, FDA
	For generic drugs (me-too Status)	OLOTEK Ophthalmic Solution.....2 mg (Innvotek pharmaceuticals) Approved in DRAP
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Eye Drop (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	Precise Biopharma Pvt. Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against i.e., Olotek DS ophthalmic solution of Innvotek
	Detail of stability batches of drug product	3 batches of 1000 bottles each (5ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	License to import issued by DRAP I&E office, Lahore dated 20-12-2023
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations · Valid GMP certificate/DML of drug substance manufacturer shall be submitted. Valid GMP certificate issued by FDA Maharashtra submitted. · Justification for adopting the conventional storage conditions instead of those recommended for semi-permeable container closure system, for conducting drug product stability studies. Firm's reply: The conventional storage conditions as per Zone IV for stability of above mentioned finished goods , justification is as under: Water loss studies of primary container closure system are performed at the conventional storage conditions as per Zone IV No deterioration has been observed during stability studies.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
51	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(SUA-SNQ-EZ89, 2024-09-10)
	Detail of Fee Submitted	30000.0, 2024-05-13,
	The proposed proprietary name / brand name	**Zetrozen 250 mg Tablet**
	Label Claim	Each film coated Tablet Contains:Azithromycin as dihydrate eq.to Azithromycin.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered by US – FDA
	For generic drugs (me-too Status)	Azitma 250mg Tablets by Sami Pharmaceuticals (Reg.No.....074899)
	Proposed Pack Size	1x6's Tablets -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD. (abbreviated as ZJGB) . Address: No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, P. R. China. Manufacturing S
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Azitma tablet of M/s Sami
	Detail of stability batches of drug product	3 batches of 3000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Documents of procurement of drug substance shall be submitted Firm's reply: Firm has submitted loan letter from M/s Stanley Pharma along with clearance certificate issued in name of M/s Stanley Pharma
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter

Sr. No	Title	Description
52	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(T9S-N2Y-UN8Y, 2024-12-19)
	Detail of Fee Submitted	75000.0, 2024-12-02,
	The proposed proprietary name / brand name	**ZOPIRAF**
	Label Claim	Each ml contains Topiramate 10mg
	Pharmacotherapeutic Group of (API)	antiepileptics, other antiepileptics, ATC code: N03AX11
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Topiramate by M/S Rosemont Ltd. MHRA Approved
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Topiramate Rosemont oral suspension 10mg/ml
	Detail of stability batches of drug product	3 batches of 100 bottles each (60ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 16-02-2023
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations · Justification shall be submitted for referring to USP monograph for drug product specifications since the available USP monograph is for Compounded Oral suspension Firm's reply: We will claim Innovator's specifications while testing method has been adopted as per USP monograph of Topriamate compounded oral suspension. However fees for change of specifications from USP to innovator specifications has been paid. · Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. Firm's reply: Drug substance specifications, analytical procedure and analytical method verification studies submitted form M/s A'raf
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
53	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(TP6-ZTZ-2XVN, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Param Injection for Infusion 10 mg/ml; 100ml**
	Label Claim	Each 100 mL vial contains Paracetamol.....1000 mg.
	Pharmacotherapeutic Group of (API)	Analgesic & Anti-Pyretic.
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Acetaminophen ® 10 mg/ml is Approved in USFDA
	For generic drugs (me-too Status)	Provas Infusion 10 mg/ml; 100 ml Injection for Infusion by Sami is DRAP Approved.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection LVP (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	M/s Zenith chemical industries (Pvt) Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against i.e., Provas Infusion of M/s Sami Pharmaceuticals.
	Detail of stability batches of drug product	2 batches of 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Drug substance manufacturer is M/s Zenith Chemicals, Lahore. Procurement documennt not provided
	Evaluation	Your instant application has been evaluated and found deficient for following observations: Observations • Batch manufacturing record of stability batches shall be submitted • Documents confirming procurement of drug substance shall be submitted You are therefore advised to submit response to above cited observations at earliest for further processing of the case.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
54	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(TSG-SE9-3AML, 2024-10-25)
	Detail of Fee Submitted	37000.0, 2024-10-07,
	The proposed proprietary name / brand name	**Exlanso 30 mg Capsule**
	Label Claim	Exlanso 30 mg CapsuleEach Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w Equivalent to Dexlansoprazole.....30mg (Innovator's Specification)
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 30 mg CAPSULES by USFDA Approved
	For generic drugs (me-too Status)	Razodex 30mg Capsule by Getz Pharma Pakistan (Pvt.) Ltd.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Razodex capsule of M/s Getz
	Detail of stability batches of drug product	3 batches of 1200 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
55	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(TX5-XXD-P8HE, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Zexa**
	Label Claim	Each ml Contains Memantine HCl 2mg
	Pharmacotherapeutic Group of (API)	Other anti-dementia drugs; N06DX
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Memantine Hydrochloride by M/S Mecleods Pharms Ltd. US-FDA Approved
	For generic drugs (me-too Status)	Zexa by M/S English pharma Lahore
	Proposed Pack Size	120 ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F F.1-10/2000-Lic (Vol-I) issued by Secretary CLB
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Namedna oral solution 2mg/ml
	Detail of stability batches of drug product	3 batches of 50 bottles each (120ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 05-1-2024
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations · Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. Firm's reply: Submitted form M/s A'raf Pharma · Drug substance stability data shall be submitted asper Zone IV conditions. Submitted at both accelerated and long term conditions
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
56	Name, address of Manufacturing site.	**AGP Limited** B-23-C, S.I.T.E., Karachi**(000348)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(U42-MDV-264Z, 2024-11-28)
	Detail of Fee Submitted	75000.0, 2024-11-06,
	The proposed proprietary name / brand name	**Agelafil Suspension 10mg/ml**
	Label Claim	Each ml contain: Sildenafil citrate 14.050mg equivalent to 10mg Sildenafil
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors..
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	REVATIO BY VIATRIS SPECIALTY LLC approved by US FDA
	For generic drugs (me-too Status)	Silagro suspension of NabiQasim
	Proposed Pack Size	112ml-De-Controlled
	GMP status of the firm	GMP certificate issued dated 15-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Dry Powder suspension (General)” vide letter no. F.2-3/92-Lic (Vol-III) issued by Secretary CLB dated 08-11-2022
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV b conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product Revatio Suspension
	Detail of stability batches of drug product	3 batches of 75 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued by DRAP I&E Karachi dated 30-08-2023
	Evaluation	Instant application has been evaluated and found deficient for following observations: • Justification shall be submitted for referring to Innovator's specification in section 1.5.6 and 3.2.P.5.1, while the BP monograph is available for applied formulation. Reply: We have performed the analysis of sildenafil oral suspension by using the USP monograph (Draft) as we planned to claim our finished product as per USP specification, Because Dissolution method present in USP Specification (Draft) but it remains located in “unofficial draft” till date. The comments have closed on 30-March-2024. Now we have performed the analysis of our stability batches as per BP specification monograph “Sildenafil powder for oral suspension” which is comply on BP specification and all result are found satisfactory. Also perform method verification of sildenafil powder for oral suspension. (Enclosed in Annexure B). We updated finished product specification from innovator specification to BP specification and updated specification enclosed • Compatibility study with reconstitution diluent shall be submitted in section 3.2.P.2.6 Reply: Water used as a diluent in sildenafil powder for oral suspension which is also same as innovator. We also performed In-use stability studies which is compatible with diluent and results found satisfactory which is enclosed • In-use stability study of re-constitution suspension shall be submitted. Reply: Firm has submitted in-use stability of reconstituted suspension study for 60 days.
	Shortcoming	
	Decision	Approved with BP specifications. Firm shall submit fee for pre-registration variation, as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>57</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td></td><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(UD2-ZGG-DBPR, 2024-08-29)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-23,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Dercutane 10mg Soft Gelatin Capsule</td></tr>
<tr><td></td><td>Label Claim</td><td>Each soft gelatin capsule contains:Isotretinoin..... 10mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Retinoids; D10BA01</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Food and Drug Administration</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>ACNOTIN 10mg Soft Gelatin Capsule</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-As per SRO,20's-As per SRO,30's-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Chongqing Huapont Pharmaceutical Co., Ltd. No. 69 Xingguang Avenue Renhe Town, Yubei District, Chongqing, P.R. China (401121)</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from C Chongqing Huapont Pharmaceutical Co., Ltd.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Myorisan 10mg soft gelatin capsule</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>3 batched of 3000 units each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 01-3-2023.</td></tr>
<tr><td></td><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Valid DML of drug substance manufacturer submitted</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Firm has submitted copy of invoice, packing list and DHL receipt</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
58	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(VEB-VP7-EQAN, 2024-08-01)
	Detail of Fee Submitted	30000.0, 2024-07-29,
	The proposed proprietary name / brand name	**BIOPAT EYE DROP (Olopatadine HCl 0.1 % ophthalmic solution)**
	Label Claim	Each ml contains:Olopatadine HCl (USP) equivalent Olopatadine ..... 1 mg
	Pharmacotherapeutic Group of (API)	Antiallergic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ALCON LABORATORIES, INC FORWORTH USA is available/approved in US, FDA
	For generic drugs (me-too Status)	OLOTEK Ophthalmic Solution.....1 mg (Innvotek pharmaceuticals) Approved in DRAP
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Eye Drop (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	Precise Biopharma Pvt. Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against i.e., Olotek ophthalmic solution of Innvotek
	Detail of stability batches of drug product	3 batches of 1000 bottles each (5ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	License to import issued by DRAP I&E office, Lahore dated 20-12-2023
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations · Valid GMP certificate/DML of drug substance manufacturer shall be submitted. Valid GMP certificate issued by FDA Maharashtra submitted. · Justification for adopting the conventional storage conditions instead of those recommended for semi-permeable container closure system, for conducting drug product stability studies. Firm's reply: The conventional storage conditions as per Zone IV for stability of above mentioned finished goods , justification is as under: Water loss studies of primary container closure system are performed at the conventional storage conditions as per Zone IV No deterioration has been observed during stability studies.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
59	Name, address of Manufacturing site.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala**(000987)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(V94-QHA-UE1U, 2024-12-26)
	Detail of Fee Submitted	75000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Defsil Suspension**
	Label Claim	Each mL of reconstituted Suspension Contains:Sildenafil as Citrate (BP).....10 mg(Product complies BP Specs)
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Silagro of NabiQaasim
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-4/2021-Lic issued by Secretary CLB dated 14-12-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-4/2021-Lic issued by Secretary CLB dated 14-12-2023.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against Sildenafil suspension of Amneal Pharma
	Detail of stability batches of drug product	3 batches of 1200 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Observations 1. · Valid DML/GMP certificate of drug substance manufacturer Reply: Valid GMP Attached valid till 31-03-2026. 2. · COA of drug substance form drug product manufacturer Reply: COA of Drug substance by Drug Product manufacturer attached. 3. · Clarification regarding drug product specifications since section 3.2.P.5.1 claims BP specification while COA in section 3.2.P.5.4 declares USP specification Reply: The claimed specification is USP Specification. We have attached the rectified specification part (3.2.P.5.1) along with. 4. · Documents of procurement of drug substance shall be submitted Reply: Loan Documents from Wnsfeild Pharmaceuticals, and Goods Declaration certificate as proof of Import is attached along with.
	Shortcoming	
	Decision	Approved Registration letter will be issued upon verification of loan letter.

Sr. No	Title	Description
60	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(WMX-AH8-RABT, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Systrears Lubricant Eye Drop (0.4 % Polyethylene Glycol 400 and 0.3% Propylene Glycol Lubricant Eye Drop)**
	Label Claim	Each mL contains:Polyethylene glycol 400 ----------4mgPropylene glycol ----------3mg
	Pharmacotherapeutic Group of (API)	Lubricant eye drop.
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ALCON LABORATORIES, INC FORWORTH USA is available as OTC drug, on Dailymed of USA
	For generic drugs (me-too Status)	Systane Alcon Laboratories, Inc.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Eye Drop (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	Anhui Eapearl Chemical,Shandong Shida Shenghua Chemical
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Systane drops
	Detail of stability batches of drug product	3 batches of 1500 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not provided
	Evaluation	Your instant application has been evaluated and found deficient for following observations: Observations Valid DML/GMP certificate of drug substance manufacturers shall be submitted. Clarification shall be submitted for the method applied for the Assay test of propylene glycol. Analytical method verification studies of drug substances and drug product shall be submitted from the drug product manufacturer. • Batch manufacturing record of stability batches shall be submitted • Documents confirming procurement of drug substance shall be submitted You are therefore advised to submit response to above cited observations at earliest for further processing of the case.
	Shortcoming	
	Decision	Deferred for submission of reply to above cited shortcomings

Sr. No	Title	Description
61	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(XG1-DEV-QUPB, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-15,
	The proposed proprietary name / brand name	**Linus Infusion 2 mg/ml; 200 ml**
	Label Claim	Each 200ml ContainsLinezolid 400mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Approved by TGA of Australia.
	For generic drugs (me-too Status)	Hilid Solution for Infusion 2 mg/ml; 200 ml Solution for Infusion by Hilton Pharma is DRAP Approved.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection LVP (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	M/s Optimus Drugs Private Limited.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against i.e., Hilid infusion of Hilton Pharma
	Detail of stability batches of drug product	2 batches of 2000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 12-12-2020
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations • Batch manufacturing record of stability batches shall be submitted • Reply: Firm has submitted BMRs of two stability batches.
	Shortcoming	
	Decision	Approved

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td rowspan="18">62</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(XYU-4WE-MQPQ, 2024-08-23)</td></tr>
<tr><td>Detail of Fee Submitted</td><td>75000.0,
2024-07-23,</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Dercutane 30mg Soft Gelatin Capsules</td></tr>
<tr><td>Label Claim</td><td>Each soft gelatin capsule contains: Isotretinoin ..... 30mg</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Retinoids ATC code: D10BA01</td></tr>
<tr><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Approved by US FDA</td></tr>
<tr><td>For generic drugs (me-too Status)</td><td>None</td></tr>
<tr><td>Proposed Pack Size</td><td>10's-As per SRO,20's-As per SRO,30's-As per SRO</td></tr>
<tr><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td>Name & address of API manufacturer</td><td>Chongqing Huapont Pharmaceutical Co., Ltd. No. 69 Xingguang Avenue Renhe Town, Yubei District, Chongqing, P.R. China</td></tr>
<tr><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Chongqing Huapont Pharmaceutical Co., Ltd.</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Myorisan soft gelatin capsule</td></tr>
<tr><td>Detail of stability batches of drug product</td><td>3 batches of 3000 capsules each</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 01-3-2023.</td></tr>
<tr><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table><tr><th>Observations</th><th>Reply</th></tr><tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Valid DML of drug substance manufacturer submitted</td></tr><tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Firm has submitted copy of invoice, packing list and DHL receipt</td></tr></table></td></tr>
<tr><td>Shortcoming</td><td></td></tr>
<tr><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
63	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(Y2N-E31-VZET, 2024-12-11)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Zaline Oral Solution**
	Label Claim	Each ml contains:Sertraline as HCL..... 20mg
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA -https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=078861
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 14-03-2024.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations • Drug substance analytical method verification studies form drug product manufacturer shall be submitted. • Submitted from M/s A’raf pharma Submit Pharmaceutical equivalence of applied product against the reference/comparator product Pharmaceutical equivalence submitted against Zoloft oral solution Stability data summary sheets shall be submitted. Firm has submitted drug product stability summary sheets Drug product stability data of 6th month time point shall be submitted. Firm has submitted drug product stability study for 6th month time point at accelerated and long term conditions
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
64	Name, address of Manufacturing site.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi**(000755)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(YB3-QHQ-1VQZ, 2024-11-11)
	Detail of Fee Submitted	75000.0, 2024-09-11,
	The proposed proprietary name / brand name	**Calcidiol 10mcg Soft Gelatin Capsule**
	Label Claim	Each soft gelatin capsule contains: Calcifediol monohydrate..... 10mcg
	Pharmacotherapeutic Group of (API)	Vitamin D and analogues, ATC code: A11CC06
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Therapeutic Goods administration (TGA) of Australia
	For generic drugs (me-too Status)	None
	Proposed Pack Size	15's-As per SRO,30's-As per SRO,60's-As per SRO,90's-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
	Name & address of API manufacturer	CARBOGEN AMCIS B.V. Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from CARBOGEN AMCIS B.V , Nieuweweg 2a 3901 BE Veenendaal The Netherlands
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product of Opti Active D capsule.
	Detail of stability batches of drug product	3 batches of 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 02-09-2022.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations Evidence of approval of “Soft gelatin capsule (General)” as new/additional section from CLB, shall be submitted. Response: Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021 Performance of Dissolution test, as recommended by USP monograph, shall be submitted in Pharmaceutical equivalence studies. Response: Firm has submitted Pharmaceutical Equivalence studies including dissolution test as per USP monograph Justification shall be submitted for not performing dissolution test as recommended by USP monograph, during drug product stability studies. Response: Firm has submitted stability reports including dissolution test. It is important to note that USP dissolution test as recommended in Calcifediol Capsules monograph is not like a routine procedure of dissolution. Rather it is just a rupture test in specified medium, RPM and time
	Shortcoming	
	Decision	Approved

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td rowspan="19">65</td><td>Name, address of Manufacturing site.</td><td>Kaizen Pharmaceuticals (Pvt) Ltd Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi(000755)</td></tr>
<tr><td>Case Category</td><td>New Section (Ammar Ashraf Awan)</td></tr>
<tr><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(YMW-L7A-NWQN, 2024-08-23)</td></tr>
<tr><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-23,</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Dercutane 20mg soft gelatin capsules</td></tr>
<tr><td>Label Claim</td><td>Each soft gelatin capsule contains:Isotretinoin.....20mg</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Retinoids ATC code: D10BA01</td></tr>
<tr><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Food and Drug Administration</td></tr>
<tr><td>For generic drugs (me-too Status)</td><td>Maxinoin Soft Gelatin Capsule 20mg</td></tr>
<tr><td>Proposed Pack Size</td><td>10's-As per SRO,20's-As per SRO,30's-As per SRO</td></tr>
<tr><td>GMP status of the firm</td><td>GMP certificate issued dated 26-06-2023</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Firm has been granted additional section of “Soft gelatin capsule (General)” vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021</td></tr>
<tr><td>Name & address of API manufacturer</td><td>Chongqing Huapont Pharmaceutical Co., Ltd No. 69 Xingguang Avenue Renhe Town, Yubei District, Chongqing, P.R. China (401121)</td></tr>
<tr><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Chongqing Huapont Pharmaceutical Co., Ltd.</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence performed against reference product Myorisan 20mg soft gelatin capsule</td></tr>
<tr><td>Detail of stability batches of drug product</td><td>3 batches of 3000 capsules each</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 01-3-2023.</td></tr>
<tr><td>Evaluation</td><td>Your instant application has been evaluated and found deficient for following observations:
Observations
<table>
<tr><th>Observations</th><th>Reply</th></tr>
<tr><td>Valid DML/GMP certificate of drug substance manufacturer shall be submitted.</td><td>Valid DML of drug substance manufacturer submitted</td></tr>
<tr><td>Documents confirming import i.e., custom clearance/Goods declaration, of the drug substance shall be submitted</td><td>Firm has submitted copy of invoice, packing list and DHL receipt</td></tr>
</table></td></tr>
<tr><td>Shortcoming</td><td></td></tr>
<tr><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
66	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(Z61-2NN-MZYX, 2024-09-30)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Ceframit 500mg Capsule**
	Label Claim	Each Capsule contains:Cephradine.....500mg
	Pharmacotherapeutic Group of (API)	First generation cephalosporin, ATC code: J01DB09
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Cephradine 500mg capsule of M/s ACS Dobfar S.p.A, Via Laurentina Km 24, 730 – 00071 Pomezia, Roma, Italy (MHRA Approved)
	For generic drugs (me-too Status)	Velosef 500mg Capsule of M/s GSK Pakistan
	Proposed Pack Size	1x5's, 1x 10's, 2x6'-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted new section of "Capsule (Cephalosporinl)" vide letter no. F.1-10/2012-Lic issued by Secretary CLB dated 07-06-2022.
	Name & address of API manufacturer	Saakh Pharma Pvt. Ltd Add: c-7/1, North Western Industrial Zone, Port qasim, Karachi, Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CD submitted against Cefaclor capsule
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Dr. Raza Pharma along with invoice and delivery challan.
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations BMRs of drug product stability batches shall be submitted. Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
67	Name, address of Manufacturing site.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan**(000840)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ZEN-YSV-WHAH, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Fero-Ject (Iron as Ferric carboxymaltose 50mg/ml)**
	Label Claim	Each ml contains:Iron as Ferric carboxymaltose.....50mg/ml (750mg/15ml)
	Pharmacotherapeutic Group of (API)	Iron trivalent, parenteral preparation, ATC Code: B03A C01
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Ferinject is Approved in DRAP
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate issued dated 19-04-2019.
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Liquid Injection SVP (General)” vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co. Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Ferinject injection of Vifor
	Detail of stability batches of drug product	3 batches of 1000 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 02-09-2022
	Evaluation	Firm has submitted rug product stability data till 6 months time point
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
68	Name, address of Manufacturing site.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore**(000685)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ZM9-57H-NVWM, 2024-12-17)
	Detail of Fee Submitted	75000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Falraf Oral Solution**
	Label Claim	Each ml contains:Pregabalin 20mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant drug
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved - https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&Ap plNo=022488
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	GMP inspection report dated 27-08-2024 declares satisfactory compliance
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Syrup (General)” vide letter no. F.1-10/2000-Lic (Vol-I) issued by Secretary CLB.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against reference product i.e., Lyrica oral solution
	Detail of stability batches of drug product	3 batches of 100 bottles each (60ml)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E office, Lahore dated 28-03-2023
	Evaluation	instant application has been evaluated and found deficient for following observations: Observations • Valid GMP certificate/DML of drug substance manufacturer shall be submitted. • Firm has submitted valid GMP certificate issued by FDA Maharshtra • Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer shall be submitted. • Drug substance specifications, analytical procedure and analytical method verification studies from M/s A’raf • Readable copies of Drug substance stability studies shall be submitted • Submitted as per Zone II conditions
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
69	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(14U-8VN-M196, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 156.25mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....125mg Potassium clavulanate eq. to Clavulanic acid....31.25mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Augmentin 156.25mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (USFDA Approved)
	For generic drugs (me-too Status)	Augmentin 156.25mg/5ml Dry suspension of M/s GSK Pakistan
	Proposed Pack Size	90mls/ As per SRO / -As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Dry Powder Suspension (Penicillin) section.
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Shandong New Time Pharmaceutical co., ltd. Add: No.1, North Outer Ring Road, Feixian County, Shandong Province, P. R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches stability data as per zone IV-A conditions Potassium clavulanate: 3 batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Augmentin suspension of GSK
	Detail of stability batches of drug product	Stability data of 3 batches each having 400 bottles batch size
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit in-use stability study data Not submitted 2. Submit documents for procurement of API Firm has submitted loan letter from Stallion Pharma including clearance certificate dated 14-12-2022.
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after submission of in-use stability study data and verification of loan letter.

Sr. No	Title	Description
70	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(297-7JA-8P3J, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefron 1G IV Injection**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone 1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Rocephin Injection 1G IV Injection F. Hoffman-La Roche Ltd. Switzerland USFDA Approved ---------- Ceftriaxone 1g powder for solution for injection (MHRA Approved)
	For generic drugs (me-too Status)	Rocephin 1g IV Injection (Martin Dow Limited) Reg. No.007014
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder injection (Cephalosporin) section
	Name & address of API manufacturer	Chongqing Tiandi Pharmaceutical Industry Co.,Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rocephin injection of Martin Dow: PE studies performed
	Detail of stability batches of drug product	3 batches: 621 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Linear pharma dated 02-02-2024 and clearance certificate dated 29-12-2023
	Evaluation	1. Submit API specifications and analytical method from API manufacturer . 2. API manufacturer specifies assay limit NLT 795ug/ml of ceftriaxone on anhydrous basis, while you have adopted limit NLT 776ug/ml of ceftriaxone. Justify how you can adopt different limits from that specified by API manufacturer, 3. As per API specifications the standard solution concentration is 0.3mg/ml while in verification studies the linearity and specificity studies are performed at 0.01mg/ml which is entirely a different concentration . Justify how your verification / validation studies are applicable on your method. 4. Submit API real time stability study data till the claimed / complete shelf life. Since only 1 year stability data is provided. 5. Clarify how 1276.8mg per vial is equivalent to 1g ceftriaxone base 6. Submit compatibility studies result in 3.2.P.2.6 7. USP specifies two different type of assay test for the drug product while you have only performed one test in drug product. Clarification is required in this regard. 8. Clarify your sample solution preparation method without any detail of reconstitution and further dilutions. Provide complete elaborative method of sample preparation. 9. Drug product sample and standard solution concentration is 0.3mg/ml while linearity test is performed at concentration range from 0.040 to 0.060mg/ml. Justify how you have developed this verification study protocol. 10. Clarify why the calculation formula for assay test in your method and raw data sheets of stability studies vare diferent from that specified by USP. 11. In your HPLC chromatogram of standard 3 and standard 4 performed on 14-03-2024 the time for date acquired and date processed is moved in another row and gets out of the sample information box, which is not possible in HPLC Empower 2 software. Clarification is required in this regard.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
71	Name, address of Manufacturing site.	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi**(000947)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(2BH-4SA-41Z2, 2024-09-24)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**JECTSOL-NS INJECTION (10ml)**
	Label Claim	Each ml of solution contains: Sodium chloride.....9mg
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	0.9% Sodium Chloride Injection (USFDA)
	For generic drugs (me-too Status)	Normal Saline 10ml solution by Otsuka Pharma
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML Issued dated 11-11-2021
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 11-11-2021 specifies Liquid Injectable Infusion (SVP) LDPE General section and Liquid Injectable Infusion (LVP) LDPE General section
	Name & address of API manufacturer	Hebei Huachen Pharmaceuticals Group Co., Ltd Huanghua Economic Development Zone, Huanghua, Hebei, China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Plasaline Injection manufactured by Otsuka Pakistan Ltd
	Detail of stability batches of drug product	3 batches having batch size of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 02-11-2022 specifying 25000 Kg Sodium chloride
	Evaluation	Source of API: Hebei Huachen Pharmaceutical Group Co.,Ltd China PE studies performed against: Plasaline Injection of Otsuka Stability batches: 3 batches of 100 bottle each Procurement documents: Clearance certificate dated 02-11-2022
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
72	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(3DY-PJ1-2495, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-21,
	The proposed proprietary name / brand name	**Maftron 8mg/4ml Injection**
	Label Claim	Each 4ml Ampoule Contains: Ondansetron as Hydrochloride Dihydrate...8mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	ONSET Injection by Pharmedic Laboratories,
	Proposed Pack Size	4mlx5's-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Liquid ampoule general (SVP) section
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Liquid ampoule general (SVP) section
	Name & address of API manufacturer	Sonia Organics Factory: # 22/2, Attibele, Industrial Area, Balagaranahalli Village/ Anekal Taluk, Bangaluru
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Injection of Pharmedic: PE studies performed
	Detail of stability batches of drug product	3 batches: 1000 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter dated 28-09-2023 from Medisave. Clarance certificate dated 08-06-2023 is also submitted
	Evaluation	1. Clarify your API supplier since COA, stability studies etc are of Anugraha pharma India, while claimed API manufacturer is Sonia Organicles. Clarification is required along with specifications, analytical method, COA and stability studies from the respective API manufacturer. 2. Provide complete analytical record of stability study data since the submitted data is only for standard 1 and standard 2 chromatograms.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
73	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(3L4-6XT-D1ZB, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Espro 40mg Capsule**
	Label Claim	Each Capsule contains: Esomeprazole (as Magnesium trihydrate enteric coated pellets).....40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Nexum Capsule by Getz
	Proposed Pack Size	14s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Nexum Capsule of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submited by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
74	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(3VX-BUJ-JXNA, 2024-08-31)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Ceftrax 500mg I.M Dry Powder Injection**
	Label Claim	Each vial contains: Ceftriaxone as sodium.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefxone injection of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Submit in-use stability studies. Response: Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
75	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(4JX-AY4-TX67, 2024-12-19)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Cipset 250mg Tablet**
	Label Claim	Each film coated tablet contains: Ciprofloxacin as HCl.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Novidat tablet by Sami
	Proposed Pack Size	10s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Pharmagen Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Novidat Tablet of Sami Pharma
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	10-05-2024: Invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
76	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(579-GXD-RTUX, 2024-12-19)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Levset P 50mg Tablet**
	Label Claim	Each Tablet Contain: Levosulpiride.....50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	AIFA Italy Approved
	For generic drugs (me-too Status)	Sulvorid Tablet of High Q
	Proposed Pack Size	20s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Altas Life Science Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Sulvorid Tablet of High Q
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter and invoice from Aries pharma is submitted.
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Justify why UV method has been adopted for assay test of the drug product. This method has been adopted to test the Drug Product because it is a validated as per ICH guidelines parameters.the result are accurate precise and repeatable as provided data attached. 5. Submit GMP certificate of API manufacturer Submitted by the firm 6. Submit evidence of procurement of API. Firm has submitted loan letter and invoice from Aries pharma.
	Shortcoming	
	Decision	Deferred . Firm shall submit drug product stability studies at the next time point of long term stability studies on the basis of HPLC method along with analytical method validation studies of the HPLC based method.

Sr. No	Title	Description
77	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(5BS-GAL-24WQ, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-30,
	The proposed proprietary name / brand name	**Skygesic 37.5/325mg Tablet**
	Label Claim	Each Film Coated Tablet contains:Paracetamol.....325mgTramadol HCl.....37.5mg
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Tramadol and Paracetamol 37.5mg/325mg Film coated tablets of M/s Aurobindo Pharma - Milpharm Ltd. (MHRA Approved)
	For generic drugs (me-too Status)	Tonoflex-P (Tramadol HCl +Paracetamol)Tablet of M/s SAMI Pharma
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section
	Name & address of API manufacturer	CarryFor Pharmaceutical (Pvt) Ltd, Add: Plot No.:- E-81, North Western Industrial Zone, Port Qasim, Karachi, Pakistan,Proto Chemicals Add: AG Tschachen 2 8756 Mitlödi (Glarus Süd) Switzerland
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed but name of comparator product is not mentioned
	Detail of stability batches of drug product	3 batches: 2500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Wimits dated 01-10-2023 along with paracetamol invoice and tramadol clearance
	Evaluation	1. Submit evidence of approval of manufacturing of paracetamol by CarryFor Pharmaceutical by Licensing Division DRAP. Not submitted. 2. CarryFor Pharmaceutical provies two different specifications and analytical method claiming that they are manufacturing both USP as well as BP grade Paracetamol seprately. While COA of API specifies that the material complies both USP and BP. Clarify. Not submitted. 3. API manufacturer of tramadol mentioned in 3.2.S.2.1 is Proto Chemicals Add: AG Tschachen 2 8756 Mitlödi (Glarus Süd) Switzerland, while GMP certificate of the same facility in India is provided. Clarification is required in this regard. Not submitted.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
78	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(5PU-YVL-MXDL, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	**Ceftrax 1gm I.M Dry Powder Injection**
	Label Claim	Each Vial contains:Ceftriaxone as sodium.....1gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Titan Injection of Macter Pharma: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Submit in-use stability studies. Response: Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
79	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(5ZA-822-LX41, 2024-12-22)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Cipset 500mg Tablet**
	Label Claim	Each film coated tablet contains: Ciprofloxacin as HCl.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Novidat tablet by Sami
	Proposed Pack Size	10s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Pharmagen Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Novidat Tablet of Sami Pharma
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	10-05-2024: Invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
80	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(7VJ-1WH-ZXR6, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Wellsef 250mg Capsule**
	Label Claim	Each Capsule contains: Cephradine (anhydrous).....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA) Approved
	For generic drugs (me-too Status)	Velosef Capsules by GSK
	Proposed Pack Size	2x6s-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef Capsule of GSK: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1662 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 14-09-2023 for 15kg cefradine
	Evaluation	Clarify if your formulation contains cephradine anhydrous or cephradine monohydrate. Response: cephradine anhydrous
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
81	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(88Y-WUE-RRG2, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefron 2g IV Injection**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone ……2g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Rocephin Injection 2g IV Injection (MHRA Approved)
	For generic drugs (me-too Status)	Oxidil 2g IV Injection Reg. No. 086609
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder injection (Cephalosporin) section
	Name & address of API manufacturer	Chongqing Tiandi Pharmaceutical Industry Co.,Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed
	Detail of stability batches of drug product	3 batches: 522 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Linear pharma dated 02-02-2024 and clearance certificate dated 29-12-2023
	Evaluation	1. Submit API specifications and analytical method from API manufacturer . 2. API manufacturer specifies assay limit NLT 795ug/ml of ceftriaxone on anhydrous basis, while you have adopted limit NLT 776ug/ml of ceftriaxone. Justify how you can adopt different limits from that specified by API manufacturer, 3. As per API specifications the standard solution concentration is 0.3mg/ml while in verification studies the linearity and specificity studies are performed at 0.01mg/ml which is entirely a different concentration . Justify how your verification / validation studies are applicable on your method. 4. Submit API real time stability study data till the claimed / complete shelf life. Since only 1 year stability data is provided. 5. Clarify how 1276.8mg per vial is equivalent to 1g ceftriaxone base 6. Submit compatibility studies result in 3.2.P.2.6 7. USP specifies two different type of assay test for the drug product while you have only performed one test in drug product. Clarification is required in this regard. 8. Clarify your sample solution preparation method without any detail of reconstitution and further dilutions. Provide complete elaborative method of sample preparation. 9. Drug product sample and standard solution concentration is 0.3mg/ml while linearity test is performed at concentration range from 0.040 to 0.060mg/ml. Justify how you have developed this verification study protocol. 10. Clarify why the calculation formula for assay test in your method and raw data sheets of stability studies vare diferent from that specified by USP. 11. In your various HPLC chromatogram, the time for date acquired and date processed is moved in another row and gets out of the sample information box, which is not possible in HPLC Empower 2 software. Clarification is required in this regard. 12. Submit in-use stability studies
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
82	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(AJX-RX8-RDV8, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Prosec 20mg Capsule**
	Label Claim	Each Capsule contains: Omeperazole (as enteric coated pellets)..... 20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Risek Capsule by Getz
	Proposed Pack Size	14s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Risek Capsule of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
83	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(AM8-39Z-HZZU, 2024-10-29)
	Detail of Fee Submitted	30000.0, 2024-08-30,
	The proposed proprietary name / brand name	**Fexo 120mg Tablet**
	Label Claim	Each film-coated tablet contains: Fexofenadine HCl 120mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	FEXO ALLERY RELIEF 120 MG FILM-COATED of M/s Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland (HPRA Approved)
	For generic drugs (me-too Status)	Fexet 120mg Tablet of M/s Getz Pharma
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section
	Name & address of API manufacturer	Vasudha Pharma Chem Limited Add: Unit II, Plot No. 79, J.N.Pharma City, Parawada, Visakhapatnam- 531021 Andhra Pradesh, INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fexo Allery Relief Tablet: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 2500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Wimits loan letter 03-10-2023 and clearance certificate dated 14-11-2022
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit details including batch number, expiry date and manufacturer of the product against which PE and CDP studies are performed Manufacturer Name: Getz Pharma (Pvt) Limited Brand Name & Strength:FEXET (Fexofenadine HCl) tablet 120mg Registration # 029435 Batch No. 23FX024 MFG Date: 06-2023 Expiry Date: 05-2025
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
84	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(AZV-R2M-UGSA, 2024-12-22)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	**Prosec 40mg Capsule**
	Label Claim	Each Capsule contains: Omeperazole (as enteric coated pellets).....40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Risek Capsule by Getz
	Proposed Pack Size	14s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Risek Capsule of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
85	Name, address of Manufacturing site.	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi**(000947)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(BGB-9XA-X9T8, 2024-09-24)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**JECTSOL-25% INFUSION (25ml)**
	Label Claim	Each ml contains: Dextrose anhydrous.....250mg
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Glucose 25% Intravenous Infusion (TGA Australia)
	For generic drugs (me-too Status)	Sterifluid- 25 by FDL
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML Issued dated 11-11-2021
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 11-11-2021 specifies Liquid Injectable Infusion (SVP) LDPE General section and Liquid Injectable Infusion (LVP) LDPE General section
	Name & address of API manufacturer	Weifang Shengtai Medicine Co., Ltd., The east of Changda Road, Changle County, Weifang city, Shandong province, P.R.China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Macsol Injection of Searle
	Detail of stability batches of drug product	3 batches having batch size of 1000 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 31-10-2022 specifying 24000 Kg Dextrose anhydrous
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
86	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(BT8-T69-Q6RE, 2024-08-19)
	Detail of Fee Submitted	30000.0, 2024-08-09,
	The proposed proprietary name / brand name	**Ceftrax 1gm I.V Dry Powder Injection**
	Label Claim	Each vial contains: Ceftriaxone as sodium.....1gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefxone injection of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Submit in-use stability studies. Response: Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
87	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(E5A-T1D-Z1JY, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Wellsef 500mg Capsule**
	Label Claim	Each capsule contains: Cephradine (anhydrous).....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA) Approved
	For generic drugs (me-too Status)	VelosefCapsules of GSK
	Proposed Pack Size	2x6's-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef Capsule of GSK: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1662 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 14-09-2023 for 15kg cefradine
	Evaluation	Clarify if your formulation contains cephradine anhydrous or cephradine monohydrate. Response: Cephradine anhydrous
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
88	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(EBS-P1P-92UD, 2024-12-22)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Dexoset 30mg cap**
	Label Claim	Each Capsule contains: Dexlansoprazole (as dual delayed release pellets).....30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Razodex Capsule by Getz
	Proposed Pack Size	3*10-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Delanzo Capsule of Sami Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
89	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(GEG-XT4-JUE3, 2024-09-19)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Ceftrax 250mg I.V Dry Powder Injection**
	Label Claim	Each vial contains: Ceftriaxone as sodium.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefxone injection of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Firm has submitted 7000 differential fee dated 11-09-2024. However the differential fee is not updated in eapp portal 1. Submit in-use stability studies Response: Submitted by the firm 2. Update the differential fee 7000/- in eapp portal Fee is updated.
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
90	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(GL5-ZXT-2UJP, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	**Cefadox 500mg Capsule**
	Label Claim	Each Capsule contains: Cefadroxil as Monohydrate.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Duricef Capsules of GSK
	Proposed Pack Size	2x6s-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Duricef Capsules of GSK: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1662 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 14-08-2023 for 15kg cefadroxil
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
91	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(GWH-8E6-DTP7, 2024-09-09)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Wellsef 125mg/5ml oral suspension**
	Label Claim	Each 5ml (reconstituted) suspension contains: Cephradine (anhydrous).....125mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Not available
	For generic drugs (me-too Status)	Velosef suspension by GSK
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefrinex suspension of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 132 bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 14-09-2023 for 15kg cefradine
	Evaluation	1. Submit evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting Response: Submitted by the firm 2. Clarify if your formulation contains cephradine anhydrous or cephradine monohydrate. Response: Cephradine anhydrous 3. Submit compatibility studies of the product with recommended diluent. Response: Submitted by the firm
	Shortcoming	
	Decision	Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.

Sr. No	Title	Description
92	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(H5X-UD1-M1EH, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 312.5mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....250mg Potassium clavulanate eq. to Clavulanic acid....62.5mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Augmentin 312.5mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (USFDA Approved)
	For generic drugs (me-too Status)	Augmentin 312.5mg/5ml Dry suspension of M/s GSK Pakistan
	Proposed Pack Size	As per SRO / DPC-As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Dry Powder Suspension (Penicillin) Section
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Shandong New Time Pharmaceutical co., ltd. Add: No.1, North Outer Ring Road, Feixian County, Shandong Province, P. R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches as per Zone IV-A Potassium Clavulanate: 3 Batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Augmentin Suspension
	Detail of stability batches of drug product	3 batches having batch size of 400 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted.
	Evaluation	1. Submit in-use stability study data Not submitted 2. Submit documents for procurement of API Firm has submitted loan letter from Stallion Pharma including clearance certificate dated 14-12-2022.
	Shortcoming	
	Decision	Approved Registration letter shall be issued after submission of in-use stability study data and verification of loan letter.

Sr. No	Title	Description
93	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(H9E-SEH-1Z1L, 2024-12-22)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Dexoset 60mg Capsule**
	Label Claim	Each Capsule contains: Dexlansoprazole (as dual delayed release pellets).....60mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Razodex Capsule by Getz
	Proposed Pack Size	3*10-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Delanzo Capsule of Sami Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
94	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(JYZ-ZMU-V3V4, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefron 500mg IM Injection**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone ……500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(MHRA Approved)
	For generic drugs (me-too Status)	Rocephin Injection 500mg IM (Martin Dow Limit) Reg. No. 008434
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder injection (Cephalosporin) section
	Name & address of API manufacturer	Chongqing Tiandi Pharmaceutical Industry Co.,Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rocephin injection of Martin Dow: PE studies performed
	Detail of stability batches of drug product	3 batches: 620 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Linear pharma dated 02-02-2024 and clearance certificate dated 29-12-2023
	Evaluation	1. Submit API specifications and analytical method from API manufacturer . 2. API manufacturer specifies assay limit NLT 795ug/ml of ceftriaxone on anhydrous basis, while you have adopted limit NLT 776ug/ml of ceftriaxone. Justify how you can adopt different limits from that specified by API manufacturer, 3. As per API specifications the standard solution concentration is 0.3mg/ml while in verification studies the linearity and specificity studies are performed at 0.01mg/ml which is entirely a different concentration . Justify how your verification / validation studies are applicable on your method. 4. Submit API real time stability study data till the claimed / complete shelf life. Since only 1 year stability data is provided. 5. Clarify how 1276.8mg per vial is equivalent to 1g ceftriaxone base 6. Submit compatibility studies result in 3.2.P.2.6 7. USP specifies two different type of assay test for the drug product while you have only performed one test in drug product. Clarification is required in this regard. 8. Clarify your sample solution preparation method without any detail of reconstitution and further dilutions. Provide complete elaborative method of sample preparation. 9. Drug product sample and standard solution concentration is 0.3mg/ml while linearity test is performed at concentration range from 0.040 to 0.060mg/ml. Justify how you have developed this verification study protocol. 10. Clarify why the calculation formula for assay test in your method and raw data sheets of stability studies vare diferent from that specified by USP. 11. In your various HPLC chromatogram, the time for date acquired and date processed is moved in another row and gets out of the sample information box, which is not possible in HPLC Empower 2 software. Clarification is required in this regard. 12. Submit in-use stability studies
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
95	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(L2V-3U1-9EWH, 2024-09-30)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 625mg Tablet**
	Label Claim	Each film coated tablet contains:Amoxicillin trihydrate eq. to Amoxicillin.....500mgPotassium clavulanate eq. to Clavulanic acid....125mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Augmentin 625mg Tablets of M/s GSK Pakistan
	Proposed Pack Size	As per SRO / DPC-As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Tablet (Penicillin) Section
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Zhuhai United Laboratories Co., Ltd. Add: No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040, P.R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches as per Zone IV-A Potassium Clavulanate: 3 Batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Augmentin Tablet
	Detail of stability batches of drug product	3 batches having batch size of 1500 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted.
	Evaluation	Submit documents for procurement of API. Response: Firm has submitted loan letter and clearance certificate from Stallion pharma.
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
96	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(L7E-63Y-BVY6, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Ceftrax 250mg I.M Dry Powder Injection**
	Label Claim	Each Vial contains: Ceftriaxone as sodium.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Inocef 250mg I.M Injection
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Inocef Injection of Barret Hodgson: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Submit in-use stability studies. Response: Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
97	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(M21-182-QSWJ, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-04,
	The proposed proprietary name / brand name	**Lazid 600mg Tablets**
	Label Claim	Each Film coated tablets contains: Linezolid.....600mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Zoldap Tablet by Getz
	Proposed Pack Size	12's-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Benova Labs private Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Zoldap Tablet of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1165 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted copy of drug import license of polyfine chempharma. Firm has also submitted clearance certificate dated 01-01-2024 and also submitted letter for intimation in DRAP dated 10-07-2024
	Evaluation	1. Submit 6th month stability study data stability study will be completed on 10/01/2025 2. Submit loan documents along with clearance certificate of M/s Polyfine chempharma. Firm has submitted copy of drug import license of polyfine chempharma. Firm has also submitted clearance certificate dated 01-01-2024 and also submitted letter for intimation in DRAP dated 10-07-2024
	Shortcoming	
	Decision	Approved . Firm shall submit 6th month stability study data before issuance of Registration Letter.

Sr. No	Title	Description
98	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(M7X-2ZG-AZMP, 2024-12-19)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Cipset 750mg Tablet**
	Label Claim	Each film coated tablet contains: Ciprofloxacin as HCl.....750mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Novidat tablet by Sami
	Proposed Pack Size	10s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Pharmagen Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Hiflox Tablet of Hilton
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	10-05-2024: Invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit evidence of procurement of API. Submitted by the firm 4. Provide details of Novidat 750mg tablet of Sami pharma against which you have performed PE and CDP studies since this product is not registered in Pakistan. Firm submitted that Novidat was mentioned mistakenly, actually they have performed studies against Hiflox Tablet of Hilton
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
99	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MH3-TWG-QEWH, 2024-11-29)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Prostam 0.4 mg Capsules**
	Label Claim	Each capsule contains: Tamsulosin HCl (as SR pellets).....0.4mg
	Pharmacotherapeutic Group of (API)	Alpha Blocker
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Maxflow Capsule by CCL
	Proposed Pack Size	2x10's-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Tamsolin Capsule of Getz
	Detail of stability batches of drug product	3 batches having batch size of 1700 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Invoice from Vision pharma dated 15-07-2024 for 1Kg Tamsulosin SR pellets.
	Evaluation	Submit 6th month stability study data. Response: stability will be completed at 19/01/2025.
	Shortcoming	
	Decision	Approved . Firm shall submit 6th month stability study data before issuance of Registraton letter.

Sr. No	Title	Description
100	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MPH-RB4-DEUX, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-12-09,
	The proposed proprietary name / brand name	**Levetra 2.5mg Tablet**
	Label Claim	Each film coated tablet contains: Letrozole.....2.5mg
	Pharmacotherapeutic Group of (API)	Aromatase inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Femara Tablet of Novartis
	Proposed Pack Size	10's-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Aspen Biopharma Labs Pvt Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Grudiz Tablet of Sami Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1700 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Polyfine dated 13-05-2024. Clarance certificate of Polyfine dated 17-04-2024. Firm has also submitted intimation letter for loan in R&I DRAP dated 10-07-2024
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
101	Name, address of Manufacturing site.	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi**(000947)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MPL-T3G-A34R, 2024-09-24)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**JECTSOL-D INJECTION (1ML)**
	Label Claim	Each 1ml ampoule contains: Cholecalciferol.....5mg
	Pharmacotherapeutic Group of (API)	Vitamin D
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	VITAMIN D3 BON 200,000 IU/1 ml solution for Injection IM ampoule (ANSM France)
	For generic drugs (me-too Status)	Sunny D Insta Ampoule by Scotmann Pharma
	Proposed Pack Size	1's & 5's-As per SRO
	GMP status of the firm	New DML Issued dated 11-11-2021
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 11-11-2021 specifies Liquid Injectable Infusion (SVP) LDPE General section and Liquid Injectable Infusion (LVP) LDPE General section
	Name & address of API manufacturer	FERMENTA BIOTECH LIMITED, Plot Nos.Z109 B&C, Dahej SEZ 1I, Village-Dahej, Taluka-Vagara, Dist.-Bharuch 392130, Gujarat, India.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Dow-D Injection of Martin Dow
	Detail of stability batches of drug product	3 batches of 1500 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan documents from Cunningham Pharma dated 9-August 2023: Clearance certificate dated 22-12-2022
	Evaluation	Submit following: 1. Clarification why PE studies are not performed against a product with same container closure system. Response: Firm has submitted pharmaceutical equivalence studies against Vydee injection of Hudson pharma which is available as LDPE ampoule.
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
102	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MVB-EHU-SMUV, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 457mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains:Ammoxicillin trihydrate eq. to Amoxicillin.....400mgPotassium clavulanate eq. to Clavulanic acid....57mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	Augmentin 457mg/5ml Dry suspension of M/s GSK Pakistan
	Proposed Pack Size	As per SRO / DPC-As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Dry Powder Suspension (Penicillin) Section
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Shandong New Time Pharmaceutical co., ltd. Add: No.1, North Outer Ring Road, Feixian County, Shandong Province, P. R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches as per Zone IV-A Potassium Clavulanate: 3 Batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Augmentin Suspension
	Detail of stability batches of drug product	3 batches having batch size of 400 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter dated 10 April and 13 April 2023 is submitted.
	Evaluation	1. Submit in-use stability study data Not submitted 2. Submit documents for procurement of API Firm has submitted loan letter from Stallion Pharma including clearance certificate dated 14-12-2022.
	Shortcoming	
	Decision	Approved Registration letter shall be issued after submission of in-use stability study data and verification of loan letter.

Sr. No	Title	Description
103	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(NUW-UP8-JPA1, 2024-09-30)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 375mg Tablet**
	Label Claim	Each film coated tablet contains:Ammoxicillin trihydrate eq. to Amoxicillin.....250mgPotassium clavulanate eq. to Clavulanic acid....125mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Augmentin 375mg Tablets of M/s GSK Pakistan
	Proposed Pack Size	12's/ As per SRO / D-As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Tablet (Penicillin) Section
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Zhuhai United Laboratories Co., Ltd. Add: No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040, P.R. China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches as per Zone IV-A Potassium Clavulanate: 3 Batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Augmentin Tablet
	Detail of stability batches of drug product	3 batches having batch size of 1500 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted.
	Evaluation	Submit documents for procurement of API. Response: Firm has submitted loan letter and clearance certificate from Stallion pharma.
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
104	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(PAU-Q72-8AQY, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**LANSET 30MG CAPSULE**
	Label Claim	Each capsule contains: Lansoprazole (as enteric coated pellets).....30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Selanz SR Capsule by Searle
	Proposed Pack Size	14s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharma Islamabad Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Q Pro Capsule of Bosch
	Detail of stability batches of drug product	3 batches having batch size of 1500 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	11-05-2024: Commercial invoice submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Submit stability study data of 3 batches of API from API manufacturer. Submitted by the firm as per Zone IV-A 5. Submit evidence of procurement of API. Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
105	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(PW7-8G3-1QX8, 2024-10-01)
	Detail of Fee Submitted	75000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Acotia 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Acotiamide HCl Hydrate.....100mg
	Pharmacotherapeutic Group of (API)	Gastroprokinetic
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Acofide Tablets 100 mg of M/s Axcount Generika Gmbh Max-Planck-Street 36 D 61381 Friedrichsdorf Germany(PMDA Approved)
	For generic drugs (me-too Status)	Dyspenal Tablet 100mg of M/s Kaizen Pharma Pvt. Ltd.
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section
	Name & address of API manufacturer	Metrochem API Private Limited, Add: Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021 India.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Acofide Tablets: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Wimits dated 11-09-2023 and Drug Import License of Wimits dated 08-09-2023
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit details including batch number, expiry date and manufacturer of the product against which PE and CDP studies are performed Japanese product name Acofide Tablets 100mg Merchant Zeria Shinyaku Kogyo Co., Ltd. JAN 4987103012900 GS1 14987103012907 Ingredient Substitute 2399015 EXP 09-24
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
106	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(QEU-Z9E-X3JQ, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-07,
	The proposed proprietary name / brand name	**SPANIL-SR 200**
	Label Claim	Each capsule contains: Mebeverine HCl (as SR pellets).....200mg
	Pharmacotherapeutic Group of (API)	Musculotropic antispasmodic drug
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA)
	For generic drugs (me-too Status)	Colospas Capsule by Nabiqasim
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Mebever MR 200mg Capsules of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 1200 Capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 24-06-2024 for 1kg mebeverine HCl SR pellets
	Evaluation	Submit 6th month stability study data. Response: stability will be completed on 28/12/24
	Shortcoming	
	Decision	Approved . Firm shall submit 6th month stability study data before issuance of Registration letter.

Sr. No	Title	Description
107	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RH6-32B-BZMP, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**Cefimaf 400mg Capsule**
	Label Claim	Each Capsule contains: Cefixime as Trihydrate.....400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Suprax 400mg USFDA Approved
	For generic drugs (me-too Status)	Cefim Capsules of Hilton
	Proposed Pack Size	1x5-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Name & address of API manufacturer	Citi pharma 3 kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Caricef capsule by Sami: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 4000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	14-10-2023 commercial invoice for 5kg cefixime
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
108	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(S3E-U34-P7EG, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefron 500mg IV Injection**
	Label Claim	Each Vial contains: Ceftriaxone Sodium eq. to Ceftriaxone ……500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(MHRA Approved)
	For generic drugs (me-too Status)	Oxidil 500IV Injection (Sami Pharmaceuticals) Reg. 022421
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder injection (Cephalosporin) section
	Name & address of API manufacturer	Chongqing Tiandi Pharmaceutical Industry Co.,Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rocephin injection of Martin Dow: PE studies performed
	Detail of stability batches of drug product	3 batches: 645 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Linear pharma dated 02-02-2024 and clearance certificate dated 29-12-2023
	Evaluation	1. Submit API specifications and analytical method from API manufacturer . 2. API manufacturer specifies assay limit NLT 795ug/ml of ceftriaxone on anhydrous basis, while you have adopted limit NLT 776ug/ml of ceftriaxone. Justify how you can adopt different limits from that specified by API manufacturer, 3. As per API specifications the standard solution concentration is 0.3mg/ml while in verification studies the linearity and specificity studies are performed at 0.01mg/ml which is entirely a different concentration . Justify how your verification / validation studies are applicable on your method. 4. Submit API real time stability study data till the claimed / complete shelf life. Since only 1 year stability data is provided. 5. Clarify how 1276.8mg per vial is equivalent to 1g ceftriaxone base 6. Submit compatibility studies result in 3.2.P.2.6 7. USP specifies two different type of assay test for the drug product while you have only performed one test in drug product. Clarification is required in this regard. 8. Clarify your sample solution preparation method without any detail of reconstitution and further dilutions. Provide complete elaborative method of sample preparation. 9. Drug product sample and standard solution concentration is 0.3mg/ml while linearity test is performed at concentration range from 0.040 to 0.060mg/ml. Justify how you have developed this verification study protocol. 10. Clarify why the calculation formula for assay test in your method and raw data sheets of stability studies vare diferent from that specified by USP. 11. In your various HPLC chromatogram, the time for date acquired and date processed is moved in another row and gets out of the sample information box, which is not possible in HPLC Empower 2 software. Clarification is required in this regard. 12. Submit in-use stability studies
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
109	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RSP-ZH9-D9ZV, 2024-08-31)
	Detail of Fee Submitted	30000.0, 2024-08-30,
	The proposed proprietary name / brand name	**Fexo 1800mg Tablet**
	Label Claim	Each film-coated tablet containsFexofenadine HCl 180mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	ALLERY RELIEF 180 MG FILM-COATED TABLETS of M/s CVS Pharmacy Inc. (USFDA Approved)
	For generic drugs (me-too Status)	Fexet 180mg Tablet of M/s Getz Pharma
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section
	Name & address of API manufacturer	Vasudha Pharma Chem Limited Add: Unit II, Plot No. 79, J.N.Pharma City, Parawada, Visakhapatnam- 531021 Andhra Pradesh, INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Allery Relief Tablet: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 2500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Wimits loan letter 03-10-2023 and clearance certificate dated 14-11-2022
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm: 2. Submit details including batch number, expiry date and manufacturer of the product against which PE and CDP studies are performed Manufacturer Name: Getz Pharma (Pvt) Limited Brand Name & Strength: FEXET (Fexofenadine HCl) tablet 180mg Registration # 029436 Batch# 25FE021 MFG. 05-2023 EXP 04-2025
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
110	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(S6J-7AQ-MQ1V, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-09-19,
	The proposed proprietary name / brand name	**ITOSET 50MG TABLET**
	Label Claim	Each film coated tablet contains: Itopride HCl.....50mg
	Pharmacotherapeutic Group of (API)	Gastroprokinetic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	PMDA Japan
	For generic drugs (me-too Status)	Ganaton Tablet of abbott
	Proposed Pack Size	3*10-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	AMI Life Sciences PVT LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Regasta Tablet of Getz Pharma
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Justify why HPLC as well as UV method has been specified for assay test of the drug product. This method has been adopted to test the Drug Product because it is a validated as per ICH guidelines parameters.the result are accurate precise and repeatable as provided data attached. 5. Submit verification studies of the analytical method of drug product in section 3.2.P.5.3 Submitted by the firm 6. Submit evidence of procurement of API. Not Submitted 7. Submit stability study data along with analytical record. Submitted by the firm
	Shortcoming	
	Decision	Deferred for submission of evidence of procurement of drug substance.

Sr. No	Title	Description
111	Name, address of Manufacturing site.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar**(000995)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RXT-NTT-RW5P, 2024-12-22)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Levset P 25mg Tablet**
	Label Claim	Each Tablet Contain: Levosulpiride.....25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	AIFA Italy Approved
	For generic drugs (me-too Status)	Nexpride Tablet by Medicraft
	Proposed Pack Size	20s-As per SRO
	GMP status of the firm	New DML Issued dated 10-05-2024
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 10-05-2024 specifies Tablet (General) and Capsule (General) section
	Name & address of API manufacturer	Altas Life Science Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Sulvorid Tablet of High Q
	Detail of stability batches of drug product	3 batches having batch size of 2000 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter and invoice from Aries pharma is submitted.
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. Submitted by the firm 3. Submit COA of relevant batch of API from API manufacturer as well as Steris Pharma in section 3.2.S.4.4. Submitted by the firm 4. Justify why UV method has been adopted for assay test of the drug product. This method has been adopted to test the Drug Product because it is a validated as per ICH guidelines parameters.the result are accurate precise and repeatable as provided data attached. 5. Submit GMP certificate of API manufacturer Submitted by the firm 6. Submit evidence of procurement of API. Loan letter and invoice from Aries pharma is submitted.
	Shortcoming	
	Decision	Deferred Firm shall submit drug product stability studies at the next time point of long term stability studies on the basis of HPLC method along with analytical method validation studies of the HPLC based method.

Sr. No	Title	Description
112	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(U4T-U4S-3BZZ, 2024-10-09)
	Detail of Fee Submitted	30000.0, 2023-12-20,
	The proposed proprietary name / brand name	**Amoxi 1000mg Tablet**
	Label Claim	Each film coated tablet contains:Ammoxicillin trihydrate eq. to Amoxicillin.....875mg, Potassium clavulanate eq. to Clavulanic acid....125mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Augmentin 1000mg Tablet USFDA Approved
	For generic drugs (me-too Status)	Augmentin 1000mg Tablets of M/s GSK Pakistan
	Proposed Pack Size	As per SRO / DPC-As per SRO
	GMP status of the firm	New DML Issued dated 18-09-2023
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 18-09-2023 specifies Tablet (Penicillin) Section
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd Add: C-7/1, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.,Zhuhai United Laboratories Co., Ltd. Add: No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong - 519040, P.R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Amoxicillin: 3 batches as per Zone IV-A Potassium Clavulanate: 3 Batches as per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Augmentin Tablet
	Detail of stability batches of drug product	3 batches having batch size of 1500 Tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted.
	Evaluation	Submit documents for procurement of API. Response: Firm has submitted loan letter and clearance certificate from Stallion pharma.
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
113	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(UQP-V4N-JDB8, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**Ceftrax 500mg I.V Dry Powder Injection**
	Label Claim	Each vial contains: Ceftriaxone as sodium.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA) Approved
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Proposed Pack Size	1x1 Vial-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder injection (Cephalosporin) section.
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefxone injection of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 833 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 16-11-2023 for 6kg ceftriaxone
	Evaluation	Submit in-use stability study data. Response: Submitted by the firm
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
114	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(UWW-N8T-JME7, 2024-08-01)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Wellsef 250mg/5ml oral suspension**
	Label Claim	Each 5ml (reconstituted) suspension contains:Cephradine (anhydrous) 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Velosef suspension by GSK
	Proposed Pack Size	60ml-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section
	Name & address of API manufacturer	Pharmagen Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefrinex suspension of Bosch: PE studies performed
	Detail of stability batches of drug product	3 batches: 132 bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 14-09-2023 for 15kg cefradine
	Evaluation	1. Submit compatibility studies of the product with recommended diluent. Response: Submitted by the firm 2. Clarify if your formulation contains cephradine anhydrous or cephradine monohydrate. Response: Cephradine anhydrous
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
115	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(V3M-ZUH-2R4S, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Rexilo 120mg Tablet**
	Label Claim	Each Film Coated Tablet contains:Relugolix.....120mg
	Pharmacotherapeutic Group of (API)	Gonadotropin-releasing hormone (GnRH) receptor antagonists
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ORGOVYX (relugolix) tablets 120mg of M/s Sumitomo Pharma America, Inc., Marlborough, MA 01752 (USFDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section & Tablet (Hormone) steroidal section dated 26-01-2024
	Name & address of API manufacturer	Lianyungang Jari Pharmaceutical Co., Ltd, Add: No. 18 Zhenhua Road, Lianyungang City, Jiangsu Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	ORGOVYX tablets: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1200 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Wimits dated 18-01-2024, and Drug Import License dated 16-01-2024
	Evaluation	Shortcomings 1. Clarify in which section, the manufacturing of this drug shall be carried out. Response: Manufacturing of this Drug shall be carried out in hormonal Tablet section. 2. Submit details including batch number, expiry date and manufacturer of the product against which PE and CDP studies are performed Product Name ORGOVYX (relugolix) tablets 120mg Manufacturer: Sumitomo Pharma America and Pfizer Inc. GTIN 00372974120016 Batch No.: S400219 Mfg Date: 09-2023 Expiry Date: 08-2025
	Shortcoming	
	Decision	Approved . Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drugs. Moreover, Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
116	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(X2A-EJN-JV3L, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**Cefimaf 200mg Capsule**
	Label Claim	Each Capsule contains: Cefixime as Trihydrate.....200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Suprax 200mg Capsule by Sanofi Aventis Spain Approved.
	For generic drugs (me-too Status)	Cefim Capsules of Hilton
	Proposed Pack Size	1x5-As per SRO
	GMP status of the firm	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Capsule (Cephalosporin) section.
	Name & address of API manufacturer	Citi pharma 3 kilometer, Head Balloki Road, Phool Nagar, Kasur-55050 Punjab Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefim Capsule: PE and CDP studies are performed
	Detail of stability batches of drug product	3batches: 4000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	14-10-2023 commercial invoice for 5kg cefixime
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
117	Name, address of Manufacturing site.	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi**(000947)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(Z9U-GPX-5PRS, 2024-09-24)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**JECTSOL-NS INFUSION (25ml)**
	Label Claim	Each ml of solution contains: Sodium chloride.....9mg
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	0.9% Sodium Chloride Injection (USFDA)
	For generic drugs (me-too Status)	Normal Saline 25ml solution by Otsuka
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML Issued dated 11-11-2021
	Evidence of approval of manufacturing facility	Issuance of DML letter dated 11-11-2021 specifies Liquid Injectable Infusion (SVP) LDPE General section and Liquid Injectable Infusion (LVP) LDPE General section
	Name & address of API manufacturer	Hebei Huachen Pharmaceuticals Group Co., Ltd Huanghua Economic Development Zone, Huanghua, Hebei, China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Plasaline Injection manufactured by Otsuka Pakistan Ltd
	Detail of stability batches of drug product	3 batches having batch size of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 02-11-2022 specifying 25000 Kg Sodium chloride
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
118	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ZGV-Z3W-187Q, 2024-10-08)
	Detail of Fee Submitted	30000.0, 2024-08-30,
	The proposed proprietary name / brand name	**Fexo 60mg Tablet**
	Label Claim	Each Film Coated Tablet contains:Fexofenadine HCl.....60mg
	Pharmacotherapeutic Group of (API)	Antihistamines
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	ALLERY RELIEF 60 MG FILM-COATED TABLETS of M/s CVS Pharmacy Inc. (USFDA Approved)
	For generic drugs (me-too Status)	Fexet 60mg Tablet of M/s Getz Pharma
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	New DML: 18-09-2023
	Evidence of approval of manufacturing facility	18-09-2023: Tablet (General) section
	Name & address of API manufacturer	Vasudha Pharma Chem Limited Add: Unit II, Plot No. 79, J.N.Pharma City, Parawada, Visakhapatnam- 531021 Andhra Pradesh, INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Allery Relief Tablet: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 2500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Wimits loan letter 03-10-2023 and clearance certificate dated 14-11-2022
	Evaluation	Shortcomings 1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Submitted by the firm 2. Submit details including batch number, expiry date and manufacturer of the product against which PE and CDP studies are performed Manufacturer Name: Getz Pharma (Pvt) Limited Brand Name & Strength: FEXET (Fexofenadine HCl) tablet 60mg Registration # 029434 Batch No. : 23FO024 MFG Date 06-23 Expiry Date 05-25
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
119	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(2A8-6T7-UAJY, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**Skycip 250mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Ciprofloxacin as HCl….250mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(MHRA Approved)
	For generic drugs (me-too Status)	Novidat 250mg/5ml Dry Powder for Suspension of M/s SAMI Pharma
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	GMP status of the firm	New License dated 18-09-2023
	Evidence of approval of manufacturing facility	Dry Powder Suspension Section
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited Add: 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data till 36 months is submitted for 03 batches under the conditions of zone IV-A.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies have been conducted against Ciproxin 250mg/5ml dry powder for suspension.
	Detail of stability batches of drug product	stability data of 3 batches till 6th month time point is submitted. (Batch size: 250 units)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter (10kg Ciprofloxacin HCl) from M/s Wimits Pharma dated 2nd December, 2023 is submitted.
	Evaluation	API manufacturer: Zenith Chemicals, Lahore API batch Number: 2CFX23/033 GMP certificate dated 24-09-2021 Shortcomings: In-use stability studies after reconstitution with the diluent. (submitted)
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
120	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(3WV-ZZH-HYZR, 2024-06-10)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	**Azysol 250mg Capsule**
	Label Claim	Each Capsule contains: Azithromycin as dihydrate.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	Zetro 250mgCapsule by M/sGetz Pharma (Private) Limited.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML dated 17-01-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	Ningxia Taiyicin Biotech Co., Ltd. 1 Pacific Road, Nuanquan Economic Zone, Helan county , Yinchuan, Ningxia China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	60 months stability data of 3 batches according to zone IV-A is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies submitted against the comparator's product Zetro tablet by M/s Getz Pharma (Batch:239C21)
	Detail of stability batches of drug product	stability data till 3rd month's time point is submitted for 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Wimits pharma is submitted
	Evaluation	Shortcomings: Please provide GMP certificate / Drug Manufacturing License of API manufacturer. Provide stability data till 6th month time point. Submitted Submit documents confirming procurement of API. submitted.
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
121	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(4ZG-Y8R-YE9H, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-12-18,
	The proposed proprietary name / brand name	**Skygab 50mg Capsule**
	Label Claim	Each Capsule Contains:Pregabalin 50mg
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Pregabalin Milpharm 50mg capsules of M/s Milpharm Limited, Ares Block, Odyssey Business Park, West End Road, Ruislip HA4 6QD, United Kingdom (MHRA Approved)
	For generic drugs (me-too Status)	Gabica Capsules 50mg of M/s Getz Pharma
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd., Add: Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches: PG120001, PG120002, PG120003
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence studies have been performed against Gabica 50mg Capsule by M/s Getz Pharna.
	Detail of stability batches of drug product	6 months stability study data for accelerated and real time is submitted. Batches: PS001, PS02, PS003 Batch size: 2500 tablets Date of manufacturing: 01-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not provided.
	Evaluation	API manufacturer: M/s CTX LifeSciences Pvt. Ltd. Block No. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat India issued by Food & Drugs Control Administration India. GMP Certificate No. 22063346 valid till 29-05-2025. API Batch Number 23L000006 The firm has not performed compatibility studies of excipients against API since the qualitative formulation is similar to the reference product. Shortcomings: Please provide documents confirming import of API. Submit detail of comparator's product (batch number, date of manufacturing etc) against which pharmaceutical equivalence and CDP have been performed. (Reply was received on 26th December, 2024)
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
122	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(5XR-7EX-XEA2, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**OME 20mg/1680mg Sachet**
	Label Claim	Each Sachet contains:Omeprazole .....20mgSodium bicarbonate .....1680mg(Innovator Spec's)
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Zegerid OTC 20mg/ 1680mg sachet, Manufacturer: Salix Pharmaceuticals, (: (Registered in USFDA)
	For generic drugs (me-too Status)	Risec Insta, Manufacturer: Getz Pharma
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Sachert General section is approved.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Omeprazole Batches: O/200605002, O/200605003, O/200605004 (60 months stability data according to zone IV-A), Sodium bicarbonate, Batch number: 150324-N.150324-A.150324-MSHC-082 (60 months stability data is submitted)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies have been performed against the comparator's product Risek 20+1680 Sachet by Getz Pharma (Batch: 852DA8)
	Detail of stability batches of drug product	3 months data is submitted, Batches: 24DT85, 24DT86, 24DT87 Batch size: 1500 sachet Date of manufacturing: 28/04/2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan from M/s Vision Pharma
	Evaluation	Omeprazole API manufacturer: Metrochem API private limited, Unit-IV, plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam (V), Parawada (M), Anakapalli district 531021, Andhra Pradesh, India, GMP certificate No. E-2242912/DD/DCA/VSP/2023 dated 01-12-2023 API batch Number: OME-P/23085 (Omeprazole) Sodium Bicarbonate: API manufacturer: Lucky Core Industries Khewra Dist. Jhelum. Batch number: 150324-N.150324-A.150324-MSHC-082 (60 months stability data is submitted) The drug product manufacturer has not performed compatibility studies since the formulation is the applied product is qualitatively similar to the reference product. Shortcomings: Documents confirming procurement of API. (submitted) Stability data till 6th month time point. (Submitted)
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
123	Name, address of Manufacturing site.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700**(000994)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(7TJ-8ZG-EXQV, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Neodexa**
	Label Claim	Each capsule contains: Delayed release pellets of Dexlansoprazole eq. to Dexlansoprazole.....30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Dexilant in USFDA
	For generic drugs (me-too Status)	Yes
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Capsule General Section is approved
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Limited, Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of 36 months is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence studies have been performed against Dextop by M/s Searle Pharma, Karachi (Batch:DRE063)
	Detail of stability batches of drug product	Stability data till 3rd month time point is submitted, Batches: T01, T02, T03 Batch size: 1500 Capsule Date of initiation of stability: 02-07-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not submitted,
	Evaluation	API manufacturer: M/s Vision Pharmaceuticals, Islamabad API Lot Number: DPL 1106 Shortcomings: Clarification is required since UV-spectrophotometric method is used for dissolution testing while HPLC method is developed for assay. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. Provide calculations for weight adjustment. 3 months stability data is submitted, please provide stability data till 6th months time point. Provide documents confirming procurement of API / pellets.
	Shortcoming	
	Decision	Deferred Clarification is required since UV-spectrophotometric method is used for dissolution testing while HPLC method is developed for assay. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. Provide calculations for weight adjustment. 3 months stability data is submitted, stability data till 6th months time point is required documents confirming procurement of API / pellets.

Sr. No	Title	Description
124	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(D3X-9RY-RDML, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-19,
	The proposed proprietary name / brand name	**NEWGAB**
	Label Claim	Each Hard Gelatin Capsule Contains:Pregabalin.....150mg
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Lyrica Capsule 150 mg® Hard Gelatin Capsule is Approved in USFDA.
	For generic drugs (me-too Status)	GABICA 150mg CAPSULE
	Proposed Pack Size	2x7's-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches: PG120001, PG120002, PG120003
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative dissolution profile in three different media and pharmaceutical equivalence by performing all the quality tests have been submitted against Lyrica Capsule 150mg (Batch: FY5662).
	Detail of stability batches of drug product	Detail of batches of FPP Batches: T001, T002, T003 Batch size: 1500 tablets Date of manufacturing: 02/05/2023, 03/05/2024, 04/05/2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	The firm has submitted copy of form 6 No. 3662 dated 22-12-2021 (Quantity: 3kg, Batch: PG213041), attested invoice number EX/RU/035/21-22 dated 22-11-2021.
	Evaluation	API manufacturer: M/s CTX LifeSciences Pvt. Ltd. Block No. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat India issued by Food & Drugs Control Administration India. GMP Certificate No. 22063346 valid till 29-05-2025. The firm has not performed compatibility studies of excipients against API since the qualitative formulation is similar to the reference product. Shortcomings: Provide Analytical method verification studies performed by drug product manufacturer. Provide certificate of analysis of the relevant batch of API from API manufacturer and drug product manufacturer used for product development. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Provide latest GMP inspection report.
	Shortcoming	
	Decision	Deferred Analytical method verification studies performed by drug product manufacturer. certificate of analysis of the relevant batch of API from API manufacturer and drug product manufacturer used for product development. specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. latest GMP inspection report.

Sr. No	Title	Description
125	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(DMZ-7J8-VRGQ, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-19,
	The proposed proprietary name / brand name	**NEWGAB**
	Label Claim	Each Hard Gelatin Capsule Contains:Pregabalin.....300mg
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Lyrica Capsule 300 mg® Hard Gelatin Capsule is Approved in USFDA.
	For generic drugs (me-too Status)	GABICA 300mg CAPSULE
	Proposed Pack Size	2x7's-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches: PG120001, PG120002, PG120003
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence is submitted aaginst the comparator's product i.e Gabica 300mg capsule by Getz Pharma.
	Detail of stability batches of drug product	Batches: T004, T005, T006 Batch size: 1500 tablets Date of manufacturing: 05/2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	The firm has submitted copy of form 6 No. 3662 dated 22-12-2021 (Quantity: 3kg, Batch: PG213041), attested invoice number EX/RU/035/21-22 dated 22-11-2021.
	Evaluation	API manufacturer: M/s CTX LifeSciences Pvt. Ltd. Block No. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat India issued by Food & Drugs Control Administration India. GMP Certificate No. 22063346 valid till 29-05-2025. The firm has not performed compatibility studies of excipients against API since the qualitative formulation is similar to the reference product. Shortcomings: Provide Analytical method verification studies performed by drug product manufacturer. Provide certificate of analysis of the relevant batch of API from API manufacturer and drug product manufacturer used for product development. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. Provide latest GMP inspection report. Provide complete module III.
	Shortcoming	
	Decision	Deferred Analytical method verification studies performed by drug product manufacturer. certificate of analysis of the relevant batch of API from API manufacturer and drug product manufacturer used for product development. specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. latest GMP inspection report. complete module III.

Sr. No	Title	Description
126	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(E1B-RSZ-1N88, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-12-18,
	The proposed proprietary name / brand name	**Skygab 300mg Capsule**
	Label Claim	Each Capsule contains:Pregabalin 300mg
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Pregabalin Milpharm 300mg capsules of M/s Milpharm Limited, Ares Block, Odyssey Business Park, West End Road, Ruislip HA4 6QD, United Kingdom (MHRA Approved)
	For generic drugs (me-too Status)	Gabica Capsules 300mg of M/s Getz Pharma
	Proposed Pack Size	1x5's, 1x6's, 2x7's,-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd., Add: Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches: PG120001, PG120002, PG120003
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence studies have been performed against Gabica 300mg Capsule by M/s Getz Pharna.
	Detail of stability batches of drug product	6 months accelarated and real time stability studies have been submitted. Batches: PW001, PW002, PW003 Batch size: 2500 tablets Date of manufacturing: 01-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	API manufacturer: M/s CTX LifeSciences Pvt. Ltd. Block No. 251-252 Sachin Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat India issued by Food & Drugs Control Administration India. GMP Certificate No. 22063346 valid till 29-05-2025. API Batch Number 23L000006 The firm has not performed compatibility studies of excipients against API since the qualitative formulation is similar to the reference product Shortcomings: Please provide documents confirming import of API. Reply: Firm has submitted loan letter form M/s Wimits Pharma along with clearance certificate issued to Wimits Pharma by DRAP I&E Office Submit detail of comparator's product (batch number, date of manufacturing etc) against which pharmaceutical equivalence and CDP have been performed. Submitted. Reply: Comparator's product (batch number, date of manufacturing etc) against which pharmaceutical equivalence and CDP have been performed are follows Brand Name & Strength: Gabica Capsules 300mg Manufacturer Name: Getz Pharma (Pvt) Limited Company Address: 29-30/27,Korangi Industrial Area karachi Composition: Each Capsule contains Pregabalin .....300mg Batch # 418C27 MFG 08-24 EXP 08-26 Registration: 047368
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon verification of loan letter.

Sr. No	Title	Description
127	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(EQ5-GJP-Z5BB, 2024-09-02)
	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	**Sopradex Capsule 30mg**
	Label Claim	Each capsule contains; Delayed release pellets of Dexlansoprazole eq. to Dexlansoprazole.....30mg(Innovator Specifications)
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 30mg delayed release capsules, Manufacturer:Takeda Pharmaceutical USA; Inc. (USFDA Approved)
	For generic drugs (me-too Status)	Razodex capsules 30mg, Manufacturer: Getz Pharma (Private) Limited
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Capsule General Section is approved
	Name & address of API manufacturer	M/s Vision Pharma
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	till 36 months
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and pharmaceutical equivalence are submitted against Razodex 30mg capsule by Getz Pharma (Batch: 095C47)
	Detail of stability batches of drug product	6 months stability data is submiktted. Batches: 24CT58, 24CT59, 24CT60 Batch size: 1500 capsule Date of manufacturing: 03-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API is procured from M/s Vision Pharma
	Evaluation	API manufacturer: M/s Vision Pharma Islamabad. API Lot Number- DLP1048 Shortcomings: HPLC method has been developed for assay but for dissolution testing, UV-spectrophotometric method has been used for analysis of pellets, please justify. HPLC method has been developed for assay but for dissolution testing, UV-spectrophotometric method has been used for analysis of finished drug product, please justify. Provide documents confirming procurement of API. Reply was received on 26th December, 2024.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
128	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(GRV-M7Z-QDLX, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**Skycip 125mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains:Ciprofloxacin HCl equivalent to Ciprofloxacin.....125mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(MHRA Approved)
	For generic drugs (me-too Status)	Novidat 125mg/5ml Dry Powder for Suspension by M/s SAMI Pharma
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	GMP status of the firm	New License dated 18-09-2023
	Evidence of approval of manufacturing facility	Dry Powder Suspension Section
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited Add: 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of 3 batches till 36 months is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies against Ciproxin for suspension 125mg/5ml is submitted.
	Detail of stability batches of drug product	Stability data of 3 batches is submitted till 6th month time point. (Batch size: 250 units)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter (10kg Ciprofloxacin HCl) from M/s Wimits Pharma dated 2nd December, 2023 is submitted.
	Evaluation	API manufacturer: Zenith Chemicals, Lahore API batch Number: 2CFX23/033 GMP certificate dated 24-09-2021 Short comings: In-use stability studies have not been provided.
	Shortcoming	
	Decision	Deferred for following: Clarification is required since CDP and PE studies are conducted against Ciproxin 125mg/5mL, 200mg/5ml and 500mg/5mL which is innovator's product and is developed as Ciprofloxacin (base) to be reconstituted with diluent (other than water). justification how CDP and PE studies have been conducted using dry powder for suspension containing Ciprofloxacin (base) which is not soluble in water. Provision of pictures of packs of ciproxin suspension along with the other details including manufacturer, invoice and batch number.

Sr. No	Title	Description
129	Name, address of Manufacturing site.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700**(000994)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(H35-78J-GNW1, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Esepro 20 mg Caspule or Neophazole 20 mg Capsule**
	Label Claim	Each capsule contains: yed realease capsule contains: delayed release pellets of Esomeprazole Magnesium as Esomeprazole.....20mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Nexium Capsule EMA UK (https://www.ema.europa.eu/en/documents/product-information/nexium-control-epar-product-information_en.pdf)
	For generic drugs (me-too Status)	Yes
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Capsule General Section is approved
	Name & address of API manufacturer	Pharmazone Lahore
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API stability data is submitted for 36months Batches: EEC-22-002, EEC-22-003, EEC-22-004
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP studies have been performed against Nexum 20mg capsule by M/s Getz Pharma (Batch:C01047)
	Detail of stability batches of drug product	3 months data is submitted, Batches: T01, T02, T03 Batch Size: 1500 capsules Date of manufacturing: 02-07-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	API manufacturer: M/s Pharma zone Chemicals (Pvt.) Limited Plot No. 37, Sunder Industrial Estate, Lahore Pakistan API batch number: EEC-22-248 shortcomings: Provide complete calculations for weight adjustment considering the submitted COA of pellets which contain Esomeprazole Magnesium as active ingredient. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. Provide stability data till 6th months' time point. Provide documents confirming procurement of pellets.
	Shortcoming	
	Decision	Deferred complete calculations for weight adjustment considering the submitted COA of pellets which contain Esomeprazole Magnesium as active ingredient. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. stability data till 6th months' time point. documents confirming procurement of pellets.

Sr. No	Title	Description
130	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(H3Z-65Q-5RBH, 2024-12-18)
	Detail of Fee Submitted	75000.0, 2024-12-17,
	The proposed proprietary name / brand name	**Skycip 500mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Ciprofloxacin as HCl.....500mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	GMP status of the firm	New License dated 18-09-2023
	Evidence of approval of manufacturing facility	Dry Powder Suspension Section
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited Add: 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data till 36 months is submitted for 3 batches according to the conditions of zone IV-A.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP an dPE studies have been conducted against Ciproxin.
	Detail of stability batches of drug product	stability data of 3 batches is submitted till 6 months. (Batch size: 250 units)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter (10kg Ciprofloxacin HCl) from M/s Wimits Pharma dated 2nd December, 2023 is submitted.
	Evaluation	API manufacturer: Zenith Chemicals, Lahore API batch Number: 2CFX23/033 GMP certificate dated 24-09-2021 Short comings: Please provide in-use stability studies for all the applied strengths. CDP and PE studies are conducted against Ciproxin 125mg/5mL, 200mg/5ml and 500mg/5mL which is innovator's product and is developed as Ciprofloxacin (base) to be reconstituted with diluent (other than water). Please justify how you have conducted the CDP and PE studies using dry powder for suspension containing Ciprofloxacin (base) which is not soluble in water. Provide pictures of packs of ciproxin suspension along with the other details including manufacturer, invoice and batch number.
	Shortcoming	
	Decision	Deferred Clarification is required since CDP and PE studies are conducted against Ciproxin 125mg/5mL, 200mg/5ml and 500mg/5mL which is innovator's product and is developed as Ciprofloxacin (base) to be reconstituted with diluent (other than water). justification how CDP and PE studies have been conducted using dry powder for suspension containing Ciprofloxacin (base) which is not soluble in water. Provision of pictures of packs of ciproxin suspension along with the other details including manufacturer, invoice and batch number.

Sr. No	Title	Description
131	Name, address of Manufacturing site.	**himark laboratories (pvt.) Ltd** 37-A sundar industrial estate lahore**(000909)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(J47-1UY-SP8E, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-08-19,
	The proposed proprietary name / brand name	**PGL-300 300mg Capsule**
	Label Claim	Each capsule contains: Pregabalin 300 mg
	Pharmacotherapeutic Group of (API)	Anti-convulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Gabica 300mg Capsule
	Proposed Pack Size	2x7-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Tablet (General & General Anti-biotic) Section is approved.
	Name & address of API manufacturer	Almelo Pvt. Ltd., Unit-II Survey Nos: 227,228 & 137,136, Sabashpally, Shivampet(M), Medak District-502334,Telangana,India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	PI Stability studies: 6months accelerated and 60 months real time according to the conditions of zone IV-A. Batches: PEF/H/18/0003, PEF/H/18/0004, PEF/H/18/0005
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The studies have been performed against Gabica Capsule by Getz Pharma.
	Detail of stability batches of drug product	6 months accelerated and real time stability data is submitted, Batches: T-101, T-102, T-103 Batch size: 1500 capsule Manufacturing date: 01/2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate No. E-6715544444716 dated 20-09-2023 is submitted.
	Evaluation	API manufacturer: Almelo Pvt. Ltd., Unit-II Survey Nos: 227,228 & 137,136, Sabashpally, Shivampet(M), Medak District-502334,Telangana,India GMP certificate No. 122351/TS/2023 valid till 29/06/2024. API Batch number SM1/E/23/0015 used for product development. Shortcomings: Please provide detail of the product i.t Gabica Capsule (batch number date of manufacturing) against which CDP and pharmaceutical equivalence are performed. Provide GMP inspection report of drug product manufacturer issued on the basis of inspection conducted in the last three years. Please submit differential fee of Rs. 7000/-. Provide COA of relevant batch used for product development by API manufacturer. The innovator has used starch, talc and lactose monohydrate in the formulation but you have not included lactose monohydrate in the formulation. Only starch and talc have been included in the formulation, please clarify. Analytical method verification studies performed by drug product manufacturer is not submitted. Reply was submitted on 31st December, 2024.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
132	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(NX7-7VX-VEEQ, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**OME 40mg/1680mg Sachet**
	Label Claim	Each Sachet contains:Omeprazole .....40mgSodium bicarbonate .....1680mg(Innovator Spec's)
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Omeprazole / sod. biocarbonate sachet 40mg/1680mg suspension by Strides Pharma, USFDA Approved
	For generic drugs (me-too Status)	Risec Insta 40mg/ 1680mg, Manufacturer: Getz Pharma
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Sachet general section is approved.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Batches: O/200605002, O/200605003, O/200605004 (60 months stability data according to zone IV-A), Batch number: 150324-N.150324-A.150324-MSHC-082 (60 months stability data is submitted)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies have been performed against the comparator's product Risek 40+1680 Sachet by Getz Pharma (Batch: 083DA9)
	Detail of stability batches of drug product	Batches: 24DT88, 24DT89, 24DT90 Batch size: 1500 sachet Date of manufacturing: 30/04/2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	loan letter from M/s Vision Pharma
	Evaluation	Omeprazole: API manufacturer: Metrochem API private limited, Unit-IV, plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam (V), Parawada (M), Anakapalli district 531021, Andhra Pradesh, India, The drug product manufacturer has not performed compatibility studies since the formulation is the applied product is qualitatively similar to the reference product. GMP certificate No. E-2242912/DD/DCA/VSP/2023 dated 01-12-2023 API batch Number: OME-P/23085 (Omeprazole) Sodium Bicarbonate: API manufacturer: Lucky Core Industries Khewra Dist. Jhelum. Batch number: 150324-N.150324-A.150324-MSHC-082 (60 months stability data is submitted) shortcomings: Provide documents confirming procurement of APIs. submitted Provide stability data till 6th month time point. submitted
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
133	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(PEZ-DES-4323, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**Azisky 200mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin as dihydrate.....200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	Zetro(Azithromycin) 200mg/5ml Powder for oral Suspension of M/s SAMI Pharma
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	GMP status of the firm	New License dated 18-09-2023
	Evidence of approval of manufacturing facility	Dry Powder Suspension Section
	Name & address of API manufacturer	Ningxia Qiyuan Pharmaceutical Co., Ltd., Add: No.1 Qiyuan Street, Wangyuan Industrial Area, Yinchuan, Ningxia, China. 750101
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data till 36 months is submitted under the conditions of zone IV-A for 3 batches.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies have been performed against Zetro for suspension by M/s Getz Pharma
	Detail of stability batches of drug product	Stability data of 3 batches till 6th month time point is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter (qty: 3kg) from M/s Wimits pharma Lahore dated 23-11-2024. Clearance certificate for M/s Wimits Pharma dated 13-06-2023.
	Evaluation	API Manufacturer: Ningxia Qiyuan Pharmaceutical Co., Ltd., Add: No.1 Qiyuan Street, Wangyuan Industrial Area, Yinchuan, Ningxia, China. GMP certificate No. NX20180003 valid till 16-04-2024 API Batch Number: 230107021
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
134	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(Q2S-QS5-PTWV, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Tacor Capsules 5mg**
	Label Claim	Each Capsule contains: Tacrolimus as Monohydrate……..5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	Inograf 5mg Capsules by Platinum Pharmaceuticalm (Pvt.) Ltd.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML dated 17-01-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	North China Pharmaceutical Huasheng Co., Ltd., No 8 Yangzai road, Shi Jia Zhuang, Economic & technological development zone, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data till 36 months according to the conditions of Zone IV-A is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies have been conducted against Inograf 5mg by M/s Platinum Pharma. (batch: 27)
	Detail of stability batches of drug product	stability data till 3rd month's time point is submitted for 03 batches.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from M/s Valor Pharmaceuticals is provided. Clearance certificate of M/s Valor Pharmaceuticals Islamabad dated 12-01-2024 is submitted.
	Evaluation	API manufacturer: North China Pharmaceutical Huasheng Co., Ltd., No 8 Yangzai road, Shi Jia Zhuang, Economic & technological development zone, China Drug production license No. Ji 20150151dated Aug 19, 2020 Shortcomings: Please provide complete stability data till 6 month's time point.
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
135	Name, address of Manufacturing site.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700**(000994)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(QMR-49G-283H, 2024-12-09)
	Detail of Fee Submitted	37000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Neodexa**
	Label Claim	Each capsule contains: Delayed release pellets of Dexlansoprazole eq to Dexlansoprazole....60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Dexilant in USFDA
	For generic drugs (me-too Status)	Yes
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Limited, Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data till 36 months is submittted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence studies have been performed against Dextop by M/s Searle Pharma, Karachi (Batch:FSE024)
	Detail of stability batches of drug product	Batches: T01, T02, T03 Batch size: 1500 Capsule Date of initiation of stability: 02-07-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not provided.
	Evaluation	API manufacturer: M/s Vision Pharmaceuticals, IslamaAPI Lot Number: DPL 1106 Shortcomings: Clarification is required since UV-spectrophotometric method is used for dissolution testing while HPLC method is developed for assay. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. Provide calculations for weight adjustment. 3 months stability data is submitted, please provide stability data till 6th months time point.
	Shortcoming	
	Decision	Deferred Clarification is required since UV-spectrophotometric method is used for dissolution testing while HPLC method is developed for assay. The acceptance criteria for r2 value mentioned in analytical method validation report is ≥0.99, please provide the reference. calculations for weight adjustment. 3 months stability data is submitted, stability data till 6th months time point is required

Sr. No	Title	Description
136	Name, address of Manufacturing site.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad.**(000860)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(S7A-T11-R9HQ, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-07-31,
	The proposed proprietary name / brand name	**Bilast 2.5mg/ml Oral Solution**
	Label Claim	Each ml of contains: Bilastine 2.5mg
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too Status)	N.A
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	GMP certificate No.F.3-7/2018 Addl.Dir(QA&LT-I)-66
	Evidence of approval of manufacturing facility	Liquid Syrup General Section was approved on 06-03-2024
	Name & address of API manufacturer	Metrochem API Private Limited , India.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability studies according to Zone IV-A of 3 batches for 24 months is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Ilaxten 2.5mg/mL oral solution
	Detail of stability batches of drug product	stsbility data of 3 batches till 3rd month time point is submitted. (Batch size 100bottles * 120mL)
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate (for 200grams Bilastine) dated 01-03-2024 is submitted issued in favor of M/s Seraph Pharmaceuticals, Islamabad.
	Evaluation	API manufacturer: Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India Batch: CUB-P/23012 GMP certificate dated 01-12-2023 Shortcomings: Provide analytical method validation studies performed by drug product manufacturer for drug substance. Please provide concentration of HCl used for pH adjustment since innovator has used specific percentage of HCl for the said purpose. Please provide detail of the product against which pharmaceutical equivalence is performed including batch number, manufacturer, approval status in RRA etc. Please justify the Accuracy and Recovery studies' results without considering / calculating RSD values for each concentration / dilution as intra-variable and inter-variable in analytical method validation studies for drug product. Justify the value of r2 since it can not be equal to 1 practically. Provide acceptance criteria and analytical record with complete calculations. Tests for Robustness parameter and Inter-day precision (reproducibility) have not been performed in analytical method validation studies for drug product. Please provide stability data till 6th month time point. (Reply has been received dated 1st Jan, 2025)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
137	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(U1U-7JG-X9QQ, 2024-09-30)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Renasev Tablets 400mg**
	Label Claim	Each Film coated tablet contains: Sevelamer HCl.....400mg
	Pharmacotherapeutic Group of (API)	Anti hyperphosphatemia
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Renavel Tablets of Genome Pharma
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML dated 17-01-2024
	Evidence of approval of manufacturing facility	17-01-2024, new DML issuance letter specifies Tablet (General) section
	Name & address of API manufacturer	Suleshvari Pvt. Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Renavel Hcl 400mg Tablets: PE and kinetic binding studies performed
	Detail of stability batches of drug product	3 batches: 1500 tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan from Seraph dated 08-01-2024, clearance certificate dated 24-10-2023
	Evaluation	
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
138	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(UY9-W75-LW8J, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**Azisky 100mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin as dihydrate.....100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too Status)	Genthro (Azithromycin) 100mg/5ml for oral Suspension of M/s Genix Pharma
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	GMP status of the firm	New License dated 18-09-2023
	Evidence of approval of manufacturing facility	Dry Powder Suspension Section
	Name & address of API manufacturer	Ningxia Qiyuan Pharmaceutical Co., Ltd., Add: No.1 Qiyuan Street, Wangyuan Industrial Area, Yinchuan, Ningxia, China. 750101
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API stability data till 48 months according to zone IV_A is submitted for 3 batches.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies have been conducted against Genthro suspension 100mg/5ml by M/s Genix Pharma.
	Detail of stability batches of drug product	Stability data till 6th month time point for 3 batches is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter (qty: 3kg) from M/s Wimits pharma Lahore dated 23-11-2024. Clearance certificate for M/s Wimits Pharma dated 13-06-2023.
	Evaluation	API Manufacturer: Ningxia Qiyuan Pharmaceutical Co., Ltd., Add: No.1 Qiyuan Street, Wangyuan Industrial Area, Yinchuan, Ningxia, China. GMP certificate No. NX20180003 valid till 16-04-2024 API Batch Number: 230107021
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
139	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(X1H-YV1-8E24, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	**Sopradex Capsule 60mg**
	Label Claim	Each capsule contains; Delayed release pellets of Dexlansoprazole eq. to Dexlansoprazole.....60mg(Innovator Specifications)
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 60mg delayed release capsules, Manufacturer: Takeda Pharmaceutical USA; Inc. (USFDA Approved)
	For generic drugs (me-too Status)	Razodex capsules 60mg, Manufacturer:Getz Pharma (Private) Limited
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Capsule General Section is approved
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted till 36 months
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and Pharmaceutical equivalence studies have been performed against Razodex 60mg capsule by Getz Pharma.
	Detail of stability batches of drug product	6 months stability data is submitted. atches: 24CT61, 24CT62, 24CT63 Batch size: 1500 capsule Date of manufacturing: 03-2024
	Documents for the procurement of API with approval from DRAP (in case of Improt)	M/s Vision Pharma (invoice is submitted)
	Evaluation	API / Pellets manufacturer: M/s Vision Pharmaceuticals, Islamabad. API Lot Number- DLP1048 Shortcomings: HPLC method has been developed for assay but for dissolution testing, UV-spectrophotometric method has been used for analysis of pellets, please justify. HPLC method has been developed for assay but for dissolution testing, UV-spectrophotometric method has been used for analysis of finished drug product, please justify. Provide documents confirming procurement of API. Reply is submitted.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
140	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(X5Z-TNY-JPBL, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Renasev Tablets 800mg**
	Label Claim	Each Film coated tablet contains:Sevelamer HCl.....800mg(Innovator Spec's)
	Pharmacotherapeutic Group of (API)	Anti hyperphosphatemia
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Renavel Hcl Tablets 800mg, Manufacturer: AMP Pharma (Pvt.) Ltd.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New DML dated 17-01-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Name & address of API manufacturer	Suleshvari Pvt. Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	API Stability data according to the conditions of zone VI-A is submitted for the following batches till 60months for real time and 6months for accelerated stability studies. Batches:1)SVMH/FP/10/001 2)SVMH/FP/10/002 3) SVMH/FP/10/003
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted including the test for phosphate binding against the reference product Renavela 800mg tablet
	Detail of stability batches of drug product	stability data of 3 batches is submitted till 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan from Seraph dated 08-01-2024, clearance certificate dated 24-10-2023
	Evaluation	API manufacturer: Suleshvari Pvt. Ltd, India
	Shortcoming	
	Decision	Approved Registration letter will be issued after verification of loan letter.

Sr. No	Title	Description
141	Name, address of Manufacturing site.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad.**(000860)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(YU3-VTJ-VQR8, 2024-09-18)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Sucraph 1g/5ml Oral Suspension**
	Label Claim	Each 5ml suspension contains: Sucralfate 1g
	Pharmacotherapeutic Group of (API)	Anti-ulcer / protectants
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	AIFA Italy Approved.
	For generic drugs (me-too Status)	Ulsanic 1g/5ml Suspension by Highnoon Laboratories Ltd
	Proposed Pack Size	1x1s-As per SRO
	GMP status of the firm	GMP certificate dated 11-11-2023 issued on the basis of inspection conducted on 11-10-2022
	Evidence of approval of manufacturing facility	New Section was approved on 06-03-2024
	Name & address of API manufacturer	Zhejiang Haisen Pharmaceutical Co., Ltd. Liushi Street, Dongyang City, Zhejiang Province, P.R. China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability of 3 batches according to zone IV-A is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Ulsanic oral suspension 1g/5mL.
	Detail of stability batches of drug product	stability of 3 batches till 6th month time point is submitted. Batch size: 100bottle * 200mL
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	Clarification regarding address of the API manufacturer is required since it is different in GMP certificate and submitted modules. Please provide detail of the product against which pharmaceutical equivalence is performed including batch number, manufacturer, approval status in RRA etc. Please justify the Accuracy and Recovery studies' results without considering / calculating RSD values for each concentration / dilution as intra-variable and inter-variable in analytical method validation studies for drug product. Justify the value of r2 since it cannot be equal to 1 practically. Provide acceptance criteria and analytical record with complete calculations. Tests for Robustness parameter and Inter-day precision (reproducibility) have not been performed in analytical method validation studies for drug product. Please provide stability data till 6th month time point. The loan letter is issued on the letter head of M/s Seraph Pharmaceuticals which is signed and stamped by MD, Seraph Phrmaceuticals, please clarify. Provide copy of clearance certificate as well. (Reply was received on 1st Jan, 2025)
	Shortcoming	
	Decision	Approved

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>142</td><td>Name, address of Manufacturing site.</td><td>Pharman Pharmaceuticals(Pvt)Ltd Khewat No.59,khatooni No. 114-120, Tehsil Wazirabad,District Gujranwala(000958)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(8GL-5Z7-MT2H, 2024-12-02)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-01-22,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Chlorpheniramine 4mg Tablet</td></tr>
<tr><td></td><td>Label Claim</td><td>Each uncoated tablet contains: Chlorphenamine Maleate ... 4mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>R06AB02: ANTIHISTAMINES FOR SYSTEMIC USE</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Chlorphenamine Maleate 4 mg Tablet, MHRA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Allergex Tablets 4mg of M/s NABIQASIM INDUSTRIES (PVT) LTD.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-De-Controlled,100's-De-Controlled,1000's-De-Controlled,20's-De-Controlled,200's-De-Controlled,30's-De-Controlled,50's-De-Controlled,500's-De-Controlled</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 30-05-2022</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Tablet Section (General) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and CDP conducted against Piriton tablets of M/s GlaxoSmithKline Pakistan Ltd.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 2000 Tablets each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 100gm API from Batala Pharma, Gujranwala along with DRAP I&E Clearance for Import of API has been submitted.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the Firm</th></tr>
<tr><td>01</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP Certificate valid till 31-12-2024 and copy of license retention valid till 31-12-2027 have been submitted.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>143</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(93W-A8P-B6U6, 2024-07-31)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-02,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>ALBET 2% Ophthalmic Ointment</td></tr>
<tr><td></td><td>Label Claim</td><td>Each gram ointment contains: Fusidic Acid (as Sodium Fusidate) ... 20mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>S01AA13: Anti-infectives, Antibiotics.</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Fucidin 20mg/g Ointment, MHRA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Fudic Ointment 2% of M/s Shaigan Pharmaceuticals.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Cream/Ointment/Gel/Lotion Section (General / Steroid) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence conducted against Fudic Ointment 2% of M/s Shaigan Pharmaceuticals have been submitted.
CDP not applicable.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 1Kg each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 1Kg API from Global Pharma, Islamabad along with Clearance documents for import of API by Global Pharma, Islamabad have been submitted.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following shortcomings / deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Firm have again submitted certificate from an Industry Association.</td></tr>
<tr><td>2.</td><td>In Stability Study Data Sheets Container Closure has been mentioned as 'Plastic Tube'. Please mention details of container closure, specifically the material of construction.</td><td>Firm have submitted that Plastic laminated aluminum tubes are used for packing of Albet Ointment 2% w/w.</td></tr>
<tr><td>3.</td><td>Furthermore, please provide evidence of Innovator's Formulation being packed in Plastic Tubes.</td><td>Firm have referred to “Fudic ointment” manufactured by Shiagan pharmaceuticals.</td></tr>
<tr><td>4.</td><td>Please mentioned Batch Size in No. of units as well.</td><td>1kg (66 Tubes 15 gm each)</td></tr>
<tr><td>5.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Registration Letter will be issued after submission of valid GMP of API Manufacturer issued by relevant Regulatory Authority of country of origin.</td></tr>
</table>

Sr. No	Title	Description
144	Name, address of Manufacturing site.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur**(000977)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(BBN-2ZN-2WR2, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2024-03-22,
	The proposed proprietary name / brand name	**Friafen 100mg/5ml Oral Suspension**
	Label Claim	Each 5ml Oral Suspension contains: Ibuprofen ... 100mg (Orange flavor)
	Pharmacotherapeutic Group of (API)	M01AE01: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Ibuprofen 100mg/5ml Oral Suspension, MHRA approved.
	For generic drugs (me-too Status)	Brufen 100mg/5ml Oral Suspension of M/s Abbot Laboratories.
	Proposed Pack Size	1's (120ml)-As per SRO,1's (60ml)-As per SRO
	GMP status of the firm	New License w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Syrup Section (General) has been submitted.
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited Address: 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station, 1 kilometer of Chundrai Road Lahore - Pakistan. Fax: +92 42 35802251 Tel : +92 42 3580192
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Brufen 100mg/5mL Oral Suspension.
	Detail of stability batches of drug product	03 Batches, 41 Bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan agreement for 0.96Kg API from Novamed Pharma, alongwith copy of Invoice from Zenith Chemical Industries, Lahore has been submitted.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Dissolution Test has been conducted as mentioned in USP Monograph, however Comparative Dissolution Studies have not been conducted with Reference / Innovator / Comparator Product. Please justify. 2) Please provide valid GMP of API Manufacturer. 3) Please provide summary of quantities of FPP utilized and required for testing till the claimed shelf life. 4) Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.
	Shortcoming	
	Decision	Deferred Submission of response to the following deficiencies: - 1) Dissolution Test has been conducted as mentioned in USP Monograph, however Comparative Dissolution Studies have not been conducted with Reference / Innovator / Comparator Product. Please justify. 2) Please provide valid GMP of API Manufacturer. 3) Please provide summary of quantities of FPP utilized and required for testing till the claimed shelf life. 4) Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.

Sr. No	Title	Description
145	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(ETX-GZ6-S143, 2024-07-31)
	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	**ALBET 2% Cream**
	Label Claim	Each gm Cream Contains: Fusidic Acid 20mg
	Pharmacotherapeutic Group of (API)	D06AX01: Other antibiotics for topical use.
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Fucidin 20 mg/g Cream, MHRA approved.
	For generic drugs (me-too Status)	Fudic Cream 2% of M/s Shaigan Pharmaceuticals.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License w.e.f. 17-01-2024.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Cream/Ointment/Gel/Lotion Section (General / Steroid) has been submitted.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Fudic Cream 2% of M/s Shaigan Pharmaceuticals have been submitted. CDP not applicable.
	Detail of stability batches of drug product	03 Batches, 65 Tubes each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan agreement for 1Kg API from Global Pharma, Islamabad along with Clearance documents for import of API by Global Pharma, Islamabad have been submitted.
	Evaluation	Following shortcomings / deficiencies have been communicated to the applicant: 01) Please provide valid GMP of API Manufacturer issued by Regulatory Authority of Country of Origin. The enclosed copy is from an Industry Association. 02) In Stability Study Data Sheets Container Closure has been mentioned as 'Plastic Tube'. Please mention details of container closure, specifically the material of construction. 03) Furthermore, please provide evidence of Innovator's Formulation being packed in Plastic Tubes. 04) Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.
	Shortcoming	
	Decision	Approved Registration letter will be issued after submission of the following: 1. Valid GMP of API Manufacturer issued by Regulatory Authority of Country of Origin 2. Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>146</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(ESG-TV6-HGWP, 2024-07-31)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-06-27,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Famodin 40mg/5ml Dry Suspension</td></tr>
<tr><td></td><td>Label Claim</td><td>Each 5ml of reconstituted suspension contains: Famotidine ... 40mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>A02BA03; H2-receptor antagonists</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Pepcid 40mg/5ml for oral suspension, USFDA **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Polypep 40mg/5ml Dry Suspension of M/s Wilson’s Pharmaceuticals Pvt. Ltd.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Dry Powder Suspension Section (General) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence conducted against Polypep 40mg/5ml Dry Suspension of M/s Wilson’s Pharmaceuticals Pvt. Ltd. has been submitted. CDP not applicable.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 100 Bottles each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 1Kg API from Alliance Pharma, Hayatabad has been submitted along with Clearance documents for import of API by Alliance Pharma, Hayatabad.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Container Closure has been mentioned as 'Plastic bottle'. Please mention details of container closure, specifically the material of construction.</td><td>Firm have submitted that HDPE bottle is used for packing of this product that is made from chemically resistant High density polyethylene (HDPE).</td></tr>
<tr><td>2.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Name of Product has been mentioned as Famodin 40mg/5ml Oral Suspension on various instances whereas the applied formulation is a dry suspension. please clarify.</td><td>Typographic error. The firm have submitted that the dosage form of applied product is dry powder for oral suspension.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Registration letter will be issued after submission of prescribed fee for Pre-registration variation.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>147</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(EVJ-5SV-9YD5, 2024-07-30)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-02,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>PERNIL 5% Lotion</td></tr>
<tr><td></td><td>Label Claim</td><td>Each ml Lotion contains: Permethrin ... 50mg (5% w/w)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>P03AC04: Antiparasitic, Scabicides.</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Could not be confirmed from USFDA</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>LOTRIX lotion of M/s GlaxoSmithKline Pakistan Ltd.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Cream/Ointment/Gel/Lotion Section (General/Steroidal) have been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone-IV by Drug Substance Manufacturer have been submitted.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence conducted against LOTRIX lotion of M/s GlaxoSmithKline Pakistan Ltd., have been submitted.
CDP not applicable.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 900grams each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Copy of Loan agreement for 0.3Kg API from Biogen Pharma, Rawat along with Clearance documents for Import of API by Biogen Pharma, Rawat have been submitted.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following shortcomings / deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid evidence of RRA status. The mentioned status could not be confirmed from USFDA Database.</td><td>Firm have submitted that Permethrin Lotion 5% w/v, manufactured by GSK, was approved in DRB M-336 page No. 479.
However, Permethrin 5% w/w Lotion could not be confirmed from MHRA.</td></tr>
<tr><td>2.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Firm have submitted that the GMP Certificate was valid at the time of procurement.</td></tr>
<tr><td>3.</td><td>The label claim has been mentioned as 'Each ml contains' as well 'Each gram contains' on separate instances of application dossier. Please justify.</td><td>Firm have submitted revised label claim as follows:
Each ml Contains: Permethrin ... 5%w/w</td></tr>
<tr><td>4.</td><td>Container Closure has been mentioned as 'Plastic bottle'. Please mention details of container closure, specifically the material of construction.</td><td>Firm have submitted that HDPE bottle is used for packing of this product that is made from chemically resistant High density polyethylene (HDPE).</td></tr>
<tr><td>5.</td><td>Batch size has been mentioned as 1Kg as well as 900grams on separate instances. Please justify. Also mention batch size in No. of units.</td><td>900grams (15 Bottles 60 ml each)</td></tr>
<tr><td>6.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Submitted.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Deferred
Submission of response to the following deficiencies: -

1. Evidence of approval of RRA for Permethrin 5% w/w Lotion.
2. Valid GMP of API Manufacturer.
3. Clarification of Label claim, whether w/w or w/v.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>148</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(GS9-ZU6-YZN8, 2024-08-26)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-07-02,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Pernil Cream 5% w/w</td></tr>
<tr><td></td><td>Label Claim</td><td>Each gm cream contains:Permethrin .....50mg(Innovators Spec.)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>P03AC04: Antiparasitic, Scabicides</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>ELIMITE 5% Cream, Topical, USFDA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Lotrix cream 5%, Manufacturer: GSK Pakistan Limited</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Cream/Ointment/Gel/Lotion Section (General / Steroid) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence conducted against LOTRIX 5% cream of M/s GlaxoSmithKline Pakistan Ltd. has been submitted. CDP not applicable.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 900grams each</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 0.3Kg API from Biogen Pharma, Rawat has been submitted along with Clearance documents for import of API by Biogen Pharma, Rawat.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Firm have stated that the GMP certificate was valid at the time of procurement.</td></tr>
<tr><td>2.</td><td>Please mention batch size in No. of units.</td><td>900gm (60 tubes, 15gm each)</td></tr>
<tr><td>3.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Submitted.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Registration letter will be issued after submission of valid GMP of API Manufacturer.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>149</td><td>Name, address of Manufacturing site.</td><td>Nagarsons Pharmaceuticals Pvt Ltd Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad(000927)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(GW9-MSN-G6AU, 2024-10-21)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-09-04,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>SEDOFEN FORTE 400mg/60mg TABLET</td></tr>
<tr><td></td><td>Label Claim</td><td>Each film coated tablet contains: Ibuprofen ... 400mg Pseudoephedrine hydrochloride ... 60mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>R01BA52: NASAL DECONGESTANTS FOR SYSTEMIC USE</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Lasynac Max Strength 400mg/60mg film coated tablets, MHRA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>ARINAC FORTE TABLETS of M/s Abbott Laboratories (Pakistan) Limited.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10,12,20,24-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 19-02-2021</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter for Tablet (Psychotropic) Section from Licensing Division has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and CDP conducted against Arinac forte Tablet</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 1500 Tablets each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Ibuprofen: Zenith Chemicals Lahore. Pseudoephedrine Hydrochloride: Alpha Chemicals Private Limited, Kasur.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies were communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>1.3.4 Valid Drug Manufacturing License (DML) of Manufacturer has not been enclosed in this section.</td><td>Submitted.</td></tr>
<tr><td>2.</td><td>1.3.5 Evidence of approval of manufacturing facility/Approved section from Licensing Authority has not been enclosed in this section.</td><td>Section approval letter from Licensing division has been submitted.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
150	Name, address of Manufacturing site.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur**(000977)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(PWV-LTB-L284, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-03-22,
	The proposed proprietary name / brand name	**Cezo 5mg/5ml Oral Solution**
	Label Claim	Each 5ml contains: Cetirizine HCl ... 5mg
	Pharmacotherapeutic Group of (API)	R06AE07: ANTIHISTAMINES FOR SYSTEMIC USE
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	ZYRTEC 5mg/5ml Oral Solution, USFDA **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*
	For generic drugs (me-too Status)	RIGIX 5mg/5ml ORAL SOLUTION of M/s
	Proposed Pack Size	1's (30ml) -As per SRO,1's(120ml)-As per SRO,1s(60ml)-As per SRO
	GMP status of the firm	New License w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Syrup Section (General) has been submitted.
	Name & address of API manufacturer	Supriya Lifesciences Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against RIGIX 5mg/5ml ORAL SOLUTION.
	Detail of stability batches of drug product	03 Batches, 41 Bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan agreement for 0.025Kg API from Novamed Pharma, along with copy of DRAP I&E Clearance has been submitted.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Please provide valid GMP of API Manufacturer. 2) Please provide summary of quantities of FPP utilized and required for testing till the claimed shelf life. 3) Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point. 4) Loan has been obtained for 0.025Kg material from Novamed Pharma. The quantity was imported for Test/analysis purpose by Novamed Pharma. Please justify whether & why the material was not utilized by Importer for its own test/analysis.
	Shortcoming	
	Decision	Deferred Submission of response to the following deficiencies: - 1) Please provide valid GMP of API Manufacturer. 2) Please provide summary of quantities of FPP utilized and required for testing till the claimed shelf life. 3) Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point. 4) Loan has been obtained for 0.025Kg material from Novamed Pharma. The quantity was imported for Test/analysis purpose by Novamed Pharma. Please justify whether & why the material was not utilized by Importer for its own test/analysis.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>151</td><td>Name, address of Manufacturing site.</td><td>Pharman Pharmaceuticals(Pvt)Ltd Khewat No.59,khatooni No. 114-120, Tehsil Wazirabad,District Gujranwala(000958)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(QQS-M15-1D81, 2024-12-02)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-06-10,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Nimesulide Tablets 100mg</td></tr>
<tr><td></td><td>Label Claim</td><td>Each tablet contains: Nimesulide ... 100mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>M01AX17: Other anti-inflammatory and antirheumatic agents, non-steroids.</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Could not be confirmed from USFDA, EMA, MHRA and HPRA (Ireland).</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Nimside Tablets 100mg of M/s NovaMed Pharmaceuticals (Pvt.) Ltd.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>10's-De-Controlled,100's-De-Controlled,20's-De-Controlled,30's-De-Controlled</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 30-05-2022</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Tablet Section (General) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and CDP conducted against Nimside Tablets 100mg of M/s NovaMed Pharmaceuticals (Pvt.) Ltd.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 2000 Tablets each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 1Kg API from Novamed Pharma, Lahore has been submitted along with DRAP I&E Clearance for Import of API.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP Certificate of API Manufacturer valid till 06 Sep 2025 have been submitted.</td></tr>
<tr><td>2.</td><td>1.5.5 Pharmacotherapeutic Group of API has been mentioned as Drugs for Constipation. Please justify with supporting evidence.</td><td>Typographic error.
Firm have stated that Pharmacotherapeutic group is mistakenly mentioned, correct one is Cox-2 selective NSAID.</td></tr>
<tr><td>3.</td><td>Please provide evidence of RRA status.</td><td>Firm have referred to decision of 339th Meeting of Registration Board.
https://www.ema.europa.eu/en/medicines/human/referrals/nimesulide-1</td></tr>
</table>
Registration Board in its previous meetings have approved the applied formulations of Nimesulide Tablets 100mg with a pack size of 15 tablets only for the clinical indications (Treatment of acute pain, Primary dysmenorrhea) as a second line choice).</td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size for 15days as per recommendations of EMA only for the following clinical indications as a second-line choice:
a) Treatment of acute pain
b) Primary dysmenorrhea</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>152</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(XZJ-2WX-4WUJ, 2024-10-30)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-08-28,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Ciprocin 250mg/5ml Dry Suspension</td></tr>
<tr><td></td><td>Label Claim</td><td>Each 5ml reconstituted Suspension contains: Ciprofloxacin ... 250mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>J01MA02: Fluoroquinolones</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>CIPRO 250mg/5ml Dry Suspension, USFDA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Novidat 250mg/5ml Dry Suspension of M/s Sami Pharmaceuticals</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Dry Powder Suspension Section (General) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and CDP conducted against Novidat 250mg/5ml Dry Suspension of M/s Sami Pharmaceuticals have been submitted.</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 200 Bottles each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Local purchase from M/s Surge Laboratories.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Firm have stated that the GMP Certificate was valid at the time of procurement.</td></tr>
<tr><td>2.</td><td>Please provide details of diluent accompanying Dry Suspension for reconstitution.</td><td>Firm have referred to decision of 331st Registration Board Meeting.</td></tr>
<tr><td>3.</td><td>Please provide in-use stability studies (after reconstitution).</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Deferred
1. Submission of valid GMP of API Manufacturer.
2. Deferred for further deliberation regarding the requirement of diluent for reconstitution.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>153</td><td>Name, address of Manufacturing site.</td><td>Solaris Life Sciences Private Limited, Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(YEM-2QH-HLBZ, 2024-09-26)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-08-13,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Ripple 10mg/ml Powder for Oral Suspension</td></tr>
<tr><td></td><td>Label Claim</td><td>Each ml of reconstituted oral suspension contains: Sildenafil (as citrate) ... 10mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Phosphodiesterase (PDE) inhibitors</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Revatio 10 mg/ml powder for oral suspension, MHRA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Could not be confirmed</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 17-01-2024.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Dry Powder Suspension Section (General) has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence conducted against Revatio 10mg/ml Oral Suspension</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 100 Bottles each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Loan agreement for 1.5Kg API from Novamed Pharma, Lahore along with DRAP I&E Clearance for Import of API has been submitted.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP certificate of API Manufacturer (M/s Rakshit Drugs Pvt Ltd.) valid until 06-01-2025 have been submitted.</td></tr>
<tr><td>2.</td><td>Composition has been mentioned throughout application dossier as 'Sildenafil citrate 10mg'. Please clarify.</td><td>Typographic error.
Firm have submitted that the Composition of Sildenafil Dry suspension is Sildenafil citrate equivalent to Sildenafil 10mg / ml as mentioned in batch formula and Batch manufacturing record i.e. Sildenafil citrate 14.05 mg equivalent to sildenafil 10 mg. However, at different intense it is mentioned 'Sildenafil citrate 10mg' mistakenly.</td></tr>
<tr><td>3.</td><td>3.2.P.7 Container Closure System: It has been mentioned that 'Ripple 10mg/ml Powder for Oral Suspension is packed in alu alu blister. Blister is packed in a printed carton along with leaflet'. Furthermore, specifications of Printed Aluminum Foil have also been provided. Please clarify.</td><td>Typographic error.
Firm have submitted that the Sildenafil Dry suspension is filled in Amber color glass bottle. In Module-III 3.2.P.7 Container Closure System, details of Ripple Tablets (sildenafil tablets) are provided mistakenly.</td></tr>
<tr><td>4.</td><td>Finished Product Specifications and Analytical Method have been claimed as per USP. Whereas the available USP Monograph is for 'Sildenafil Compounded Oral Suspension'. Please justify with supporting evidence.</td><td>Firm have submitted that the Specification of finished product was initially adopted according to the USP monograph, as the analytical method in USP Monograph for Sildenafil Citrate (API) and monograph of British pharmacopeia Sildenafil Suspension (Product) is same. The Specification of finished product is revised according to the British Pharmacopeia and the Stability studies of 6 month time point performed according to the analytical method of British pharmacopeia. Revised specifications / analytical method is enclosed in revised module-III 3.2.P.5.1 and stability studies of 6 month time point in 3.2.P.8.3 for consideration.</td></tr>
<tr><td>5.</td><td>Please provide Stability Study Results / Calculation Data Sheet and Chromatograms / Audit Trails etc., for 06th Month Time Point.</td><td>Stability studies of 6 month time point according to the analytical method of British pharmacopeia is enclosed in revised Module-III 3.2.P.8.3.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
1. Approved with 'BP Specifications'.
2. Registration Letter will be issued after submission of prescribed fee for Pre-registration variation / correction of data.</td></tr>
</table>

Item No. VI. Additional Agenda
Registration Board 344 Meeting Additional/Supplementary Minutes:

Sr. No	Title	Description
1	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(275-WZB-N7LM, 2024-09-13)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Diclo-Wari Injection 75mg/3ml**
	Label Claim	Each 3ml ampoule contains:Diclofenac Sodium.....75mg
	Pharmacotherapeutic Group of (API)	M01AB05
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Voltarol Ampoules 75mg/3ml, solution for injection by Novartis Pharmaceuticals UK Limited
	For generic drugs (me-too Status)	Dicloran 75mg/3ml Injection by M/s Sami Pharmaceuticals
	Proposed Pack Size	5’s x 3ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	M/s AARTI DRUGS LIMITEDPlot No. G - 60, M.I.D.C., Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Voltral Injection Batch No. 6297
	Detail of stability batches of drug product	T055, T056, T057 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Amros
	Evaluation	Copies of executed BMR are not submitted. Submitted
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon verification of loan letter.

Sr. No	Title	Description
2	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(3AS-MZV-5E73, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-06-03,
	The proposed proprietary name / brand name	**Lawadox 40mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains:Cefpodoxime as Proxetil 40mg
	Pharmacotherapeutic Group of (API)	J01DD13
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Cefpodoxime Proxetil 40 mg/5 ml Powder for Oral Suspension by Sandoz GMBH Biochemistrasse 10 Kundl A6250, Austria
	For generic drugs (me-too Status)	Orelox 40mg/5ml Dry powder for suspension by M/s Sanofi Aventis Pakistan
	Proposed Pack Size	50ml-As per SRO
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Granted vide letter dated 31.10.2023
	Name & address of API manufacturer	M/s Covalent Laboratories Private Limited Survey No. 374, Gundla Machanoor Village Hathnoor (Mandal), Sangareddy (Dist) - 502 296 Telangana State, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	ORELOX 40MG/5ML DRY SUSPENSION Batch No. M3159 M/s Sanofi
	Detail of stability batches of drug product	T019, T020, T021 250 bottles Each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of clearance certificate attached. Taken Loan from M/s Convell Pharma
	Evaluation	Copies of BMR of trial batches are required. Firm has submitted the copies of BMRs 3.2.P.8: 3rd Time point stability data is not submitted. In-use stability Studies data is also required. Firm has submitted the required stability studies data.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with sign and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
3	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(3TE-R8E-DRNW, 2024-12-06)
	Detail of Fee Submitted	37000.0, 2024-10-17,
	The proposed proprietary name / brand name	**Aizomed 250mg Tablet**
	Label Claim	Each film coated tablet contains: Azithromycin Dihydrate Eq. To Azithromycin.....250MG (USP Specification)
	Pharmacotherapeutic Group of (API)	J01FA10
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Azitma 250mg Tablet (Sami Pharma) Reg. No. 074899
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	M/S Citi Pharmaceuticals (Pvt.) Limited, 3-KM Head Baloki Road Bhai Pheru Phool Nagar, Dist. Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azitma250mg Tab M/s Sami
	Detail of stability batches of drug product	3 batches, 1000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	Copies of BMRs of trial batches are required. Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
4	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(5J6-4QW-PHE8, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-09-16,
	The proposed proprietary name / brand name	**Meco-Wari 500mcg Injection**
	Label Claim	Each 1ml ampoule Contains:Mecobalamin....500mcg
	Pharmacotherapeutic Group of (API)	B03BA05
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	METHYCOBAL Solution for injection by Eisai Co. Ltd, 4-6-10 Koishikawa, Bunkyo-ku, Tokyo, Japan
	For generic drugs (me-too Status)	Cyno-12 Injection 500mcg/ml by M/s Aulton Pharmaceuticals
	Proposed Pack Size	10's (1ml) -As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	Mahima Life Sciences Pvt. Ltd. BST. Road, Ganaur-131101 Sonepat, Haryana (India)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Methycobal injection batch No. 3691
	Detail of stability batches of drug product	T058, T059, T060 1000 ampoule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Amros
	Evaluation	Copies of BMR of trial batches are not submitted. Submitted
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with sign and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
5	Name, address of Manufacturing site.	**Getz Pharma (Pvt.) Ltd. - (Unit I)** Plot No. 1, Sector 25, Korangi Industrial Area**(000933)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(5LH-Q9V-HW96, 2024-11-05)
	Detail of Fee Submitted	30000.0, 2023-12-22,
	The proposed proprietary name / brand name	**Cefoproxil Plus Powder for Oral Suspension 100mg/5mL**
	Label Claim	Each reconstituted 5mL contains:Cefpodoxime proxetil USP equivalent to Cefpodoxime.....100mg
	Pharmacotherapeutic Group of (API)	J01DD13
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Vantin Oral Suspension 100mg/5mL by /s Pharmacia & Upjohn Company division of Pfizer Inc., New York (USFDA approved)
	For generic drugs (me-too Status)	Cefpower Suspension 100mg/5ml (Reg. No.: 047178) by M/s Platinum Pharmaceuticals (Pvt.) Ltd..
	Proposed Pack Size	100mL-As per SRO,30mL-As per SRO,50mL-As per SRO,60mL-As per SRO,90mL-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	letter dated 27.02.2023
	Name & address of API manufacturer	Hubei Lingsheng Pharmaceutical Co. Ltd. 1, 10 Road, Xiangcheng economic development zone, xiangyang Hubei China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Prelox Plus DS batch No. R240278 M/s Bosch
	Detail of stability batches of drug product	3 batches. 2000 bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 is submitted.
	Evaluation	3rd time point stability data and in-use stability data is not submitted.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of following. 1. 3rd time point stability data 2. In-use stability data of reconstituted suspension

Sr. No	Title	Description
6	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(BPG-L6T-R96X, 2024-10-07)
	Detail of Fee Submitted	30000.0, 2024-09-03,
	The proposed proprietary name / brand name	**Amka-Wari 500mg/2ml Injection**
	Label Claim	Each 2ml ampoule contains:Amikacin as Sulphate.....500mg
	Pharmacotherapeutic Group of (API)	J01GB06
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Amikacin 250 mg/ml Injection Hospira UK Ltd, Walton Oaks, Walton-On-The-Hill, Dorking Road, Tadworth, Surrey, KT20 7NS, UK
	For generic drugs (me-too Status)	Grasil 500mg/2ml Injection by M/s Sami Pharmaceuticals
	Proposed Pack Size	5's x 2ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	Zhejiang Jinhua Conba Bio-pharm. Co., Ltd. No. 288, Jinqu Road, Jinhua City, Zhejiang Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Amkay injection Batch No. M986
	Detail of stability batches of drug product	3 batches, 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Safe Pharmaceuticals
	Evaluation	Copies of BMR of trial batches are not submitted. Submitted.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
7	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(EAN-V68-8AMW, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Ligno-Wari Injection**
	Label Claim	Each 2ml ampoule contains:Lignocaine hydrochloride (as Monohydrate).....20mg
	Pharmacotherapeutic Group of (API)	M01AB05
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Lidocaine Hydrochloride Injection B.P. 1.0% w/v by ADVANZ Pharma, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK
	For generic drugs (me-too Status)	Lignocaine 1% injection by M/s Surge Laboratories
	Proposed Pack Size	5's x 2ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	ALCON BIOSCIENCES PRIVATE LIMITED. A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	xylocaine 1% injection batch No. 6297
	Detail of stability batches of drug product	t061, t061, t063 1000 Ampoules Each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	AD attested invoice submitted. Taken loan from M/s Wimits Pharma
	Evaluation	Copies of BMR of trial batches are not submitted. Submitted. Manufacturer of reference product used in pharmaceutical equivalence is not mentioned. Xylocaine 1% injection Batch No. 6297 mfg by M/s Barret Hodgson Ltd.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
8	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(G17-Y4X-YWQA, 2024-12-20)
	Detail of Fee Submitted	30000.0, 2024-06-07,
	The proposed proprietary name / brand name	**Linzomed 100mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains;Linezolid.....100mg Innovator's Specifications
	Pharmacotherapeutic Group of (API)	J01XX08
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Barizold Suspension (Barrett Hodgson Karachi) Reg. No. 076343
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	Optimus Drugs Private Limited Unit-III, Survey No. 145A, 145/AA & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri (D), Talangana, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ecasil 100mg/5ml susp batch BUM003 M/s Sami
	Detail of stability batches of drug product	3 batches, 100 packs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Obsons
	Evaluation	Copies of BMR of trial batches are required. Submitted.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
9	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(JGU-WH7-B3HU, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	**Sanzol Capsule**
	Label Claim	Each capsule contains: Fluconazole.....150mg (BP Specification)
	Pharmacotherapeutic Group of (API)	J02AC01
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Diflucan Capsule (M/s Pfizer Pakistan Ltd) Reg. No. 011828
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	Raj Pioneer Laboratories (India) Pvt. Ltd. 94-A, 95-B & 96-A, Industrial area No.1, A.B. Road, Dewas
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diflucan 150mg cap Batch No. HN4526 M/s Pfizer
	Detail of stability batches of drug product	3 batches, 1500 caps each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Genesis Pharma Lahore
	Evaluation	AD attested invoice or Clearance certificate of drug substance is required. Submitted CDP and pharmaceutical equivalence studies are not submitted. Submitted Copies of BMR of trial batches are not submitted. Submitted
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
10	Name, address of Manufacturing site.	**Getz Pharma (Pvt.) Ltd. - (Unit I)** Plot No. 1, Sector 25, Korangi Industrial Area**(000933)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(JSJ-8GL-43YB, 2024-09-25)
	Detail of Fee Submitted	30000.0, 2023-12-22,
	The proposed proprietary name / brand name	**Cefoproxil Powder for Oral Suspension 40mg/5mL**
	Label Claim	Each reconstituted 5mL contains:Cefpodoxime proxetil equivalent to Cefpodoxime USP.....40mg
	Pharmacotherapeutic Group of (API)	J01DD13
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Vantin Oral Suspension 40mg/5mL by by M/s Pharmacia & Upjohn Company division of Pfizer Inc., New York (USFDA approved)
	For generic drugs (me-too Status)	Buticef Suspension 40mg/5ml (Reg. No.: 046055) by M/s Martin Dow Limited.
	Proposed Pack Size	100mL-As per SRO,25mL-As per SRO,40mL-As per SRO,50mL-As per SRO,60mL-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	letter dated 27.02.2023
	Name & address of API manufacturer	Hubei Lingsheng Pharmaceutical Co. Ltd. 1, 10 Road, Xiangcheng economic development zone, xiangyang Hubei China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Prelox DS batch No. R240209M/s Bosch
	Detail of stability batches of drug product	3 batches. 2000 bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 is submitted.
	Evaluation	3rd time point stability data and in-use stability data is not submitted.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of following. 1. 3rd time point stability data 2. In-use stability data of reconstituted suspension

Sr. No	Title	Description
11	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(L1B-TW6-B2G2, 2024-10-25)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**Lodal Injection**
	Label Claim	Each 2ml ampoule contains:Tramadol Hydrochloride.....100mg
	Pharmacotherapeutic Group of (API)	N02AX02
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Tramadol Hydrochloride 50mg/ml Solution for Injection or Infusion by Brown &Burk UK Ltd. 5 Marryat Close, Hounslow West Middlesex, TW4 5DQ United Kingdom
	For generic drugs (me-too Status)	Tonoflex Injection 100mg/2ml ampoule by Sami Pharma
	Proposed Pack Size	5's x 2ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	M/s LUCENT DRUGS PVT LTD Address: Sy No. 10, Gaddapotharam Village, Jinnaram Mandal, Sanga Reddy District, Telangana State, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tramal injection Batch No. 5693
	Detail of stability batches of drug product	T061, T062, T063 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	AD attested invoice submitted. Taken loan from M/s Caliph Pharma
	Evaluation	Copies of BMRs of trial batches are not submitted. SUBMITTED
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
12	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(Q3Q-DV2-HDN7, 2024-11-11)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Lawather 80mg/ml Injection**
	Label Claim	Each 1ml ampoule contains:Artemether.....80mg
	Pharmacotherapeutic Group of (API)	P01BE02
	Reference to Finished product specifications	The International Pharmacopeia
	The status in reference regulatory authorities	Artemether Injection 80mg/ml (PMDA Japan approved)
	For generic drugs (me-too Status)	Artem 80mg/ml Injection by M/s Hilton Pharmaceuticals
	Proposed Pack Size	1ml x 6's-As per SRO
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Granted vide letter dated 31.10.2023
	Name & address of API manufacturer	MICRO ORGO CHEM 57, C-1/B, GIDC, LIC Sector, Vapi, Gujarat, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Misomal Inj Batch No. 8691
	Detail of stability batches of drug product	T064, T065, T066 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of clearance certificate attached. Taken Loan from M/s Amros Pharma
	Evaluation	Copies of executed BMRs of trial batches are required. Submitted
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
13	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(QEM-TN9-G67M, 2024-12-06)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	**Medilox Tablet 400mg**
	Label Claim	Each film coated tablet contains:-Moxifloxacin Hydrochloride Eq. to Moxifloxacin.....400mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	J01MA14
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Moxiget 400mg Tablet (Getz Pharma) Reg. No. 047117
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	M/s Pharmagen Ltd. Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Avelox 400mg Batch No. ITA6258 M/s bayer
	Detail of stability batches of drug product	3 batches, 1000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	Copies of BMRs of Trial batches are required. SUBMITTED
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
14	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(RWN-QDS-9T19, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	**Getcip 500mg Tablet**
	Label Claim	Each film coated tablet contains:-Ciprofloxacin Hydrochloride Eq. to Ciprofloxacin.....500mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	J01MA02
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	CIPVAL 500mg Tablet (GSK) Reg. No. 050687
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ciproxin 500mg Batch No. ,BAC475 M/s Bayer
	Detail of stability batches of drug product	3 batches, 1000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	System Suitability is not performed as per procedure of USP monograph. Revised Analytical method is submitted that is as per USP monograph. Copies of BMRs of trial batches are not submitted. SUBMITTED
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of fee of Rs. 9000/- for pre-registration variation.

Sr. No	Title	Description
15	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(T1A-MT3-VJ5A, 2024-09-25)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	**Amka-Wari 100mg/2ml Injection**
	Label Claim	Each 2ml ampoule contains:Amikacin as Sulphate.....100mg
	Pharmacotherapeutic Group of (API)	J01GB06
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Amikin Injection 100 mg/2 ml by Bristol-Myers Squibb Pharmaceuticals uc
	For generic drugs (me-too Status)	Amikacin 100mg/2ml Injection by M/s Zafa Pharmaceuticals
	Proposed Pack Size	5's x 2ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	Zhejiang Jinhua Conba Bio-pharm. Co., Ltd, No. 288, Jinqu Road, Jinhua City, Zhejiang Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Amkay injection Batch No. 6297
	Detail of stability batches of drug product	3 batches, 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Safe Pharmaceuticals
	Evaluation	Copies of BMR of trial batches are not submitted. SUBMITTED
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
16	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(TP5-RD3-RAPN, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**AIZOMED 500MG TABLET**
	Label Claim	Each film coated tablet contains: Azithromycin Dihydrate Eq. To Azithromycin.....500mg (USP Specification)
	Pharmacotherapeutic Group of (API)	J01FA10
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Azithromycin 500mg Tablet MHRA Approved
	For generic drugs (me-too Status)	Azomax 500mg Tablet (AGP Pharma) Reg. No. 112798
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	M/S Citi Pharmaceuticals (Pvt.) Limited, 3-KM Head Baloki Road Bhai Pheru Phool Nagar, Dist. Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	azomax 500mg tab Batch No. SC5W
	Detail of stability batches of drug product	3 batches, 1000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	Copies of BMRs of Trial batches are not submitted. SUBMITTED
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
17	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(U7Z-VNH-SLV1, 2024-12-06)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**Aizomed 250mg Capsule**
	Label Claim	Each capsule contains: Azithromycin Dihydrate Eq. To Azithromycin.....250mg (USP Specification)
	Pharmacotherapeutic Group of (API)	J01FA10
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Azomax 250mg Capsule (AGP Pharma) Reg. No. 112797
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	M/s Citi Pharma Ltd. 3 Km Head Balloki Road, Phool Nagar, Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azomax 250mg batch C3191
	Detail of stability batches of drug product	3 batches, 1500 caps each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	In chromatograms submitted, the response signal is in AU (Absorbance Units), that is specific for UV/Vis detectors. As per USP monograph and the method of analysis submitted, Amperometric electrochemical detector is required, the output/ response signal of amperometric detectors is in form of current (microAmps or nano Amps). This indicate that proper detector has not been used for performance of any analysis, please clarify. Firm has submitted the reply as under; As we have HPLC with UV/Vis Detector so due to non-availability of Amperometric electrochemical detector with HPLC, we adopted USP Azithromycin Tablet Assay method with UV/Vis Detector response for finished product and Stability studies and also verified it.
	Shortcoming	
	Decision	Deferred The firm shall submit test results of trial batches on next stability time point as per the USP monograph of Azithromycin capsule, based upon the Amperometric electrochemical detector along with analytical method verification studies for the same method.

Sr. No	Title	Description
18	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(VLB-MSE-5311, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-09-30,
	The proposed proprietary name / brand name	**Linco-Wari 600mg/2ml Injection**
	Label Claim	Each 2ml ampoule contains:Lincomycin as Hydrochloride Monohydrate.....600mg
	Pharmacotherapeutic Group of (API)	J01FF02
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	LINCOCIN® Injection 600 mg/2 mL by Pharmacia & Upjohn Co, Division of Pfizer Inc, NY, NY 10017
	For generic drugs (me-too Status)	Lincocin 600mg/2ml Injection by Pfizer Ltd
	Proposed Pack Size	5's x 2ml-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	TOPFOND PHARMACEUTICAL CO.,LTD No.66 Jianshe Road, High -Tech Industrial Development District, Zhumadian City (China)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lincocin injection M/s pfizer
	Detail of stability batches of drug product	3 batches, 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Amros
	Evaluation	Copies of BMR of trial batches are required. Submitted. 3.2.P.5 & 3.2.P.8: The limit of Lincomycin B in USP monograph is that it should not be greater than 5%, same is mentioned in specifications of drug substance, the chromatograms submitted indicate presence of Lincomycin at concentration of around 40% in every sample, please justify. Reply: Firm has stated that USP defines limits of Lincomycin B in Raw material and same was checked by the API manufacturer and drug product manufacturer. However, in case of Lincomycin Injection USP neither defines the test of lincomycin B nor specifies its limits so lincomycin B test is not applicable. The response of firm is misleading as they have not submitted chromatograms of drug substance testing, Further USP monograph of Lincomycin Injection states under Assay; "Proceed as directed for Procedure in the Assay under Lincomycin Hydrochloride". In Lincomycin HCl injection monograph under Assay Procedure its mentioned that; "Separately inject equal volumes (about 20 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the areas for the major peaks. The relative retention times are about 0.5 for lincomycin B and 1.0 for lincomycin." Then Under heading of Limit of Lincomycin B in USP monograph its stated that; "Use the chromatogram obtained from the Assay preparation in the Assay: the area of the lincomycin B peak is not greater than 5.0% of the sum of the areas of the lincomycin B peak and the lincomycin peak. " USP monograph of product directs to the drug substance monograph for assay procedure, the substance monograph states that Chromatogram of Assay should be used to assess that Lincomycin B is less than 5%, Somehow Lincomycin B is around 40% in product, which indicates that Drug substance would also have around 40% Lincomycin B. Lincomycin B is a different chemical entity having one methyl group less than Lincomycin, so it's neither an enantiomeric impurity nor any small molecule that can be produced in manufacturing of drug product, being a chemical impurity having only 1 methyl group less than the drug substance means it's coming from the drug substance, indicating firm has used substandard drug substance if evaluated against USP monograph of Lincomycin Hydrochloride.
	Shortcoming	
	Decision	Rejected Keeping in view the fact that firm has used drug substance having impurity Lincomycin B more than prescribed limits in USP as evident from the chromatograms of drug product testing, the board rejected the application.

Sr. No	Title	Description
19	Name, address of Manufacturing site.	**Lawari international** Valley Road Gulkada saidu sharif Swat**(000658)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(YLA-E9D-7M4J, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-10-14,
	The proposed proprietary name / brand name	**Trize 250mg Injection IM**
	Label Claim	Each vial contains:Ceftriaxone as Sodium.....250mg
	Pharmacotherapeutic Group of (API)	M01AB05
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Rocephin 250mg Powder for Solution for Injection or Infusion by Roche Products Limited, UK
	For generic drugs (me-too Status)	Aventriax 250mg Injection by Sanofi-Aventis Pakistan Limited
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	New Section, 31.10.2023
	Evidence of approval of manufacturing facility	Copy of letter submitted
	Name & address of API manufacturer	SINOPHARMWEIQIDAPHARMACEUTICALCO.,LTD.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Aventriax 250mg Injection batch No. D7361 M/s Sanofi
	Detail of stability batches of drug product	T064, T065, T066 1500 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Nicholas
	Evaluation	Drug substance taken loan from Nicholas Pharmaceuticals. Copy of clearance certificate is submitted.
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
20	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(YTL-5RE-34ZY, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-06-07,
	The proposed proprietary name / brand name	**Linzomed 600mg Tablet**
	Label Claim	Each film coated tablet contains;Linezolid.....600mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	J01XX08
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Barizold 600mg M/s Barrett
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	Optimus Drugs Private Limited Unit-III, Survey No. 145A, 145/AA & 147,Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri (D), Talangana, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Barizold 600mg tablet batch No. D5990 M/s Barrett Hodgson
	Detail of stability batches of drug product	3 batches, 1000 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate submitted. Taken loan from M/s Obsons
	Evaluation	Copies of BMR of trial batches are not submitted. Submitted
	Shortcoming	
	Decision	Approved Letter shall be issued after submission of undertaking, from drug substance lender stating that they have given drug substance as loan to the drug product manufacturer, along with signed and stamped loan agreement and signed and stamped copy of clearance certificate/AD attested invoice of that specific batch.

Sr. No	Title	Description
21	Name, address of Manufacturing site.	**Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore**(000749)**
	Case Category	New Section (Adil Saeed)
	Application Form Dy. No / Tracking ID & date of submission	(YZA-Q2D-6RVQ, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**AIZOMED 200MG/5ML DRY SUSPENSION**
	Label Claim	Each 5ml of reconstituted suspension contains;Azithromycin Dihydrate Eq. to Azithromycin....200mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	J01FA10
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Azitma Suspension (Sami Pharma) Reg. No. 074902
	Proposed Pack Size	15ml-As per SRO
	GMP status of the firm	New Section.
	Evidence of approval of manufacturing facility	Letter dated 16.02.2023
	Name & address of API manufacturer	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azitma 200mg suspension Batch No. SM026 M/s Sami
	Detail of stability batches of drug product	3 batches, 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	NA (Local)
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
22	Name, address of Manufacturing site.	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore**(000563)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(21Z-1T9-1WVD, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-06-12,
	The proposed proprietary name / brand name	**Oncare 8mg**
	Label Claim	Each Film Coated tablet contains:Ondansetron HCL .2H2O equivalent to Ondansetron ……..8mg
	Pharmacotherapeutic Group of (API)	Anti emetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Zofran 8mg tablet by GSK
	Proposed Pack Size	10's-As per SRO,20's-As per SRO
	GMP status of the firm	28-08-2023 GMP certificate granted
	Evidence of approval of manufacturing facility	new tablet general section granted dated 16-12-2024 against the approval from CLB in its 290th meeting held on 28-04-2023 and subsequent correction by CLB in title of section in its 302 meeting dated 20-11-2024
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone II
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Onset tablet
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clerance certificat eissue din nam eof Shaigan pharma submitted along withloan letter form shaigan pharma in name of care pharmaceutical submitted
	Evaluation	Following shall be submitted: Drug substance stability data as per Zone IV conditions. Reply: Submitted Clarification regarding the wavelength applied for the performance of Asay test since it is not evident form submitted chromatograms. Reply: With Reference to your observation we want to present our clarification that during in process we did not check mark the wavelength option (as per system default setting) due to which in submitted chromatograms did not show the applied wavelength. Moreover in submitted method clearly mentioned the wavelength and method is validated and showing stable results at given wavelength. we will take care of this in future and request you to consider our application and approved the case we shall be very thankful to you for this act of kindness.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
23	Name, address of Manufacturing site.	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore**(000655)**
	Case Category	Any Other (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(2BD-S2Y-G5B7, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	**Sterile Solvent (0.9% Sodium Chloride w/v per ml) 10ml**
	Label Claim	Each Ampoule Contains: 0.9 % Sodium Chloride w/v per ml
	Pharmacotherapeutic Group of (API)	data including chromatograms
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Sodium chloride injection BP 0.9% w/v of M/s Hameln Pharma Ltd Nexus, Gloucester Business Park, Gloucester, GL3 4AG, UK approved by MHRA
	For generic drugs (me-too Status)	Celine of M/s Surge Laboratories (Pvt.) Ltd.
	Proposed Pack Size	1’s, 20’s, 50’s & 10-As per SRO
	GMP status of the firm	13-09-2023 GMP certificate issued.
	Evidence of approval of manufacturing facility	Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) general section granted on 01-05-2024. Previously firm has been granted Paentral (Liquid andlyophilized) section dated 31-01-2009
	Name & address of API manufacturer	Name: HUB-PAK SALT REFINERY Official Address: 10, Bangalore Town, Main Shahrah-e-Faisal, PO Box # 75350 Karachi, Pakistan Site Address: Site # 1 C-206, Industrial Trading Estate, Hub, Balochistan, Pa
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Surge product
	Detail of stability batches of drug product	3 batches of 300 ampoules, 2000 ampoules and 2000 ampoules
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Firm vide its letter no. nil dated 30-12-2024 has submitted as under: "We would like to bring in your kind notice that we are planning to manufacture Sterile Solvent “Sodium Chloride 0.9% w/v” for supply as Free of Cost “FOC” SOLVENT with our registered drug Esomega 40mg Injection (Reg#098037). In order to facilitate Free of Cost supply of Solvent with Esomega Injection, we are requesting to consider our below mentioned molecule as Priority Approval “Out of Queue” Consideration, during DRB Meeting No.344." For instant application firm has submitted source of drug substance as HUB-PAK SALT REFINERY Official Address: 10, Bangalore Town, Main Shahrah-e-Faisal, PO Box # 75350 Karachi, Pakistan Site Address: Site # 1 C-206, Industrial Trading Estate, Hub, Balochistan, for which firm has submitted certificate issued by Alberk QA technic Corp, Turkey, declaring that firm has implemented and maintained GMP approach as per PS 3844 general Principals of Food Hygeine covering 21 CFR part 110 manufacturing of Food and Pharmaceutical grade salt (NaCl), valid till 07-12-2026 The case is presented for consideration please
	Shortcoming	
	Decision	Approved Approved as diluent for Esomega injection (Reg#098037) on "Free of Cost" basis

Sr. No	Title	Description
24	Name, address of Manufacturing site.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore**(000530)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(2RW-ET2-3TWQ, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-15,
	The proposed proprietary name / brand name	**ANAC GEL 1%**
	Label Claim	Each gram of gel Contains: Diclofenac diethylamine 11.6mg equivalent to Diclofenac sodium...10mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Voltarol 1.16% Emulgel, gel by Haleon UK Trading Limited, The Heights, Weybridge, Surrey, KT13 0NY, UK (https://products.mhra.gov.uk/product/?product=VOLTAROL%201.16%25%20EMULGEL%20GEL
	For generic drugs (me-too Status)	Voltral Emulgel 1% by GlaxoSmithKline Consumer Healthcare Pakistan Limited (083991)
	Proposed Pack Size	20gm-As per SRO
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	New section of Cream/Ointment (General) granted on 29-02-2024)
	Name & address of API manufacturer	AARTI DRUGS LTD ,Plot No.G-60, MIDC, Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Votral Emulgel
	Detail of stability batches of drug product	3 batches of 4Kg each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted intimation letter dated 06-03-2024 regarding borroiwng of API form Fynk Pharma
	Evaluation	Following shall be submitted: Drug substance procurement document issued by DRAP in name of the firm form which loan has been taken. Reply: Firm has submitted clearance certificate issued in name of Fynk Pharma, by DRAP I&E office 6th month drug product stability data Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
25	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(2Y6-R6Q-1338, 2024-11-28)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Cipo-z 250mg Tablet**
	Label Claim	Cipo-Z 250mg TabletEach film coated tablet Contains: -Ciprofloxacin Hydrochloride eq. to Ciprofloxacin .....250mg (USP Specs).
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	CIPRO 250mg Tablet By US Food and Drug Administration approved
	For generic drugs (me-too Status)	Ciproquine 250mg Tablets by Macter International Limited.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	Carryfor Pharmaceuticals Pvt.Ltd. North Western Industrial Zone Port Qasim Bin Qasim Town, Karachi, Karachi City, Sindh
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Ciproquine tablet of M/s Macter
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Process validation protocol shall be submitted. Reply: Submitted • CD studies in 0.1N HCl buffer shall be submitted at minimum of three time points. Reply: CDP report submitted for 0.1NHCl dissolution medium • Analytical record for the dissolution test performed during drug product stability studies shall be submitted. Reply: Firm has submitted UV spectrums for the dissolution test • BMRs of drug product stability batches shall be submitted. Reply: Submitted for drug product stability batches.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
26	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(32S-4EW-P9M1, 2024-09-18)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Levo-Z 5mg tablet**
	Label Claim	Levo-Z 5mg Tablet Each film coated tablet Contains: - Levocetirizine Dihydrochloride.....5mg (USP Specification).
	Pharmacotherapeutic Group of (API)	antihistamine for systemic use
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	XYZAL 5mg Tablet By US Food and Drug Administration approved Co-marketed by Sanofi-Aventis.
	For generic drugs (me-too Status)	Neo Sedil 5mg Tablet by SAMI Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	METROCHEM API PRIVATE LIMITED Flat no 302,Bhanu Enclave,Sunder Nagar,Erragada Hyderabad-500 038 A.P.India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Neo Sedil tablet of M/s Sami
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Neutro Pharma by DRAP I&E Office, Lahore along with loan letter firm M/s Neutro in name of M.s Auspec.
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Drug substance stability study data shall be submitted as per Zone IV conditions. Reply: Submitted • Analytical record for the performance of dissolution test in drug product stability studies shall be submitted Reply: Submitted the UV spectrums
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
27	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(34J-1GU-1PZW, 2024-09-10)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Mirogab 15mg Tablet**
	Label Claim	Each Film Coated Tablet contains:Mirogabalin Besylate equivalent to Mirogabalin 15mg
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Tarlige Tablets 15mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd. Add: No.9a1,Tianheng Road, Gaoqing City, Shandong Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Tarlige tablet
	Detail of stability batches of drug product	3 batches of 900 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued in name of M/s Wimits pharmaceuticals dated 23-04-2024.
	Evaluation	Following shall be submitted: • BMR of drug product stability batches. Reply: Submitted for drug product stability batches • Valid GMP/DML of drug substance manufacturer issued by relevant regulatory authority. Reply: Copy of valid DML submitted • Drug substance stability data as per Zone IV conditions shall be submitted Reply: Submitted • Drug product stability data of 6th month time point shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
28	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(3JU-9ER-ZYLX, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Tacor Capsules 0.5mg**
	Label Claim	Each Capsule contains:Tacrolimus Monohydrate equivalent to Tacrolimus……..0.5mg(USP Specifications)
	Pharmacotherapeutic Group of (API)	Immunosuppressants
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Tacrolimus Capsules 0.5mg, USP, Manufacturer: Mylan Pharmaceuticals Inc. (NDA): 090596, USFDA Approved
	For generic drugs (me-too Status)	Tacgraf 0.5mg Capsules, Manufacturer: CCL Pharmaceuticals
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Tacgraf capsule of M/s CCL Pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Valor Pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Valor Pharma in name of M/s Solaris.
	Evaluation	The case has been processed against the New DML priority. Firm has adopted dissolution test 2 of USP monograph Following shall be submitted: • 6th month time point stability data of drug product shall be submitted Reply: Submitted
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon verification of loan letter.

Sr. No	Title	Description
29	Name, address of Manufacturing site.	**Al Barakat Pharmaceutical Industries** Plot # B/66-A, S.I.T.E, Nooriabad**(000973)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(426-BG3-QWQR, 2024-09-18)
	Detail of Fee Submitted	30000.0, 2024-02-28,
	The proposed proprietary name / brand name	**Phenir - M Injection**
	Label Claim	Each 1ml contains: Pheniramine Maleate BP.....22.7mg
	Pharmacotherapeutic Group of (API)	Anti allergy
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Brand Name: Avil Injection Market Authorization: Sanofi-Aventis France
	For generic drugs (me-too Status)	Avil Injection Strength: 22.7mg/1ml Dosage Form: IV/IM Injection Pack Size: 2mlx50's Regn No.000226 Manufacturer: Sanofi Aventis Pakistan Limited.
	Proposed Pack Size	2ml x 50's -As per SRO
	GMP status of the firm	New DML granted 17-10-2023 including Liquid Ampoule general section
	Evidence of approval of manufacturing facility	New DML granted 17-10-2023 including Liquid Ampoule general section
	Name & address of API manufacturer	N/R
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Avil injectin
	Detail of stability batches of drug product	3 batches of ^ ltrs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	CLearance certificate issued in name of M.s Amros pharm asubmitted
	Evaluation	Submit following: Evidence of approval of applied formulation by any of the reference regulatory authorities adopted by Registration Board in its 275th meeting is required. Loan letter from M.s Amros Pharma shall be submitted for the borrowed drug substance. Analytical method verification studies of drug substance shall be submitted.
	Shortcoming	
	Decision	Deferred for evidence of approval of applied formulation by any of the reference regulatory authorities adopted by Registration Board in its 275th meeting

Sr. No	Title	Description
30	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(433-P62-3YSW, 2024-10-03)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Silodin 8mg Capsules**
	Label Claim	Each capsule contains;Silodosin…….8mg(Innovator Specifications)
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonists indicated for treatment of the signs and symptoms of benign prostatic hyperplasia
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Rapaflo Capsule 8mg, Company: Allergan, (NDA): 022206, USFDA Approved
	For generic drugs (me-too Status)	Silorap 8mg capsules, Manufacturer:Getz Pharma (Pvt.) Limited
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Oral liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Silorap capsule of M/s Getz Pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Global Pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Global Pharma in name of M/s Solaris.
	Evaluation	Following shall be submitted: • 6th month time point stability data of drug product shall be submitted Reply: Submitted
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon verification of loan letter.

Sr. No	Title	Description
31	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(437-A3M-YS2U, 2024-12-12)
	Detail of Fee Submitted	37000.0, 2024-11-25,
	The proposed proprietary name / brand name	**Maxifer tablet 100 mg**
	Label Claim	Each Chewable Tablet Contains:Iron (III) hydroxide polymaltose complex eq. to elemental Iron 100mg
	Pharmacotherapeutic Group of (API)	Trivalent iron, oral preparation, ferric oxide polymaltose complexes
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	--
	For generic drugs (me-too Status)	Megatron 100mg Chewable Tablet of m/s Rotex pharma Reg.#068686
	Proposed Pack Size	02x10's Tablets -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	CHEMIWORLD PRIVATE LIMITED. Address : Chemiworld Private Limited Plot no 97, J- Industrial estate Hayatabad, Peshawar. Telephone: +92-91-5891884-7, Fax: +92-91-5891884-7, Person to Contact: Mr. Fahim Kh
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Maxifer tablet of M/s Albro
	Detail of stability batches of drug product	3 batches of 10,000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Following shall be submitted: • Justification shall be submitted for no including dissolution test in drug product specifications. Maxifer 100 mg tablet is chewable tablet and Dissolve in mouth so there is no need of dissolution test. Firm has further sated that applied formulation is chewable tablet that MUST be chewed and for which there is no alternative route of administration. The labels and labeling for these products will also include a labeling statement indicating that the tablets MUST be chewed.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
32	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(4B7-R1G-A6TG, 2024-09-19)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**OME 40mg/1100mg Capsules**
	Label Claim	Each Capsule contains:Omeprazole .....40mgSodium bicarbonate .....1100mg(Innovator Spec's)
	Pharmacotherapeutic Group of (API)	proton pump inhibitors (PPIs) WHO ATC Code Omeprazole:A02BC01 WHO ATC Code Sodium bicarbonate: B05CB04
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Zegerid 40mg/ 1,100mg capsule, Manufacturer: Salix Pharma USA (USFDA Approved)
	For generic drugs (me-too Status)	TEpH Insta 40mg/1100mg capsules, Manufacturer: Sami Pharmaceuticals (Pvt.) Ltd.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Teph Insta40 40mg/1100mg Capsules of M/s Sami pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Vision pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Vision pharma in name of M/s Solaris for Omeprazole
	Evaluation	Following shall be submitted: • Valid DML/GMP certificate of the drug substance manufacturer of Sodium bicarbonate shall be submitted. As per the agreement with Luky Core Industires (LCI) Pakistan, PharmacopealGrade, Sodium Bi-Carbonate is purchased form LCI, and the material is tested according to the USP Specifications. COA of Manufacturer and Test report Sodium bicarbonate according to USP Specs is enclosed in Module-III 3.2.S.4.4.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
33	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(53X-GAZ-8T3L, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Mirogab 10mg Tablet**
	Label Claim	Each Film coated tablet containsMirogabalin besilate equivalent to Mirogabalin.....10mg
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd. Add: No.9a1,Tianheng Road, Gaoqing City, Shandong Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Tarlige tablet
	Detail of stability batches of drug product	3 batches of 900 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued in name of M/s Wimits pharmaceuticals dated 23-04-2024.
	Evaluation	Firm has requested vide letter no. Nil dated 17-2-2024 to consider the instant application against priority quota of their additional section of Tablet general granted vide vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024. Following shall be submitted: • BMR of drug product stability batches. BMR s of drug product stability batches submitted • Valid GMP/DML of drug substance manufacturer issued by relevant regulatory authority. Valid copy of DML submitted. • Drug substance stability data as per Zone IV conditions shall be submitted Submitted as per Zone IVa • Drug product stability data of 6th month time point shall be submitted. Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
34	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(5MQ-NHV-2W2V, 2024-12-25)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**Ompra 40mg caspule**
	Label Claim	Each Capsule contains: Omeprazole enteric coated pellets eq to omeprazole..... .. 40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	usfda approved
	For generic drugs (me-too Status)	risek 40mg capsule by getz pharma
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Capsul (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	vision pharmaceuticals pvt.ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of both real time and accelerated condition for drug substance from M/s Vision Pharma as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Risek 20mg capsules, Batch No. C04107 manufactured by M/s Getz Pharma.
	Detail of stability batches of drug product	02 batches of each 5000 capsules.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API is locally purchased and invoice submitted.
	Evaluation	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
35	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(6RT-Y8W-H5SG, 2024-10-30)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**OME 20mg/1100mg Capsules**
	Label Claim	Each Capsule contains:Omeprazole .....20mgSodium bicarbonate .....1100mg(Innovator Spec's)
	Pharmacotherapeutic Group of (API)	proton pump inhibitors (PPIs) WHO ATC Code Omeprazole:A02BC01 WHO ATC Code Sodium bicarbonate: B05CB04
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Zegerid 20mg/1,100mg capsule, Manufacturer: Salix Pharma USA, (NDA): 021849 (USFDA Approved)
	For generic drugs (me-too Status)	TEpH Insta 20mg/1100mg capsules, Manufacturer: Sami Pharmaceuticals (Pvt.) Ltd.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Capsule (General)" vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Name & address of API manufacturer	M/S: Lucky Core Industries Limited Address: Khewra Dist. Jhelum ,M/S: Spansules Pharmatech Private Limited Address: Plot No:59, G-3, Srivenkateswara Towers, Bhagyanagar Colony, Opp-KPHB, Hyderabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Teph Insta20 20mg/1100mg Capsules of M/s Sami pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Vision pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Vision pharma in name of M/s Solaris for Omeprazole
	Evaluation	Following shall be submitted: • Valid DML/GMP certificate of the drug substance manufacturer of Sodium bicarbonate shall be submitted. Reply: As per the agreement with Luky Core Industires (LCI) Pakistan, PharmacopealGrade, Sodium Bi-Carbonate is purchased form LCI, and the material is tested according to the USP Specifications. COA of Manufacturer and Test report Sodium bicarbonate according to USP Specs is enclosed in Module-III 3.2.S.4.4.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
36	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(72B-B4A-8LSL, 2024-09-18)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Mirogab 5mg Tablet**
	Label Claim	Each Film coated tablet containsMirogabalin besilate equivalent to Mirogabalin..... 5mg
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd. Add: No.9a1,Tianheng Road, Gaoqing City, Shandong Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Tarlige tablet
	Detail of stability batches of drug product	3 batches of 900 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued in name of M/s Wimits pharmaceuticals dated 23-04-2024.
	Evaluation	Firm has requested vide letter no. Nil dated 17-2-2024 to consider the instant application against priority quota of their additional section of Tablet general granted vide vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024. Following shall be submitted: Following shall be submitted: • BMR of drug product stability batches. BMR s of drug product stability batches submitted • Valid GMP/DML of drug substance manufacturer issued by relevant regulatory authority. Valid copy of DML submitted. • Drug substance stability data as per Zone IV conditions shall be submitted Submitted as per Zone IVa • Drug product stability data of 6th month time point shall be submitted. Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
37	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(8J5-5S4-DV2E, 2024-09-05)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Esopar 20mg Capsule**
	Label Claim	Esopar 20mg CapsuleEach Capsule Contains: Enteric coated pellets of Esomeprazole Magnesium Trihydrate equivalent toEsomeprazole……..20mg (USP Specifications).
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Esomeprazole 20 mg Capsule (USFDA Approved)
	For generic drugs (me-too Status)	ESSO 20 Capsule by Shaigan Pharmaceuticals.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd. Plot No.22-23, Industrial Triangle ,Kahuta Road, Islamabad-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Esso capsule of M/s Shaigan
	Detail of stability batches of drug product	3 batches of 1200 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Analytical record for the dissolution test performed during drug product stability studies shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
38	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(8UD-9MW-AN3A, 2024-12-13)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**ST-Met 50/500mg Tablet**
	Label Claim	Each Film Coated Tablet Contains:Sitagliptin phosphate monohydrate equivalent to sitagliptin .....50mgMetformin hydrochloride.....500 mg
	Pharmacotherapeutic Group of (API)	A10BD Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	usfda approved
	For generic drugs (me-too Status)	janumet 50/500mg tablet by searle pakistan limited
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	Ruyun hec pharma co., ltd,smruthi organics limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of both real time and accelerated condition for Sitagliptin phosphate monohydrate and Metformin HCl from concerned manufacturers as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Treviamet 50mg+500mg Tablets, Batch No. F09101 manufactured by M/s Getz Pharma.
	Detail of stability batches of drug product	02 batches of 5000 tablets each are manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter submitted, however, no clearance submitted.
	Evaluation	Your application is evaluated and found deficient for the following; • Specifications for the applied formulation are innovator specification while official monograph for the applied formulation is available in BP. Clarification shall be submitted. Reply: The product is included recently in official pharmacopiea and we will update our method accordingly • API clearance documents for both the drug substances shall be submitted. Reply: Firm has submitted Copy of COA, and Goods Declaration along with Invoice not attested by DRAP I&E office • Valid copies of GMP certificate for both the drug substances shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Deferred For submission of procurement documents of drug substances attested by DRAP I&E office.

Sr. No	Title	Description
39	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(9W5-T7G-HRZV, 2024-09-11)
	Detail of Fee Submitted	30000.0, 2024-08-21,
	The proposed proprietary name / brand name	**Aczi 200mg/5ml Dry Suspension**
	Label Claim	ACZI 200mg /5ml Suspension Each 5ml of reconstituted suspension contains: Azithromycin Dihydrate Eq. to Azithromycin.....200mg (USP Specification).
	Pharmacotherapeutic Group of (API)	Macrolide antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Zithromax powder for Oral suspension MHRA approved
	For generic drugs (me-too Status)	Azitma 200mg/5ml Suspension by Sami Pharmaceuticals .
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	17-02-2023. Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB
	Evidence of approval of manufacturing facility	17-02-2023. Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB
	Name & address of API manufacturer	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan. Tel: +92 49 4510192, 510189
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Azitma suspension of M/s Sami Pharma
	Detail of stability batches of drug product	3 batches of 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application has been processed against new DML Following shall be submitted: • In-use stability study for the reconstituted suspension shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
40	Name, address of Manufacturing site.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh**(000038)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(9YZ-5HL-Z7DZ, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**Cutica Ointment 0.005%**
	Label Claim	Each gram contains:Fluticasone Propionate B.P.....0.05mg
	Pharmacotherapeutic Group of (API)	Corticosteroids for topical use
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Brand Name: CUTIVATE OINTMENT 0.005% Manufacturer: PharmaDerm® A division of Fougera Pharmaceuticals Inc. - USFDA
	For generic drugs (me-too Status)	Brand name: Cutivate Ointment 0.005% Manufacturer: M/s GlaxoSmithKline Pakistan Limited
	Proposed Pack Size	10gram-As per SRO,15gram-As per SRO,30gram-As per SRO,50gram-As per SRO,5gram-As per SRO
	GMP status of the firm	01-08-2023 GMP certificate issued
	Evidence of approval of manufacturing facility	Cream/Ointment /Gel (steroid) section granted as additional section on 26-10-2020
	Name & address of API manufacturer	NA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Cutivate ointment
	Detail of stability batches of drug product	3 batches of 900gm with pack size of each tube of 10gm
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of commercial invoice attested by AD I&E Peshawar dated 23-08-2021
	Evaluation	Following shall be submitted Valid DML/GMP certificate issued by relevant regulatory authority of country of origin.
	Shortcoming	
	Decision	Approved Firm shall submit valid copy of DML/GMP certificate issued by relevant regulatory authority of country of origin before issuance of registration letter.

Sr. No	Title	Description
41	Name, address of Manufacturing site.	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad**(000955)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(DQ6-WUD-PGZV, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	**Vonopine 10mg Tablets**
	Label Claim	Each film coated tablet contains:Vonoprazan fumarate equivalent to Vonoprazan 10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Takecab 10mg Tablets by PMDA Japan Approved
	For generic drugs (me-too Status)	Vonozan 10mg tablet by Getz Pharma Karachi, Pakistan
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-8/2019-Lic issued by Secretary CLB dated 29-04-2022.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-8/2019-Lic issued by Secretary CLB dated 29-04-2022.
	Name & address of API manufacturer	M/S Guangdong Xianqiang Pharmaceutical Co.,, No.6 Zhongjing Road Zhongshan Torch Hi-tech Industrial Development Zone, Zongshan City, Guangdong Province, China(528437)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence CDP performed against Vonozan tablet of M/s Getz
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued to M/s Caliph pharma dated 08-9-2023 by DRAP I&E office Peshawar, along with loan letter in name of M/s Pine pharma from M/s Caliph pharma.
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Valid GM P certificate/DML of drug substance manufacturer issued by the relevant regulatory authority of country of origin shall be submitted Reply: GMP certificate issued by Guangdong Pharmaceutical center for Economic Development has been submitted • Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. Reply: Drug substance analytical procedure has been submitted, • Dissolution parameters applied shall be justified against the recommended by US FDA approved drug product. Reply: Firm has referred to the submitted CDP studies stating that the applied formulation is comparable to the reference product
	Shortcoming	
	Decision	Approved Firm shall submit following before issuance of registration letter: Valid GMP certificate/DML of drug substance manufacturer issued by the relevant regulatory authority of country of origin. Analytical method verification studies of drug substance performed by drug product manufacturer. Revised drug product specifications with dissolution parameters as recommended by US FDA for innovator drug product. Fee for pre-registration variation i.e. Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.

Sr. No	Title	Description
42	Name, address of Manufacturing site.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan**(000578)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(DYZ-RHW-QSJQ, 2024-12-26)
	Detail of Fee Submitted	37000.0, 2024-12-23,
	The proposed proprietary name / brand name	**ICOJIN 100MG**
	Label Claim	Each Capsule Contains:Immediate Release Pellets of Itraconazole Eq. to Itraconazole .....100mg (USP Specification
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	SPORANOX 100 mg Capsule By Janssen Ortho LLC, Gurabo, Puerto Rico 00778 (USFDA Approved)
	For generic drugs (me-too Status)	Rolac 100mg Capsule (Sami Pharma Karachi)
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021.
	Evidence of approval of manufacturing facility	Firm has been granted renewal of DML including section of “Capsule general dated 20-09-2021.
	Name & address of API manufacturer	VISION PHARMACEUTICALS PVT LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IVb conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence against reference product of Rolac capsule of M/s Sami
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against balance priority quota of Capsule general section Following shall be submitted: • BMRs of drug product stability batches shall be submitted
	Shortcoming	
	Decision	Deferred Registration Board referred to its following decision of 286th meeting: "Registration Board after thorough deliberation and considering the decision of 14th meeting of Policy Board decided to grant 10 products per section for all the firms for which section approval was granted by Central Licensing Board before 14th meeting of Policy Board of DRAP held on10th & 11th of Sep, 2015. However, only those firms shall be considered for grant of registration of ten products per section, whose registered products as of today are less than ten products per section." While referring to the above cited decision it was noted that as per available record M/s Jinnah Pharmaceuticals has already availed registration of more than 10 products in the "Capsule general" section, hence the Board deferred the instant application for consideration on its turn.

Sr. No	Title	Description
43	Name, address of Manufacturing site.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh**(000038)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(DZE-AHV-TELT, 2024-11-18)
	Detail of Fee Submitted	75000.0, 2024-11-11,
	The proposed proprietary name / brand name	**Clasco Cream 1%**
	Label Claim	Each gram contains:Clascoterone.....10mg
	Pharmacotherapeutic Group of (API)	Androgen Receptor Inhibitor
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Brand Name: WINLEVI CREAM 1% Manufacturer: Cosmo S.p.A via Cristoforo Colombo, 120045, Lainate Milan ,Italy - USFDA
	For generic drugs (me-too Status)	NA
	Proposed Pack Size	10gram-As per SRO,15gram-As per SRO,30gram-As per SRO,50gram-As per SRO,5gram-As per SRO
	GMP status of the firm	01-08-2023 GMP certificate issued
	Evidence of approval of manufacturing facility	Cream/Ointment /Gel (steroid) section granted as additional section on 26-10-2020
	Name & address of API manufacturer	NA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against innovator product Winlevit
	Detail of stability batches of drug product	3 batches of 666gm with pack size of each tube of 15gm
	Documents for the procurement of API with approval from DRAP (in case of Improt)	License to import issued by DRAP I&E Office dated 08-09-2023
	Evaluation	Clascoterone cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. Following shall be submitted: Justification for not including "In-Vitro Release test " in drug product specification as recommended by innovator drug product. Drug product stability data of 6th month time point
	Shortcoming	
	Decision	Approved Firm shall submit following before issuance of registration letter: Revised drug product specifications including "In-Vitro Release test " as recommended by innovator drug product with performance of the same at next time point of stability studies. Drug product stability data of 6th month time point Fee for pre-registration variation i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.

Sr. No	Title	Description
44	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(EMB-316-2VEJ, 2024-11-30)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**ASOMP 40 mg Capsule**
	Label Claim	ASOMP 40mg CapsuleEach Capsule contains: Omeprazole (as enteric coated pellets) .....40mg(USP Specification).
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too Status)	Risek Capsules 40mg (Omperazole) by Getz Pharma (Pvt) Limited.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	17-02-2023. Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB
	Evidence of approval of manufacturing facility	17-02-2023. Firm has been granted new DML including section of “Dry powder suspension (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd. Plot No.22-23, Industrial Triangle ,Kahuta Road, Islamabad-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditionsas per Zone IV conditions from Chongqing Huapont Pharmaceutical Co., Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Risek capsule of M/s Getz Pharma
	Detail of stability batches of drug product	3 batches of 1200 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Process validation protocol shall be submitted. Reply: Submitted • Chromatographic conditions applied for the Assay analysis shall be justified in terms of gradient time with reference to the USP monograph. Reply: We have used mobile phase and diluent as per USP and have used isocratic method when our product approved we will shift to gradient method. • BMRs of drug product stability batches shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
45	Name, address of Manufacturing site.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore**(000530)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(GRD-MHG-6DNZ, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Trim-Z Cream**
	Label Claim	Each gram of cream contains: Clotrimazole…10mg
	Pharmacotherapeutic Group of (API)	Antimycotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Clotrimazole Cream 1% byGenerics [UK] Limited t/a Mylan Station Close,Potters Bar, Herts EN6 1TL (MHRA Approved)
	For generic drugs (me-too Status)	Canesten cream by Manufactured by Novartis Pharma (Pakistan) Limited ; Manufactured For Bayer Pakistan (Pvt.) Ltd.
	Proposed Pack Size	10gm-As per SRO
	GMP status of the firm	New section of Cream/Ointment (General) granted on 29-02-2024)
	Evidence of approval of manufacturing facility	New section of Cream/Ointment (General) granted on 29-02-2024)
	Name & address of API manufacturer	NB Healthcare Pvt. Ltd, Survey No. 784/2, Village; Adroda, Tal.- Bavla, District.- Ahmedabad- 382 220
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Against Clotrimazole cream
	Detail of stability batches of drug product	3 batches of 200 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued by DRAP I&E Lahore in nam eof M/s Fynk Lahore, by I&E DRAP Lahore along with intimation letter to DRAP dated 08-03-2024 regarding borrowing of API.
	Evaluation	Following shall be submitted: Loan letter for borrowing of API from M.s Fynk Pharma shall be submitted Reply: Loan letter from M/s Fynk Pharma dated 16-02-2024 has been submitted Analytical record including chromatograms for the drug product stability studies shall be submitted since, firm has submitted drug substance stability data reports in section 3.2.P.8.3 Reply: Not submitted 6th month time point stability data shall be submitted for drug product Reply: not submitted
	Shortcoming	
	Decision	Deferred for following: Analytical record including chromatograms for the drug product stability studies shall be submitted since, firm has submitted drug substance stability data reports in section 3.2.P.8.3 6th month time point stability data shall be submitted for drug product

Sr. No	Title	Description
46	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(GT2-VAE-48TG, 2024-12-13)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**ST-Met 50/1000mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Sitagliptin phosphate monohydrate equivalent to sitagliptin .....50mg Metformin hydrochloride.....1000 mg
	Pharmacotherapeutic Group of (API)	A10BD Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	usfda approved
	For generic drugs (me-too Status)	janumet 50/1000mg tablet by searle pakistan limited
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	Ruyun hec pharma co., ltd,samruthi organics limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of both real time and accelerated condition for Sitagliptin phosphate monohydrate and Metformin HCl from concerned manufacturers as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Treviamet 50mg+1000mg Tablets, Batch No. F08088 manufactured by M/s Getz Pharma.
	Detail of stability batches of drug product	02 batches of 5000 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API loan letter is submitted while no clearance documents are submitted.
	Evaluation	Your application is evaluated and found deficient for the following; • Specifications for the applied formulation are innovator specification while official monograph for the applied formulation is available in BP. Clarification shall be submitted. Reply: The product is included recently in official pharmacopiea and we will update our method accordingly • API clearance documents for both the drug substances shall be submitted. Reply: Firm has submitted Copy of COA, and Goods Declaration along with Invoice not attested by DRAP I&E office • Valid copies of GMP certificate for both the drug substances shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Deferred For submission of procurement documents of drug substances attested by DRAP I&E office.

Sr. No	Title	Description
47	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(HAM-3V1-VWAX, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**Levo-Z 2.5mg/5ml oral solution**
	Label Claim	Levo-Z 2.5mg/5ml Oral Solution Each 5ml Contains: - Levocetirizine Dihydrochloride.....2.5mg (Innovator Specifications).
	Pharmacotherapeutic Group of (API)	antihistamine for systemic use
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	XYZAL 2.5mg /5ml Oral solution By US Food and Drug Administration approved
	For generic drugs (me-too Status)	Neo-Sedil 2.5mg/5ml by SAMI Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Oral liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Oral liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	METROCHEM API PRIVATE LIMITED Flat no 302,Bhanu Enclave,Sunder Nagar,Erragada Hyderabad-500 038 A.P.India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Neo Sedil oral solution of M/s Sami
	Detail of stability batches of drug product	3 batches of 150 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Neutro Pharma by DRAP I&E Office, Lahore along with loan letter firm M/s Neutro in name of M.s Auspec.
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Drug substance stability study data shall be submitted as per Zone IV conditions. Reply: Submitted • BMR of the drug product stability batches shall be submitted since submitted BMRs are of tablet. Reply: BMRs of drug product stability batches of syrup submitted • Limits of Ph test shall be submitted for dug product Reply: pH value is set to in-house range of 4.1-7.0.
	Shortcoming	
	Decision	Approved Firm shall submit results of pH test performance at the next time point of long-term stability studies.

Sr. No	Title	Description
48	Name, address of Manufacturing site.	**AHSONS Drug Company** T/1 S.I.T.E Tando Adam**(000138)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(HB7-XPH-PX84, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-21,
	The proposed proprietary name / brand name	**Parahos Infusion 1gm/100ml**
	Label Claim	Each100ml contains: Paracetamol BP.....1gm
	Pharmacotherapeutic Group of (API)	Antipyretic and analgesic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Brand Name: Paracetamol Infusion 10mg/ml Market Authorization: M/s. Accord –UK Ltd Reference Regulatory Authority: MHRA of UK Approved
	For generic drugs (me-too Status)	Brand Name: Provas Infusion 1gm/100ml. Strength: 1gm/100ml Dosage Form: IV Infusion Pack Size: 100ml Regn No.053223 Manufacturer: Sami Pharmaceuticals (Pvt) Ltd.
	Proposed Pack Size	100ml-As per SRO
	GMP status of the firm	Firm has submitted letter for grant of Renewal of DML dated 11-05-2022 wherein Liquid Vial SVP (General) section is included.
	Evidence of approval of manufacturing facility	Firm has submitted letter for grant of Renewal of DML dated 11-05-2022 wherein Liquid Vial SVP (General) section is included.
	Name & address of API manufacturer	Saakh pharma
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE Submitted against Provas infusion of Sami pharma
	Detail of stability batches of drug product	3 batches of 300 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice form Saakh Pharma submitted
	Evaluation	Following shall be submitted: Evidence of first approval from Central Licensing Board for the required manufacturing facility f "Liquid Vial SVP (general) section BMRs of drug product stability batches.
	Shortcoming	
	Decision	Deferred for following: Evidence of first approval from Central Licensing Board for the required manufacturing facility f "Liquid Vial SVP (general) section BMRs of drug product stability batches.

Sr. No	Title	Description
49	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(HPA-MHQ-6N27, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Silodin 4mg Capsules**
	Label Claim	Each capsule contains;Silodosin…….4mg(Innovator Specifications)
	Pharmacotherapeutic Group of (API)	alpha-adrenoreceptor antagonists indicated for treatment of the signs and symptoms of benign prostatic hyperplasia
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Rapaflo Capsule 4mg, Company: Allergan, (NDA): 022206, USFDA Approved
	For generic drugs (me-too Status)	Silorap 4mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Silorap capsule of M/s Getz Pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Global Pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Global Pharma in name of M/s Solaris.
	Evaluation	Following shall be submitted: • 6th month time point stability data of drug product shall be submitted Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
50	Name, address of Manufacturing site.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore**(000576)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(HWQ-WU3-X3L3, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Vortin 20mg Tablet**
	Label Claim	Each film coated tablet Contains:Vortioxetine Hydrobromide equivalent tovortioxetine 20mg
	Pharmacotherapeutic Group of (API)	Other antidepressants, ATC code: N06AX26
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Brintellix by Takeda Pharmaceuticals (FDA approved)
	For generic drugs (me-too Status)	Vrontil by Genix
	Proposed Pack Size	14’s, 28’s -As per SRO
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 14-04-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	Tablet (General) section (second floor) approved vide letter No. F. 1-3/2003-Lic (Vol-III) dated 30-04-2022.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Brintellix tablet
	Detail of stability batches of drug product	3 batches of 3000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of commercial invoice attested by AD I&E lahore, dated 18-10-2019
	Evaluation	Following shall be submitted: Analytical method verification studies of drug substance performed by M/s Neutro Reply: submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
51	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(JJ9-1BP-SGDD, 2024-12-05)
	Detail of Fee Submitted	75000.0, 2024-01-31,
	The proposed proprietary name / brand name	**Genart**
	Label Claim	Each suppository contains:Artesunate 300mg
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Artesunate suppository, WHO
	For generic drugs (me-too Status)	Not Applicable
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	GMP status of the firm	GMP certificate granted on 13-06-2023
	Evidence of approval of manufacturing facility	Additional section of suppository granted on 27-12-2023
	Name & address of API manufacturer	Ipca Laboratories Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Artesuante suppository capsule
	Detail of stability batches of drug product	3 batches of 500 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued in name of m.s Genix Pharma dated 24-07-2023
	Evaluation	• Following shall be submitted: Evidence from WHO or other reference regulatory authorities regarding the approval of applied formulation in 300mg strength 6th month drug product stability data. Name of manufacturer of reference product applied for pharmaceutical equivalence studies.
	Shortcoming	
	Decision	Deferred for following: Evidence from WHO or other reference regulatory authorities regarding the approval of applied formulation in 300mg strength since submitted reference is of 100mg strength Name of manufacturer of reference product applied for pharmaceutical equivalence studies.

Sr. No	Title	Description
52	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(L6N-6YN-Z624, 2024-11-11)
	Detail of Fee Submitted	37000.0, 2024-10-25,
	The proposed proprietary name / brand name	**Maxifer syrup 50mg/5mL**
	Label Claim	Each 5mL Syrup Contains:Iron (III) hydroxide polymaltose complex eq. to elemental Iron 50mg
	Pharmacotherapeutic Group of (API)	Trivalent iron, oral preparation, ferric oxide polymaltose complexes
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	--
	For generic drugs (me-too Status)	BISLERI SYRUP by Sami Pharmaceuticals (Reg.No.....033003)
	Proposed Pack Size	60 ml / bottle -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Oral Liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Oral Liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	CHEMIWORLD PRIVATE LIMITED. Address : Chemiworld Private Limited Plot no 97, J- Industrial estate Hayatabad, Peshawar. Telephone: +92-91-5891884-7, Fax: +92-91-5891884-7, Person to Contact: Mr. Fahim Kh
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Bisleri syrup of M/s Sami
	Detail of stability batches of drug product	3 batches of 500 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
53	Name, address of Manufacturing site.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,**(000992)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(LE7-71Z-XS7V, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-08-13,
	The proposed proprietary name / brand name	**Tacor Capsules 1mg**
	Label Claim	Each Capsule contains:Tacrolimus Monohydrate equivalent to Tacrolimus……..1mg(USP Specifications)
	Pharmacotherapeutic Group of (API)	Immunosuppressants
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Tacrolimus Capsules 1mg, USP, Manufacturer: Mylan Pharmaceuticals Inc. (NDA): 090596 (USFDA Approved)
	For generic drugs (me-too Status)	Tacgraf 1mg Capsules, Manufacturer: CCL Pharmaceuticals
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.1-8/2015-Lic(Pt) issued by Secretary CLB dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Oral liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Tacgraf capsule of M/s CCL Pharma
	Detail of stability batches of drug product	3 batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued in name of M/s Valor Pharma by DRAP I&E Office, Islamabad along with loan letter firm M/s Valor Pharma in name of M/s Solaris.
	Evaluation	The case has been processed against the New DML priority. Firm has adopted dissolution test 2 of USP monograph Following shall be submitted: • 6th month time point stability data of drug product shall be submitted Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
54	Name, address of Manufacturing site.	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad**(000955)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(M25-ZYQ-R8AG, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	**Vonopine 20mg Tablets**
	Label Claim	Each film coated tablet contains:Vonoprazan fumarate equivalent to Vonoprazan 20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Takecab 20mg Tablets by PMDA Japan Approved
	For generic drugs (me-too Status)	Vonozan 20mg tablet by Getz Pharma Karachi, Pakistan
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-8/2019-Lic issued by Secretary CLB dated 29-04-2022.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-8/2019-Lic issued by Secretary CLB dated 29-04-2022.
	Name & address of API manufacturer	M/S Guangdong Xianqiang Pharmaceutical Co.,, No.6 Zhongjing Road Zhongshan Torch Hi-tech Industrial Development Zone, Zongshan City, Guangdong Province, China(528437)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence CDP performed against Vonozan tablet of M/s Getz
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted clearance certificate issued to M/s Caliph pharma dated 08-9-2023 by DRAP I&E office Peshawar, along with loan letter in name of M/s Pine pharma from M/s Caliph pharma.
	Evaluation	Following shall be submitted: • Valid GM P certificate/DML of drug substance manufacturer issued by the relevant regulatory authority of country of origin shall be submitted Reply: GMP certificate issued by Guangdong Pharmaceutical center for Economic Development has been submitted • Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. Reply: Drug substance analytical procedure has been submitted, • Dissolution parameters applied shall be justified against the recommended by US FDA approved drug product. Reply: Firm has referred to the submitted CDP studies stating that the applied formulation is comparable to the reference product
	Shortcoming	
	Decision	Approved Firm shall submit following before issuance of registration letter: Valid GMP certificate/DML of drug substance manufacturer issued by the relevant regulatory authority of country of origin. Analytical method verification studies of drug substance performed by drug product manufacturer. Revised drug product specifications with dissolution parameters as recommended by US FDA for innovator drug product. Fee for pre-registration variation i.e. Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.

Sr. No	Title	Description
55	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(M4R-PSH-ATJQ, 2024-12-13)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**Ompra 20mg caspule**
	Label Claim	Each Capsule contains: Omeprazole enteric coated pellets eq to omeprazole..... .. 20mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	usfda approved
	For generic drugs (me-too Status)	UI-RID 20mg capsule by zians pharmaceuticals pvt.ltd
	Proposed Pack Size	14's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Capsul (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	vision pharmaceuticals pvt.ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of both real time and accelerated condition for drug substance from M/s Vision Pharma as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Risek 20mg capsules, Batch No. C03089 manufactured by M/s Getz Pharma.
	Detail of stability batches of drug product	02 batches of each 5000 capsules.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API is locally purchased and invoice submitted.
	Evaluation	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
56	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(MD7-JLN-NMVP, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**I-Phen 100mg/5ml Oral liquid suspension**
	Label Claim	I-Phen 100mg/5ml Oral liquid suspensionEach 5ml oral suspension contains: Ibuprofen .....100mg. (BP Specification).
	Pharmacotherapeutic Group of (API)	Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Ibuprofen 100 mg/5Ml Oral suspension. (USFDA Approved)
	For generic drugs (me-too Status)	Brufen by ABBOTT Pharma Karachi
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Oral Liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Oral Liquid (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	HuBei Biocause Heilen Pharmaceuticals Co.,Ltd. 122 Yangman Road, Jingmen City, Hubei Province, P.R.China 448000.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Brufen suspension of M/s Abbott
	Detail of stability batches of drug product	3 batches of 65 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted commercial invoice only
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Drug substance stability study data shall be submitted as per Zone IV conditions. • Process validation protocol shall be submitted. • Comparative Dissolution Studies with the reference/comparator product shall be submitted. • Justification shall be submitted for not including dissolution test in drug product specifications, as recommended by BP monograph of “Ibuprofen Oral Suspension.” • Documents confirming import of drug substance issued by DRAP I&E Office shall be submitted.
	Shortcoming	
	Decision	Deferred for submission of reply to above cited shortcomings since no attachment of requisite documents have been made in firm' previous reply.

Sr. No	Title	Description
57	Name, address of Manufacturing site.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat,**(000911)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(MJJ-G4R-AT67, 2024-11-19)
	Detail of Fee Submitted	30000.0, 2024-05-10,
	The proposed proprietary name / brand name	**Eflocin 13.9% Cream**
	Label Claim	Each gram contains: Eflornithine hydrochloride ... 139mg(13.9%w/w anhydrous)
	Pharmacotherapeutic Group of (API)	Other dermatologicals indicated for the reduction of unwanted facial hair in women
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Vaniqa Cream (approved by MHRA as 11.5% Eflornithine as hydrochloride monohydrate cream which is eq. to 13.9 Eflornithine hydrochloride (anhydrous)
	For generic drugs (me-too Status)	Eflogen Cream 13.9% 15g ; Product Form · Cream ; Pack Size · 15g ; Manufactured By · Biogen Pharma -
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	GMP certificate granted dated 13-12-2023
	Evidence of approval of manufacturing facility	New DML granted 14-02-2020 including Cream section
	Name & address of API manufacturer	MICRO ORGO CHEM 57 C-1B, LIC Sector GIDC, Vapi-396195, Gujarat, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies against Eflogin crema of Biogen Pharma
	Detail of stability batches of drug product	3 batches of 250tubes each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate issued in name of M/s Biogen Pharma dated 01-08-2022 by DRAP I&E Islamabad office
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
58	Name, address of Manufacturing site.	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore**(000655)**
	Case Category	Any Other (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(Q6W-W5G-GBGA, 2024-06-10)
	Detail of Fee Submitted	30000.0, 2023-05-11,
	The proposed proprietary name / brand name	**Sterile Solvent (0.9% Sodium Chloride w/v per ml)5ml 5ml**
	Label Claim	Each Ampoule Contains:0.9 % Sodium Chloride w/v per ml
	Pharmacotherapeutic Group of (API)	IV Solution Additives / Electrolyte Solutions
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Sodium chloride injection BP 0.9% w/v of M/s Hameln Pharma Ltd Nexus, Gloucester Business Park, Gloucester, GL3 4AG, UK approved by MHRA
	For generic drugs (me-too Status)	Sodium Chloride 0.9% w/v Injection of M/s Getz Pharma Pakistan (Pvt.) Ltd.
	Proposed Pack Size	1’s, 20’s, 50’s & 10-As per SRO
	GMP status of the firm	13-09-2023 GMP certificate issued.
	Evidence of approval of manufacturing facility	Injectable (Ampoule/Vial) SVP (Lyophilized/Liquid) general section granted on 01-05-2024. Previously firm has been granted Paentral (Liquid andlyophilized) section dated 31-01-2009
	Name & address of API manufacturer	Name: HUB-PAK SALT REFINERY Official Address: 10, Bangalore Town, Main Shahrah-e-Faisal, PO Box # 75350 Karachi, Pakistan Site Address: Site # 1 C-206, Industrial Trading Estate, Hub, Balochistan, Pa
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against GEtz Pharma product
	Detail of stability batches of drug product	3 batches of 400 ampoules, 2000 ampoules and 2000 ampoules
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Firm vide its letter no. nil dated 30-12-2024 has submitted as under: "We would like to bring in your kind notice that we are planning to manufacture Sterile Solvent “Sodium Chloride 0.9% w/v” for supply as Free of Cost “FOC” SOLVENT with our registered drug Esomega 40mg Injection (Reg#098037). In order to facilitate Free of Cost supply of Solvent with Esomega Injection, we are requesting to consider our below mentioned molecule as Priority Approval “Out of Queue” Consideration, during DRB Meeting No.344." For instant application firm has submitted source of drug substance as HUB-PAK SALT REFINERY Official Address: 10, Bangalore Town, Main Shahrah-e-Faisal, PO Box # 75350 Karachi, Pakistan Site Address: Site # 1 C-206, Industrial Trading Estate, Hub, Balochistan, for which firm has submitted certificate issued by Alberk QA technic Corp, Turkey, declaring that firm has implemented and maintained GMP approach as per PS 3844 general Principals of Food Hygeine covering 21 CFR part 110 manufacturing of Food and Pharmaceutical grade salt (NaCl), valid till 07-12-2026 The case is presented for consideration please
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
59	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(S6V-QA6-S4EU, 2024-09-10)
	Detail of Fee Submitted	75000.0, 2024-08-27,
	The proposed proprietary name / brand name	**Mirogab 2.5mg Tablet**
	Label Claim	Each Film Coated Tablet contains:Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd. Add: No.9a1,Tianheng Road, Gaoqing City, Shandong Province, China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Tarlige tablet
	Detail of stability batches of drug product	3 batches of 900 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued in name of M/s Wimits pharmaceuticals dated 23-04-2024.
	Evaluation	Firm has requested vide letter no. Nil dated 17-2-2024 to consider the instant application against priority quota of their additional section of Tablet general granted vide vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024. Following shall be submitted: • BMR of drug product stability batches. Reply: Submitted • Valid GMP/DML of drug substance manufacturer issued by relevant regulatory authority. Reply: Valid copy of DML submitted • Drug substance stability data as per Zone IV conditions shall be submitted Reply: Submitted • Drug product stability data of 6th month time point shall be submitted. Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
60	Name, address of Manufacturing site.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore**(000789)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(U3T-ZQN-X4JQ, 2024-10-29)
	Detail of Fee Submitted	75000.0, 2024-03-19,
	The proposed proprietary name / brand name	**Upanib 15mg PR Tablet**
	Label Claim	Each Film Coated Extended-Release Tablet contains:Upadacitinib Hemihydrate equivalent to Upadacitinib.....15mg
	Pharmacotherapeutic Group of (API)	L04AF Janus-associated kinase (JAK) inhibitors. It is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Rinvoq (upadacitinib) 15mg Extended-release Tablet of M/s AbbVie Inc. (USFDA Approved)
	For generic drugs (me-too Status)	Upada ER Tablets 15mg of M/s Searle
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’-As per SRO
	GMP status of the firm	GMP certificate issued dated 14-11-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of Tablet general vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024
	Name & address of API manufacturer	Zhejiang Hongyuan Pharmaceutical Co., Ltd Add: Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Rinvoq tablet
	Detail of stability batches of drug product	3 batches of 1500 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted MOU and loan letter from M/s Searle Company Karachi dated 13-02-2023 in name of M/s Wimits Pharma along with License to import issued in name of M/s Searle Company Karachi dated 15-12-2022.
	Evaluation	• Verification Firm has requested vide letter no. Nil dated 17-2-2024 to consider the instant application against priority quota of their additional section of Tablet general granted vide letter no. F.1-10/2012-Lic (Vol-I) issued by Secretary CLB dated 02-12-2024. Following shall be submitted: • BMR of drug product stability batches. Reply: Submitted • GMP/DML of drug substance manufacturer issued by relevant regulatory authority
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon submission of following: Verification of loan letter. Valid DML/GMP certificate of drug substance manufacturer

Sr. No	Title	Description
61	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(W2X-DY8-SAU9, 2024-12-13)
	Detail of Fee Submitted	37000.0, 2024-12-04,
	The proposed proprietary name / brand name	**Starsed 100mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Flurbiprofen.....100mg
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Health Canada approved as film coated.
	For generic drugs (me-too Status)	Ansaid 100mg tablet by pfizer pharmaceuticals
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	integrin life sciences pvt.ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability data is not as per zone IVa.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Ansaid Tablets, Batch No. LL2567 manufactured by M/s Pfizer Pakistan.
	Detail of stability batches of drug product	02 batches of 5000 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API clearance is submitted with approval from DRAP. API loan letter is not submitted.
	Evaluation	Provide the following; Stability data of the drug substance as per Zone IVa shall be submitted. Reply: Submitted API loan letter from M/s Shaheen pharma shall be submitted. Reply: Loan letter form M/s Shaheen Pharma has been submitted
	Shortcoming	
	Decision	Approved Registration letter shall be issued upon verification of loan letter

Sr. No	Title	Description
62	Name, address of Manufacturing site.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore**(000576)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(WBR-B5U-QGE6, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-06-20,
	The proposed proprietary name / brand name	**Vortin 10mg Tablet**
	Label Claim	Each film coated tablet Contains:Vortioxetine Hydrobromide equivalent to vortioxetine 10mg
	Pharmacotherapeutic Group of (API)	Other antidepressants, ATC code: N06AX26
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Brintellix by Takeda Pharmaceuticals (FDA approved)
	For generic drugs (me-too Status)	Vrontil by Genix
	Proposed Pack Size	14’s, 28’s -As per SRO
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 14-04-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	Tablet (General) section (second floor) approved vide letter No. F. 1-3/2003-Lic (Vol-III) dated 30-04-2022.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Brintellix tablet
	Detail of stability batches of drug product	3 batches of 3000 units each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of commercial invoice attested by AD I&E lahore, dated 18-10-2019
	Evaluation	Following shall be submitted: Analytical method verification studies of drug substance performed by M/s Neutro Reply: Submitted
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
63	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(XA3-S76-Z4L3, 2024-12-12)
	Detail of Fee Submitted	37000.0, 2024-12-11,
	The proposed proprietary name / brand name	**Granton 50mg Tablet**
	Label Claim	Each film coated Tablet Contains:Itopride HCl eq. to Itopride 50mg
	Pharmacotherapeutic Group of (API)	Gastro prokinetic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	PMDA japan
	For generic drugs (me-too Status)	ITP 50mg Tablets by Sami Pharmaceuticals (Reg.No.....075851)
	Proposed Pack Size	1x10's Tablets -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	PRAYOSHA HEALTH CARE PVT.LTD. Plot No. 6209, GIDC Ind. Estate Ankleshwar. Dist; Bharuch INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against ITP tablet of M/s Sami
	Detail of stability batches of drug product	3 batches of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Following shall be submitted: • Drug substance analytical procedure shall be submitted from both drug substance and drug product manufacturer shall be submitted. Reply: Firm has submitted drug substance analytical procedure. • Revision of label claim shall be submitted as per reference product. Reply: Firm has submitted following label claim: "Each film coated Tablet Contains: Itopride HCl .....50mg" • Drug product analytical procedure of the assay test shall be submitted. Reply: Submitted • Batch manufacturing record for the drug product stability batches shall be submitted. Reply: BMR submitted for all three drug product stability batches. • Justification shall be submitted for the UV spectrophotometric method applied for the performance of drug product Assay test. Reply: The drug substance manufacturer performs the Drug substance Assay on Titration method (The Titration method is attached above). Whereas the Drug Product not found in any pharmacopeia and Specification of the product as in house specification. So Assay test perform on the UV Spectrophotometer method which is validated and the Validation record attached here for their Justification. • Document confirming procurement of drug substance shall be submitted. Reply: Firm has submitted loan letter form M.s Seraph Pharma along with clearance certificate issued by DRAP I&E office to M/s Seraph
	Shortcoming	
	Decision	Approved With following label claim: Each film coated Tablet Contains: Itopride HCl .....50mg. Firm shall submit following before issuance of registration letter: Fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024. Verification of loan letter

Sr. No	Title	Description
64	Name, address of Manufacturing site.	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur**(000920)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(XG9-3T9-ZJ9G, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-10-07,
	The proposed proprietary name / brand name	**MOFAX 400mg tablet**
	Label Claim	Each film coated Tablet Contains:Moxifloxacin HCl eq. to Moxifloxacin 400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered by US – FDA
	For generic drugs (me-too Status)	MOXIGET 400mg Tablets by Getz Pharmaceuticals (Reg.No.....047117)
	Proposed Pack Size	1x5's Tablets -As per SRO
	GMP status of the firm	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of "Tablet (General)" vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 30-09-2020.
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBagaRaiwind Kahna Road Raiwind Pakistan Tel: +92 42 35376001 – 06 Fax: +92 42 35376007 Contact Person: Mr. Syed Saleem Razzaq Manager Quality Assurance Zenith Chemical Industries (Pvt) L
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Moxiget tablet of M/s Getz
	Detail of stability batches of drug product	3 batches of 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
65	Name, address of Manufacturing site.	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan**(000942)**
	Case Category	New Section (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(XV4-WQG-R4AZ, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-06-04,
	The proposed proprietary name / brand name	**Texet Tablet 37.5/325mg**
	Label Claim	Each Film Coated Tablet Contains:Paracetamol.....325mgTramadol Hydrochloride....37.5mg(USP Specification)
	Pharmacotherapeutic Group of (API)	Analgesic/ Opioid Analgesic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Tramadol/Paracetamol 37.5mg / 325mg tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) MHRA Approved
	For generic drugs (me-too Status)	Tonoflex-P Tablet (SAMI Pharmaceuticals Karachi (Reg. No. 067163)
	Proposed Pack Size	1x5’s, 1x10’s, 2x7’s-As per SRO
	GMP status of the firm	Firm has been granted additional section of “Tablet section (General)” vide letter no. F.1-25/2008-Lic (Vol-I) issued by Secretary CLB dated 21-01-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of “Tablet section (General)” vide letter no. F.1-25/2008-Lic (Vol-I) issued by Secretary CLB dated 21-01-2023
	Name & address of API manufacturer	M/s. Aurobindo Pharma Limited, L/L M/s. SLR Pharma Private Limited Plot No: A-69,New Survey No.: 522, API Estate, Settipalli (Post), Tirupati-517506, Chittoor (dist.), Andhra Pradesh, INDIA,PHARMAGEN LIMITED Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies against Tonoflex P tablet
	Detail of stability batches of drug product	3 batches of 1000 tablet each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	For tramadol firm has submitted loan letter from De Mmt Research Laboratories along with clearance certificate issued by DRAp I&E Lahore dated 14-06-2022 in name of M/s Demont Research Laboratories
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
66	Name, address of Manufacturing site.	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan**(000980)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ZBX-G8A-ESDP, 2024-12-28)
	Detail of Fee Submitted	30000.0, 2024-03-13,
	The proposed proprietary name / brand name	**G-MYCIN 250MG CAPSULE**
	Label Claim	Each capsule conatins: Azithromycin as dihydrate.... 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too Status)	ZITHROMAX 250MG CAPSULE
	Proposed Pack Size	12's-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Capsule (General)” vide letter no. F.4-3/2023-Lic issued by Secretary CLB dated 25-10-2023.
	Name & address of API manufacturer	Citi Pharma Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per Zone IV conditons
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP against reference product of Azomax capsule
	Detail of stability batches of drug product	3 batches of 2500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Following shall be submitted: • Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted. Reply: Firm has submitted Drug substance specifications, analytical procedure and analytical method verification studies
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
67	Name, address of Manufacturing site.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT**(000941)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ZHG-5XY-B2ET, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-09-30,
	The proposed proprietary name / brand name	**Sewpram 20mg Tablet**
	Label Claim	Each film coated tablet contains: Escitalopram oxalate equivalent to Escitalopram ..... 20mg (Product Specs: USP Specs.)
	Pharmacotherapeutic Group of (API)	ntidepressants, selective serotonin reuptake inhibitors ATC-code: N 06 AB 10
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	approved by US FDA
	For generic drugs (me-too Status)	Citanew 20mg tablet
	Proposed Pack Size	as per SRO's-As per SRO
	GMP status of the firm	Firm has been granted new DML vide letter no. 1-42/2011-Lic dated 16-09-2021 including tablet section
	Evidence of approval of manufacturing facility	Firm has been granted new DML vide letter no. 1-42/2011-Lic dated 16-09-2021 including tablet section
	Name & address of API manufacturer	Smilax Laboratories Limited Address: Plot No: 12/A, Phase – III, IDA Jeedimetla, Hyderabad – 500 055, Telangana state, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Citanew tablet
	Detail of stability batches of drug product	3 batches of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted License to import issued by DRAP I&E Office along with Airway Bill and commercial invoice
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
68	Name, address of Manufacturing site.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore.**(000964)**
	Case Category	New License (Ammar Ashraf Awan)
	Application Form Dy. No / Tracking ID & date of submission	(ZMZ-99W-ZLN2, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-10-11,
	The proposed proprietary name / brand name	**Diclof 50 mg tablet**
	Label Claim	Diclof 50mg TabletEach Film Coated Tablet Contains:-Diclofenac Potassium.....50mg(USP Specification) .
	Pharmacotherapeutic Group of (API)	Anti-inflammatory
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Cataflam® Table USFDA Approved.
	For generic drugs (me-too Status)	Diclorep 50 mg Tablet by SAMI Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “Tablet (General)” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Name & address of API manufacturer	AARTI DRUGS LIMITED Plot No. G - 60, M.I.D.C., Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Diclorep tablet of M/s Sami
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	The case has been processed against the New DML priority. Following shall be submitted: • Drug substance analytical method verification studies shall be submitted from M.s Auspec Pharmaceuticals Reply: Submitted • Process validation protocol shall be submitted. Reply: Submitted • Analytical record for the dissolution test performed during drug product stability studies shall be submitted. Reply: UC spectrums have been submitted • BMRs of drug product stability batches shall be submitted. Reply: Submitted for drug product stability batches
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
69	Name, address of Manufacturing site.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore**(000590)**
	Case Category	New Section (Dr. Farhad Ullah)
	Application Form Dy. No / Tracking ID & date of submission	(GQY-U3D-N69X, 2024-11-14)
	Detail of Fee Submitted	30000.0, 2024-08-19,
	The proposed proprietary name / brand name	**Zorva 200mg Injection**
	Label Claim	Each vial contains: Voriconazole sterile lyophilized powder.....200mg
	Pharmacotherapeutic Group of (API)	Triazole and tetrazole derivatives
	Reference to Finished product specifications	Any Other
	The status in reference regulatory authorities	VFEND (voriconazole) 200mg for injection USFDA Approved
	For generic drugs (me-too Status)	Vecot 200mg Powder for Injection by m/S Nabiqasim Industries (Reg# 89050)
	Proposed Pack Size	1's-De-Controlled
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional sections dated 25-10-2023 specifying Dry powder for Injection (General) section.
	Name & address of API manufacturer	Rajasthan Antibiotics Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of drug substance as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Vfend 200mg injection
	Detail of stability batches of drug product	3 batches having batch size of 268 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted copy of clearance certificate cleared dated 27-12-2023 specifying 01kg Voriconazol Sterile Powder. The clearance certificate is cleared by AD (I&E) DRAP.
	Evaluation	The firm has applied for JP specifications. Shortcomings 1. Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required 2 Submit details of innovator/comparator product including manufacturer name, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed 3 Justification is required for not including the test for water content, appearance and clarity of reconstituted solution and osmolality in finished product specification as recommended by EMA public assessment report. Firm's Response: 1. Firm has submitted copy of cGMP certificate of API manufacturer issued by Food Safety & Drugs Control Commissionerate, Government of Rajastan India valid upto 21-02-2026 2. Firm has submitted details of innovator/comparator product. Brand Name: Vfend I.V.; Manufacturer name: M/s Pfizer Batch No: HP3823 Expiry date: 03/2026 3. The firm submitted that we are testing our product in accordance with the Japanese Pharmacopoeia (JP) specifications and submitted the monograph of applied product.
	Shortcoming	
	Decision	Approved Approved with JP specifications

Sr. No	Title	Description
70	Name, address of Manufacturing site.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore**(000590)**
	Case Category	New Section (Dr. Farhad Ullah)
	Application Form Dy. No / Tracking ID & date of submission	(WHL-YQ5-YP8Q, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-11-07,
	The proposed proprietary name / brand name	**Vironov**
	Label Claim	Each Vial Contains: Acyclovir Sodium eq. to Acyclovir.....500mg
	Pharmacotherapeutic Group of (API)	Antivirals
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Zovirax for Injection 500mg, USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too Status)	Acyclovir injection 500mg by M/s Abbott Laboratories (Reg#21397)
	Proposed Pack Size	1's -As per SRO
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional sections dated 25-10-2023 specifying Dry powder for Injection (General) section.
	Name & address of API manufacturer	RAJASTHAN ANTIBIOTIC LTD.,
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of drug substance as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Acyclovir 500mg injection manufactured by M/s Abbot Laboratories Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 500 vials each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Firm has submitted copy of clearance certificate cleared dated 27-12-2023 specifying 01kg Acyclovir sterile powder. The invoice is cleared by AD (I&E) DRAP.
	Evaluation	Shortcomings 1. Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response: 1. Firm has submitted copy of cGMP certificate of API manufacturer issued by Food Safety & Drugs Control Commissionerate, Government of Rajastan India valid upto 21-02-2026
	Shortcoming	
	Decision	Deferred Registration Board deferred the case for submission of evidence of applied formulation in Reference Regulatory Authorities as pre-lyophilized ready to fill powder.

Sr. No	Title	Description
71	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(19T-4P8-G96P, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Ofyl 400mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: -Doxoyfylline.....400mg
	Pharmacotherapeutic Group of (API)	methylxanthine derivative
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	AIFA Italy Approved.
	For generic drugs (me-too Status)	Unifyline 400mg Tablet by Platinum Pharmaceuticals
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with Tablet General section
	Name & address of API manufacturer	Aarey Drugs and pharmaceuticals pvt.Ltd. 1227, Hubtown Solaris,12th Floor, N.S. Phadke Marg, Opp-Telli Galli, Andheri Flyover Bridge, Andheri East, Mumbai.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Unifylline Tablet of Platinum: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	29-08-2023 clearance certificate from EG pharma submitted. Loan letter from EG is required
	Evaluation	1. Submit API specifications and analytical method from API manufacturer. Submitted by the firm 2. Submit API verification studies from drug product manufacturer Submitted by the firm 3. Submit complete HPLC chromatograms for stability studies. Complete stability study data of all the three batches for all tim epoints is not submitted. 4. Submit BMR of stability batches Submitted by the firm 5. Submit loan letter from EG Pharma Firm has submitted loan letter from EG pharma and DRAP intimation letter dated 13-03-2024.
	Shortcoming	
	Decision	Deferred for submission of analytical record of stability study data of all batches along with raw data sheets and COA.

Sr. No	Title	Description
72	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(27Y-JMQ-7UB7, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-14,
	The proposed proprietary name / brand name	**Azimis Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains:Azithromycin Dihydrate Eq. toAzithromycin..... 200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too Status)	Azitma 200mg/5ml Dry Powder Suspension by SAMI Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	15ml/30ml-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Dry powder General Section
	Name & address of API manufacturer	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azitma Suspension by Sami: PE studies performed
	Detail of stability batches of drug product	3 batches: 100 bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	Submit documents for procurement for API Response: Firm has submitted commercial invoice dated 04-09-2023
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
73	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(B1N-6MV-4JDD, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-08-10,
	The proposed proprietary name / brand name	**Metmaf**
	Label Claim	Each 100ml glass Vial Contains: Metronidazole...500mg
	Pharmacotherapeutic Group of (API)	nitroimidazole antimicrobials
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Metrozine Injection, TGA, Australia approved
	For generic drugs (me-too Status)	Flagyl Injection by Sanofi-Aventis Limited, Pakistan
	Proposed Pack Size	100mlx1's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid vial SVP injection (general) Section
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flagyl -Hoescht (PE performed)
	Detail of stability batches of drug product	3 batches : 10 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	16-11-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
74	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(2NM-15P-TP3G, 2024-10-25)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Azimis 250mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin 250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US-FDA
	For generic drugs (me-too Status)	Azitma 250mg Tablet by Sami Pharmaceuticals, Karachi-Pakistan
	Proposed Pack Size	1x10's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azitma Tablet of Sami: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	Submit evidence of procurement of API Response: Firm has submitted commercial invoice dated 04-09-2023
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
75	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(2RM-8T9-JR3D, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Minafine 125mg Tablet**
	Label Claim	Each Tablet Contains: Terbinafine as HCl...125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Lamisil Tablet, TGA Approved
	For generic drugs (me-too Status)	Terbisil 125mg Tablet by Saffron Pharmaceuticals, Faisalabad-Pakistan
	Proposed Pack Size	1x10's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Tagoor Laboratories Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Terbisil Tablet by Saffron: PE and CDP studies approved
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 24-10-2023 of Magns Pharma is submitted
	Evaluation	1. Submit API stability data as per zone IV-A conditions Response: API stability data is submitted as per zone IV-A 2. Submit loan letter. Firm has submitted loan letter from Magns Pharma
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
76	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(3U1-SX5-RQQS, 2024-11-29)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefas 400mg Capsule**
	Label Claim	Each capsule contains: Cefixime as Trihydrate.....400mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Suprax 400mg Capsule (USFDA Approved)
	For generic drugs (me-too Status)	Cefiget 400mg Tablet (Opal Lab. Karachi) Reg. No. 045118)
	Proposed Pack Size	5-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with Capsule (Cephalosporin) section
	Name & address of API manufacturer	Pharmagen
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefiget capsule of Getz: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	12-03-2024: Invoice submitted
	Evaluation	1. Submit API specifications and analytical method from API manufacturer. Submitted by the firm 2. Submit complete HPLC chromatograms for stability studies. Complete stability study data of all the three batches for all time points is not submitted.
	Shortcoming	
	Decision	Deferred for submission of analytical record of stability study data of all batches along with raw data sheets and COA.

Sr. No	Title	Description
77	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(Q9M-8L7-ST2G, 2024-08-07)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Koratol**
	Label Claim	Each 1ml Ampoule Contains: Ketorolac Tromethamine 30mg
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Available i.e. Toradol Injection 30mg/ml by Martin Dow Marker, Quetta-Pakistan
	Proposed Pack Size	1mlx5's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	Perkin Laboratories Hyderababad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Toradol -Martin dow (PE performed)
	Detail of stability batches of drug product	3 batches : 1800 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	28-09-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
78	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(43L-SQZ-ZPRD, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-31,
	The proposed proprietary name / brand name	**Linnco 600mg/2ml injection**
	Label Claim	Each 2ml ampoule Contains:Lincomycin(as HCl Monohydrate).....600mg
	Pharmacotherapeutic Group of (API)	Antiobiotics
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Lincocin Pfizer USFDA approved
	For generic drugs (me-too Status)	Lincocin Injection For Pfizer Pakistan Ltd
	Proposed Pack Size	2mlx5ampoules-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	ningxia taiyicin Biotech Co Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lincocin - Pfizer: P.E performed
	Detail of stability batches of drug product	3 batches : 10 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	07-03-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
79	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(43N-69U-4A8Y, 2024-09-18)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**XINFAX 150MG XR CAPSULE**
	Label Claim	Each capsule contains: Venlafaxine HCl SR pellets eq. to Venlafaxine 150mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Efexor 150mg XR Capsules by Pfizer
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Efexor Capsule of Pfizer: P and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	05-04-2024: invoice submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Justify how 333.33mg of 33% pellets is equivalent to 150mg venlafaxine. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
80	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ULE-8SL-6RDB, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-21,
	The proposed proprietary name / brand name	**Nalfin**
	Label Claim	Each 1ml Ampoule Contains: Nalbuphine Hydrochloride...10mg
	Pharmacotherapeutic Group of (API)	opioid analgesic
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Health Canada
	For generic drugs (me-too Status)	Nalfy Injection by Global Pharmaceuticals, Islamabad-Pakistan
	Proposed Pack Size	1mlx5's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	Rusan Pharma
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nalfy -Global Pharma (PE performed)
	Detail of stability batches of drug product	3 batches : 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	06-07-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
81	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(4X8-538-U9X8, 2024-11-18)
	Detail of Fee Submitted	37000.0, 2024-10-30,
	The proposed proprietary name / brand name	**Skygab 25mg Capsule**
	Label Claim	Each Capsule contains:Pregabalin.....25mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Gabica Capsules 25mg of M/s Getz Pharma
	Proposed Pack Size	1x5’s, 1x6’s, 2x7’s,-As per SRO
	GMP status of the firm	18-09-2023: New DML
	Evidence of approval of manufacturing facility	18-09-2023: Capsule General Section
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd., Add: Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Pregabalin Milpharm 25mg Capsule: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 2500 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from wimits pharma and clearance certificate is also submitted
	Evaluation	
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
82	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(52R-RNS-QJT1, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-10-10,
	The proposed proprietary name / brand name	**PREVEXA 20MG TABLETS**
	Label Claim	Each Flm coated Tablet contains:Escitalopram Oxalate equivalent to Escitalopram 20mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Brand Name Escitalopram Oxalate 20mg Tablet Marketing Authorization holder: USA
	For generic drugs (me-too Status)	Citanew 20mg Tablet by Hilton Pharma
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	SHODHANA LABORATORIES PRIVATE LIMITED, PLOT NO. 24,25 & 26, PHASE-I, IDA, JEEDIMETLA, HYDERABAD, JEEDIMETLA – PHASE – I & II VILLAGE QUTHBULLAPUR (MANDAL), MEDCHAL – MALKAJGIRI, DISTRICT PINCODE 500055, TELANGANA STATE, INDIA(India)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cipralex Tablet by Lundbeck: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	20-03-2024: Clearance certificate submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit 6th month stability study data. 6. Submit BMR of stability batches 7. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
83	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(5AN-1B8-HVRD, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-09-02,
	The proposed proprietary name / brand name	**Mafcobal 500ug/1ml Injection**
	Label Claim	Each 1ml ampoule contains:Mecobalamin J.P 500mcg
	Pharmacotherapeutic Group of (API)	Cobalamin derivatives
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	PMDA JAPAN approved
	For generic drugs (me-too Status)	Methycobal 500ug Injection
	Proposed Pack Size	1mlx10ampoules-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	Mahima Life sciences (pvt) Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Methycobal -Hilton (PE performed)
	Detail of stability batches of drug product	3 batches : 2 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	26-05-2022: Clearance certificate submitted
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
84	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(5Y6-V7A-9D31, 2024-10-30)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**OZAPINE 7.5mg TABLETS**
	Label Claim	Each Film coated Tablet contains:OLANZAPINE 7.5mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ZYPREXA (olanzapine) Tablet for Oral use F.D.A Approved.
	For generic drugs (me-too Status)	Zyprexa 7.5mg Tablets By Eli lilly Pharma
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Smilax Laboratories Limited Hyderabad, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit 6th month stability study data. 6. Submit BMR of stability batches 7. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP. 8. Submit documents for procurement of API including clearance certificate
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
85	Name, address of Manufacturing site.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore**(000845)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(6LB-1BV-R7VL, 2024-08-09)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Eprogen 25mg/mL Oral Solution**
	Label Claim	Each ml of Oral Solution contains: Topiramate ... 25mg
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Eprontia 25mg/mL- Azurity Pharmaceuticals, Inc.-USFDA
	For generic drugs (me-too Status)	Not applicable
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	25-03-2022: GMP certificate
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s Bal Pharma Limited (Unit – II). 61-B, Bommasandra Industrial Area Bangalore – 560 099, INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Eprontia oral solution: PE studies performed
	Detail of stability batches of drug product	2 Batches: 2000 Bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 18-10-2022 submitted
	Evaluation	1. Submit evidence of approval of manufacturing facility / section approval letter on the basis of which you have claimed new section priority. Response: Firm has submitted layout plan approval letter dated 05-01-2021, however letter for section approval is not submitted.
	Shortcoming	
	Decision	Deferred for evidence of required manufacturing facility / section from Licensing Division.

Sr. No	Title	Description
86	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(88V-9A8-PS4W, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	**Micam**
	Label Claim	Each Tablet Contains: Piroxicam as Beta-Cyclodextrin...20mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	AIFA Approved
	For generic drugs (me-too Status)	Brexin 20mg Tablet by Chiesi Pharmaceuticals Pvt. Ltd., Lahore-Pakistan
	Proposed Pack Size	2x10's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Nantong Jinghua Pharmaceutical co Ltd China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brexin Tablet of Chiesi: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 2000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Quaper and claerance certificate dated 19-06-2022
	Evaluation	Analytical method of drug product specifies HPLC method for assay test, while only UV data is submitted in analytical record of stability studies. Response: We have done all the testing regarding drug substance and drug product on UV-Spectrophotometer.
	Shortcoming	
	Decision	Deferred for clarification for adopting UV method for the analysis of drug product since the innovator's product recommend HPLC testing.

Sr. No	Title	Description
87	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(8TR-9PU-B776, 2024-09-30)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	**Onofas 8mg Tablet**
	Label Claim	Each film coated tablet contains: Ondansetron as (hydrochloride dihydrate).....8mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved 8mg film coated tablet
	For generic drugs (me-too Status)	Onset Tablets 8mg by Pharmedic Laboratories (Pvt.) Ltd Lahore
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with Tablet General section
	Name & address of API manufacturer	Symed Labs Limited, Unit-VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri Bhuvangiri (Dist) – 508 252, Telangana, INDIA.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Tablet of Pharmedic: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from linear pharma submitted. However clearance certificate is not submitted
	Evaluation	1. Submit API specifications and analytical method from API manufacturer. Submitted by the firm 2. Submit API verification studies from drug product manufacturer Submitted by the firm 3. Submit complete HPLC chromatograms for stability studies. Complete stability study data of all the three batches for all time points is not submitted. 4. Submit API loan letter Firm has submitted loan letter from Linear pharma and DRAP intimation letter dated 14-11-2023. 5. Submit BMR of stability batches Submitted by the firm 6. Submit API stability data as per zone IV-A We have informed the supplier about the requirement for Zone IVa data from the API stability study. Once we receive it, we will submit it to you.
	Shortcoming	
	Decision	Deferred for following submissions: 1. Analytical record of stability study data of all batches along with raw data sheets and COA. 2. API stability data as per zone IV-A

Sr. No	Title	Description
88	Name, address of Manufacturing site.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi**(000718)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(96D-78N-N1YT, 2024-12-26)
	Detail of Fee Submitted	37000.0, 2024-12-12,
	The proposed proprietary name / brand name	**Terbicid Cream**
	Label Claim	Each gram of cream contains: Terbinafine Hydrochloride.....10mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	Any Other
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Lamisil 1% cream by GSK
	Proposed Pack Size	10gram-As per SRO
	GMP status of the firm	17-01-2024: Grant of New DML (Afresh)
	Evidence of approval of manufacturing facility	17-01-2024: Cream/ointment section
	Name & address of API manufacturer	M/s Synergene Active Ingredients Pvt Ltd India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lamisil Cream by GSK: PE studies performed
	Detail of stability batches of drug product	3 batches: 500 tubes
	Documents for the procurement of API with approval from DRAP (in case of Improt)	25-04-2019: AD clearance invoice
	Evaluation	Justify how your application falls under new section category since your license is Afresh. Response: Medisynth pharmaceuticals was granted Dml in 2011 with two sections only i-e Tablet and Capsule . In 2020 we were granted approval of two more sections.i-e Sachet and Cream/Oinmet but no registration was applied in these two section for one or another reason. In 2023 we changed our manufacturing address and same section were applied for Drug manufacturing Licence and A fresh license was granted by Licensing Board in Janurary 2024 .it is therefore requested that the product may be considered on priority as no product is registered in these sections.
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
89	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(9DY-AN2-6Q5J, 2024-10-28)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**XINFAX 37.5MG XR CAPSULE**
	Label Claim	Each capsule contains: Venlafaxine HCl SR pellets eq. to Venlafaxine 37.5mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Efexor 37.5mg XR Capsules by Pfizer
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Efexor Capsule of Pfizer: P and CDP performed
	Detail of stability batches of drug product	3 Batches: 1540 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	05-04-2024: invoice submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Justify how 113.64mg of 33% pellets is equivalent to 37.5mg venlafaxine. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP. 9. Commercial invoice specifies that material was procured on 05-04-2024, while the stability study initiation date is 04-04-2024. Justify how stability could be initiated even before purchase of raw material.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
90	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ANP-VYR-Q6RR, 2024-10-21)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Ondron 8mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Ondansetron as Hydrochloride Dihydrate...8mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	ONSET 8mg Tablet by Pharmedic Laboratories, Lahore-Pakistan
	Proposed Pack Size	1x10's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Sonia Organics. Factory: # 22/2, Attibele, Industrial Area, Balagaranahalli Village/ Anekal Taluk, Bangaluru – 562107- INDIA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Onset Tablet of Pharmedic: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Medisave Pharma and clearance certificate of Medisave dated 08-06-2022 submitted.
	Evaluation	
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
91	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(AWT-YT2-GMW9, 2024-10-28)
	Detail of Fee Submitted	30000.0, 2024-08-16,
	The proposed proprietary name / brand name	**XINFAX 75MG XR CAPSULE**
	Label Claim	Each capsule contains: Venlafaxine HCl SR pellets eq. to Venlafaxine.....75mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Efexor 75mg XR Capsules by Pfizer
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Efexor Capsule of Pfizer: P and CDP performed
	Detail of stability batches of drug product	3 Batches: 1540 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	05-04-2024: invoice submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Justify how 227.27mg of 33% pellets is equivalent to 75mg venlafaxine. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP. 9. Commercial invoice specifies that material was procured on 05-04-2024, while the stability study initiation date is 04-04-2024. Justify how stability could be initiated even before purchase of raw material.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
92	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(D9Y-J6P-P2VP, 2024-10-09)
	Detail of Fee Submitted	30000.0, 2024-07-05,
	The proposed proprietary name / brand name	**BIODEX 30MG CAPSULE**
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Dextol 30MG DDR Capsule M/s Seraph Pharmaceutical, Islamabad
	Proposed Pack Size	10's,14,s, 2's, 28's-As per SRO
	GMP status of the firm	13-09-2022: New DML
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Razodex Capsule of Getz: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 22-03-2024 submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Justify how 177mg of 17% pellets is equivalent to 30mg dexlansoprazole. 6. The analytical method of drug product specifies that standard solution testing is performed at 0.6mg/ml concentration, while your validation studies parameters are conducted at 0.24mg/ml concentration. Justify how this difference can be scientifiically justified. 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
93	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(DBS-LJV-Q2M8, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-05-02,
	The proposed proprietary name / brand name	**Skydol Solution for Infusion 1g/100ml**
	Label Claim	Each 100ml vial contains: Paracetamol.....1000mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Provas 1g/100ml Infusion of M/s SAMI
	Proposed Pack Size	100ml, As per SRO-As per SRO
	GMP status of the firm	18-09-2023: New DML
	Evidence of approval of manufacturing facility	26-01-2024: Liquid vial general section SVP
	Name & address of API manufacturer	M/s Pharmagen Limited, Add: Kot Nabi Bukhsh Wala, 34-KM, Ferozpur Road, Lahore, Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provas Infusion of Sami: PE studies performed
	Detail of stability batches of drug product	3 batches: 500 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from wimits pharma with invoice
	Evaluation	
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
94	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ED4-Q6M-MEUS, 2024-09-20)
	Detail of Fee Submitted	30000.0, 2024-07-05,
	The proposed proprietary name / brand name	**Itrosaq**
	Label Claim	Each Capsule Contains: Itraconazole IR Pellets...100mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Icon 100mg Capsule By Ferozsons Laboratories-Nowshera
	Proposed Pack Size	1x4's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Capsule General Section
	Name & address of API manufacturer	Vision Pharmaceuticals (PVT) LTD. Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Humak Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Icon capsule of Ferozeson: PE studies conducted
	Detail of stability batches of drug product	3 batches: 2000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit CDP studies Response: Firm has submitted CDP studies against Icon capsule of Ferozesons. 2. Submit documents for procurement of API Response: Firm has submitted commericial invoice dated 08-11-2023
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
95	Name, address of Manufacturing site.	**Highnoon Laboratories Ltd** 17.5 KM, Multan Road,**(000155)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ERT-BHQ-ZUYZ, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-03,
	The proposed proprietary name / brand name	**FAVAIR 62.5MCG/25MCG ROTACAPS**
	Label Claim	Each capsule contains:Umeclidinium (as bromide) ……62.5mcgVilanterol (as trifenatate) ……25mcgEach delivered dose contains:Umeclidinium (as bromide) ……55mcgVilanterol (as trifenatate) ……22mcg
	Pharmacotherapeutic Group of (API)	adrenergics in combination with anticholinergics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA (ANORO ELLIPTA)
	For generic drugs (me-too Status)	Not Avaialable
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	GMP certifcate: Inspection date 12-06-2024
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	INKE, S.A. Área Industrial del Llobregat, C/ Argent, 1 08755 CASTELLBISBAL (Barcelona) SPAIN
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted as per zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	ANORO ELLIPTA: PE studies performed
	Detail of stability batches of drug product	3 batches: 24000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	AD cleared invoice: 11-01-2021
	Evaluation	1. Submit evidence of approval of manufacturing facility / section approval letter from Licensig Division 2. The innovator's product contains 2 foil blister strips each containing seprate API while your product contains both ingredients mixed in a single capsule. Clarify how your product can be considered equivalent or comparable to the reference product. 3. Submit compatibility studies of both drug substances, since the reference product do not have both drug substances mixed together in a single capsule or pouch. 4. Justify the assay limit 80% - 120% for the drug product. 5. Submit details of the device to be used along with the applied product.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
96	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(H6E-G51-HUJ6, 2024-09-12)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Micip 250mg Tablet**
	Label Claim	Each film Coated Tablet Contains: -Ciprofloxacin Hydrochloride Eq. to.Ciprofloxacin.....250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Ciprofloxacin 250 mg Film-coated Tablets M/s Aurobindo Pharma Ltd MHRA approved
	For generic drugs (me-too Status)	Cip Val Tablet 250mg (GlaxoSmithKline Pakistan Limited F/268, SITE Karachi) Reg. No. 050687
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Pharmagen Limited 34-Km, Ferozepur Road, Lahore
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ciproxin Tablet of Bayer: PE and CDP studies conducted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	23-10-2023 commercial invoice submitted
	Evaluation	Submit differential fee, since your application was received in DRAP after 1st September 2024
	Shortcoming	
	Decision	Approved . Firm shall submit 7000 differential fee before issuance of Registration letter.

Sr. No	Title	Description
97	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(JG7-DNP-BU2B, 2024-12-10)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Cefas 200mg/5ml Suspension**
	Label Claim	Each 5ml of Reconstituted Suspension Contains:-Cefixime (As Trihydrate) 200mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml (USFDA Approved)
	For generic drugs (me-too Status)	Cefspan D.S Suspension by Barret Hodgson
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder suspension (Cephalosporin) section
	Name & address of API manufacturer	Pharmagen Limited 5-A Zafar Ali Rd, Gulberg V, Lahore, Punjab.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefspan DS suspension: PE studies performed
	Detail of stability batches of drug product	3 batches: 666 bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	06-03-2024: Invoice submitted
	Evaluation	1. Submit API specifications and analytical method from API manufacturer . 2. Submit complete HPLC chromatograms for stability studies. 3. Submit compatability studies 4. Submit in-use stability studies 5. Submit preservative effectiveness studies
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
98	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(LAZ-XGG-S4Q3, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Lidon**
	Label Claim	Each 2ml Ampoule Contains: Lidocaine HCl 20mg
	Pharmacotherapeutic Group of (API)	Anesthetic agent
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Xylex 1% Injection by Venus Pharma, Lahore,Pakistan
	Proposed Pack Size	2mlx100's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Surgicain injection - Harmann (PE performed)
	Detail of stability batches of drug product	3 batches : 500 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Material Loan from N.S Pharma, Lahore
	Evaluation	
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
99	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(M7S-239-61NV, 2024-10-17)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Minafine Cream**
	Label Claim	Each Gram Cream Contains: Terbinafine HCl...10mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	Any Other
	The status in reference regulatory authorities	Lamisil 1% Cream, TGA Approved
	For generic drugs (me-too Status)	Terbisil 1% Cream by Saffron Pharmaceuticals, Faisalabad-Pakistan
	Proposed Pack Size	1x15g-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Cream / Ointment General Section
	Name & address of API manufacturer	Tagoor Laboratories Private Limited, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Terbisil Cream by Saffron: PE studies approved
	Detail of stability batches of drug product	3 batches: 500 Tubes
	Documents for the procurement of API with approval from DRAP (in case of Improt)	24-10-2023: Clearance certificate of Magns Pharma is attached
	Evaluation	Submit loan letter from Magns Pharma Response: Firm has submitted copy of loan letter from Magns Pharma
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
100	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MT6-THT-516A, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-07-05,
	The proposed proprietary name / brand name	**BIODEX 60MG CAPSULE**
	Label Claim	Each capsule contains:Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 60MG
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Dexilant 60mg Capsule Marketing Authorization holder: Takeda Pharmaceuticals America, Inc.
	For generic drugs (me-too Status)	Dextol 30MG DDR Capsule M/s Seraph Pharmaceutical, Islamabad
	Proposed Pack Size	10's,14,s, 28's, 30'-As per SRO
	GMP status of the firm	13-09-2022: New DML
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Razodex Capsule of Getz: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1245 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Commercial invoice dated 20-03-2024 submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Justify how 267mg of 22.5% pellets is equivalent to 60mg dexlansoprazole. 6. The analytical method of drug product specifies that standard solution testing is performed at 0.6mg/ml concentration, while your validation studies parameters are conducted at 0.24mg/ml concentration. Justify how this difference can be scientifiically justified. 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
101	Name, address of Manufacturing site.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi**(000718)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(MYP-9BD-9333, 2024-12-26)
	Detail of Fee Submitted	37000.0, 2024-12-12,
	The proposed proprietary name / brand name	**Blikast 4mg Sachet**
	Label Claim	Each Sachet Contains: Montelukast as Sodium.....4mg
	Pharmacotherapeutic Group of (API)	eukotriene receptor antagonist
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Lucast 4mg Sachet
	Proposed Pack Size	14s-As per SRO
	GMP status of the firm	17-01-2024: Grant of New DML (Afresh)
	Evidence of approval of manufacturing facility	17-01-2024: Sachet section
	Name & address of API manufacturer	Morepen Laboratories Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Singulair Sachet: PE and CDP performed.
	Detail of stability batches of drug product	3 batches: 1500 Sachet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Polyfine and clearance certificate submitted.
	Evaluation	Justify how your application falls under new section category since your license is Afresh. Response: Medisynth pharmaceuticals was granted Dml in 2011 with two sections only i-e Tablet and Capsule . In 2020 we were granted approval of two more sections.i-e Sachet and Cream/Oinmet but no registration was applied in these two section for one or another reason. In 2023 we changed our manufacturing address and same section were applied for Drug manufacturing Licence and A fresh license was granted by Licensing Board in Janurary 2024 .it is therefore requested that the product may be considered on priority as no product is registered in these sections.
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
102	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(N8J-RU4-1HRW, 2024-10-10)
	Detail of Fee Submitted	30000.0, 2024-08-10,
	The proposed proprietary name / brand name	**Levoflo**
	Label Claim	Each 100ml Vial Contains: Levofloxacin as Hemihydrate...500mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones Antibiotics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Leflox I.V. Infusion 500 mg/100ml by Getz Pharma Pvt. Ltd. Karachi-Pakistan
	Proposed Pack Size	100mlx1's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid vial injection SVP (general) Section
	Name & address of API manufacturer	Zhejiang East-Asia Pharmaceutical Co. Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Leflox Infusion- Getz (PE performed)
	Detail of stability batches of drug product	3 batches : 10 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	clearance certificate - 31-08-2023
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
103	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(P3D-8MV-7XZT, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Mipram 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Escitalopram as Oxalate...10mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Precipra Tablets 10mg by Pfizer Pakistan
	Proposed Pack Size	as per SRO-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Shodhana Laboratories Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Precipra Tablet of Pfizer: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Biorex Pharma submitted
	Evaluation	Stability batches are developed on 08-09-2023 while drug import license of December 2023 is submitted. Kindly submit clearance certifcate of relevant batch.
	Shortcoming	
	Decision	Deferred for submission of evidence of procurement of API used in the manufacturing of stability batches.

Sr. No	Title	Description
104	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(PZ8-2TP-9EWS, 2024-10-23)
	Detail of Fee Submitted	30000.0, 2024-08-10,
	The proposed proprietary name / brand name	**Cipmaf**
	Label Claim	Each 100ml Vial Contains: Ciprofloxacin as Lactate...200mg
	Pharmacotherapeutic Group of (API)	Quinolones
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Novidat Infusion 200mg/100ml by Sami Pharmaceuticals, Karachi Pakistan
	Proposed Pack Size	100mlx1's-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid vials injection SVP (general) Section
	Name & address of API manufacturer	Shangyu Jingxin Pharmaceutical Co., Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches at Zone II
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Novidat Infusion - Sami Pharma (PE performed)
	Detail of stability batches of drug product	3 batches : 10 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	21-09-2022 - clearance certificate
	Evaluation	At section 3.2.S.7 of Module III, Please submit stability data active pharmaceutical ingredient at Zone iv-a at 30 degree celcius and 65% humidity as per climatic conditions of Pakistan OR submit the transport trail of API from API manufacturer to your manufacturing plant . your case will be further processed after provision of the desired documents Response: Submitted by the firm
	Shortcoming	
	Decision	Deferred for further deliberation regarding salt form of ciprofloxacin.

Sr. No	Title	Description
105	Name, address of Manufacturing site.	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore**(000395)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(Q2R-AY3-5H1W, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-11-11,
	The proposed proprietary name / brand name	**Ibtol Tablets**
	Label Claim	Each Film coated tablet contains Ibuprofen ...400 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA / EMC Approved
	For generic drugs (me-too Status)	ibuprofen 400mg tablets by British Pharmaceuticals
	Proposed Pack Size	50's, 100's, 250's, -As per SRO
	GMP status of the firm	22-03-2024: GMP certificate
	Evidence of approval of manufacturing facility	05-11-2019: Grant of additional section Tablet General-II
	Name & address of API manufacturer	Zenith Chemical Industries
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ibuprofen Tablet of British Pharma: PE and CDP studies perfromed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit evidence of procurement of API. 2. Submit BMR of stability batches
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
106	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(QL7-P2T-U6YX, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	**MIRTAGET 15MG TABLETS**
	Label Claim	Each Flm coated Tablet contains:MIRTAZAPINE 15MG
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	REMERON® (mirtazapine) Tablets USFDA Approved.
	For generic drugs (me-too Status)	Mitaz Tablet by Glitz
	Proposed Pack Size	20's, 30's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Almon industries Address: 408/409/410, Baleshwar City, Block A, Near Hathijan Circle, Ahmedabad, Gujarat, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	30 degree / 60% RH
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nassa Tablet by Genetics: PE and CDP submitted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate of Kanel pharma dated 19-10-2022 submitted.
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit API stability study data as per zone IV-A conditions. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
107	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(R7W-669-W4RL, 2024-12-04)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Azimis 500mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Azithromycin as Dihydrate.....500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Zetro 500mg Tablet by Getz Pharma-Karachi-Pakistan
	Proposed Pack Size	1x6's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit Pharmaceutical equivalence and CDP studies Response: Firm has submitted PE and CDP studies against Azomax Tablet 2. Submit evidence of procurement of API Response: Firm has submitted commercial invoice dated 04-09-2023
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
108	Name, address of Manufacturing site.	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan**(000619)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RE2-7YZ-ALTV, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-06-20,
	The proposed proprietary name / brand name	**Foxi 2gm Injection**
	Label Claim	Each vial contains: Cefoxitin as sodium.....2gm
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Cefoxitin 2gm is approved in USFDA link is : https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=065414
	For generic drugs (me-too Status)	Xitevo Injection 2 gm Reg # 100652 Mfg by Evolution Pharmaceutica Pvt Ltd.
	Proposed Pack Size	1s-As per SRO
	GMP status of the firm	Not Submitted
	Evidence of approval of manufacturing facility	22nd Dec, 2020: Dry Powder Injection Cephalosporin
	Name & address of API manufacturer	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 Batches as per Zone-IVA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefoxitin Injection of Fresenius Kabi, Italy: PE studies performed
	Detail of stability batches of drug product	3 Batches: 1000 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	05 Aug, 2021: Commercial invoice cleared by ADC
	Evaluation	1. Submit API specifications and analytical method from drug product manufacturer. 2. Submit drug substance verification studies from drug product manufacturer. 3. Submit GMP certificate of drug product manufacturer. GMP certificate issued on the basis of inspection dated 07-08-2024 is submitted.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
109	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RVD-TVW-6UXJ, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**OZAPINE 5mg TABLETS**
	Label Claim	Each Film coated Tablet contains:OLANZAPINE 5mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ZYPREXA (olanzapine) Tablet for Oral use F.D.A Approved.
	For generic drugs (me-too Status)	Zyprexa Tablets by Eli lilly
	Proposed Pack Size	10,20,30,50,100 pack-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Smilax Laboratories Limited Hyderabad, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zyprexa Tablet of Eli Lilly: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	22-04-2024: Clearance certificate submitted
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit 6th month stability study data. 6. Submit BMR of stability batches 7. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
110	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(RW9-88H-B7VM, 2024-10-10)
	Detail of Fee Submitted	37000.0, 2024-09-10,
	The proposed proprietary name / brand name	**Minafine 250mg Tablet**
	Label Claim	Each Tablet Contains: Terbinafine as HCl...250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Lamisil Tablet, TGA Approved
	For generic drugs (me-too Status)	Terbisil 250mg Tablet by Saffron Pharmaceuticals, Faisalabad-Pakistan
	Proposed Pack Size	1x10's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Tagoor Laboratories Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Terbsisil Tablet of Saffron: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate dated 24-10-2023 of Magns Pharma is submitted
	Evaluation	1. Submit API stability data as per zone IV-A conditions Response: API stability data is submitted as per zone IV-A 2. Submit loan letter. Firm has submitted loan letter from Magns Pharma
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
111	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(S43-D1V-V14P, 2024-09-20)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**Mipram 5mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Escitalopram as Oxalate...5mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Precipra Tablets 5mg by Pfizer Pakistan
	Proposed Pack Size	as per SRO-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section
	Name & address of API manufacturer	Shodhana Laboratories Private Limited India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Precipra Tablet of Pfizer: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Biorex Pharma submitted
	Evaluation	Stability batches are developed on 08-09-2023 while drug import license of December 2023 is submitted. Kindly submit clearance certifcate of relevant batch.
	Shortcoming	
	Decision	Deferred for submission of evidence of procurement of API used in the manufacturing of stability batches.

Sr. No	Title	Description
112	Name, address of Manufacturing site.	**Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan**(000061)**
	Case Category	Any Other (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(S7J-NBH-EAXS, 2024-06-14)
	Detail of Fee Submitted	75000.0, 2024-04-09,
	The proposed proprietary name / brand name	**Wellma**
	Label Claim	Each Film Coated Tablet contains: Vitamin A (as Vitamin A Palmitate).....800µg, Vitamin B1 (as Thiamine mononitrate).....1.4mg, Vitamin B2 (as Riboflavin Sodium Phosphate)....1.4mg, Vitamin B3 (as Nicotinamide).....18mg, Vitamin B6 (as Pyridoxine HCl).....1.9mg, Vitamin B9 (as Folic acid).....400µg, Vitamin B12 (Cyanocobalamin).....2.6µg, Vitamin C (as Sodium ascorbate).....70mg, Vitamin D3 (as Cholecalciferol).....5µg (200IU), Vitamin E 50% (as Alpha-tocopheryl acetate).....10mg, Zinc (as Zinc sulfate)....15mg, Iodine (as Potassium iodide).....150µg, Selenium (as Sodium selenite).....65µg, Copper (as Copper sulfate).....2mg, Iron (as Ferrous fumarate)....30mg
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Kirk Humanitarians UNIMMAP-MMS Product
	For generic drugs (me-too Status)	Not applicable
	Proposed Pack Size	HDPE bottle contain-As per SRO,Alu-PVC blisters of -As per SRO,HDPE bottle containi-As per SRO
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	Dr. Paul Lohmann GmbH & Co. KGAA Dr. Paul Lohmann GmbH & Co. KGaA Hauptstrasse 2 D-31860 Emmerthal Germany,Fermenta Biotech Limited Z-109 B&C SEZ-II Dahej Taluka-Vagara Dist:Bharuch 392130 Gujarat India,Heilongjiang NHU Biotechnology Co Ltd No.2 Haotian Road Economic and Technological Development Zone Suihua, Heilongjiang, China,HUBEI GUANGJI PHARMACEUTICAL CO LTD The New and High-Industrial Park Wuxue City Hubei Province China,Jiangxi Tianxin Pharmaceutical Co Ltd Leanjiang Industrial Zone Leping Jiangxi China 333300 China,Jiangxi Tianxin Pharmaceutical Co Ltd. Leanjiang Industrial Zone Leping Jiangxi China 333300 China,Ningxia Kingvit Pharmaceutical Co Ltd The New Chemical Materials Park Zone B of Ningdong Chemical and Energy Industrial Base Ningxia China,Sigma-Aldrich Riedstrabe 2 89555 Steinheimam Albuch Germany,Western Drugs Limited F-271 A Mewar Industrial Area Madri Udaipur-313003 Rajasthan India,Xinchang NHU Vitamins Company Ltd. High-tech industry zone Meizhu Xinchang county Zhejiang province P.R China,Xinchang NHU Vitamins Company Ltd. High-tech industry zone Meizhu Xinchang county Zhejiang province P.R. China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Case was deferred in 340th RB meeting where the Board decided as under: The Board deliberated the matter in detail and while considering the fact that the product is neither approved by any reference regulatory authority nor approved previously by Registration Board and is only available in essential medicine list, decided to refer the case to DRAP Authority along with the request of the firm. The case was considered by DRAP Authority in its 196th meeting, where the Authority decided as under: "The Authority after detailed deliberation, decided to acceded the request of M/s Remington Pharmaceuticals Pvt Limited for registration of pharmaceutical product namely, "WELLMA" as per Vitamin Policy approved by the Policy Board in its 51st meeting held on 20th March, 2024 and the communication of UN agency referred during deliberation."
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
113	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(S7W-JTV-6NPA, 2024-10-03)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**Omesaq 40mg Capsule**
	Label Claim	Each capsule contains: Omeprazole (as enteric coated pellets).....40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Risek 40mg Capsule by Getz Pharma-Karachi
	Proposed Pack Size	2x7's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Capsule General Section
	Name & address of API manufacturer	Name: Vision Pharmaceuticals (PVT) LTD. Site Address: Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Humak Islamabad, Islamabad Capital Territory Responsibility Manufacturing, testing, batch release
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Risek Capsule by Getz: PE studies performed
	Detail of stability batches of drug product	3 batches: 2000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	08-11-2023: Commercial invoice for 3kg pellets
	Evaluation	Submit CDP studies Response: Firm has submitted CDP studies against Risek Capsule
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
114	Name, address of Manufacturing site.	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore**(000395)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(SD3-BTT-XASV, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-08-01,
	The proposed proprietary name / brand name	**Cefidon**
	Label Claim	Each Capsule contains:Cefixime as Cefixime Trihydrate.....200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Manufacturer Specification
	The status in reference regulatory authorities	Cefixima Norman, Spain (CIMA Approved)
	For generic drugs (me-too Status)	Cefim Capsule by Hilton pharma
	Proposed Pack Size	5’s 7’s 14’s 50’s -Controlled
	GMP status of the firm	22-03-2024: GMP certificate
	Evidence of approval of manufacturing facility	11-04-2017: Additional section approval
	Name & address of API manufacturer	Citi Pharma Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefim capsule by Hilton: PE and CDP studies performed
	Detail of stability batches of drug product	3 batches: 1500 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not submitted
	Evaluation	1. Submit evidence of procurement of API. 2. Submit BMR of stability batches
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
115	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(SNN-E2N-M4V2, 2024-10-22)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	**MIRTAGET 45MG TABLETS**
	Label Claim	Each Flm coated Tablet contains:MIRTAZAPINE 45mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	REMERON® (mirtazapine) Tablets F.D.A Approved
	For generic drugs (me-too Status)	Mitaz Tablet by Glitz
	Proposed Pack Size	10's,20's, 30's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Almon industries Address: 408/409/410, Baleshwar City, Block A, Near Hathijan Circle, Ahmedabad, Gujarat, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	30 degree / 60% RH
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate of Kanel pharma dated 19-10-2022 submitted.
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit API stability study data as per zone IV-A conditions. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP. 9. Submit pharmaceutical equivalence studies and comparative dissolution profile studies.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
116	Name, address of Manufacturing site.	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road**(000971)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(T2S-PSJ-HJLT, 2024-07-29)
	Detail of Fee Submitted	75000.0, 2024-05-06,
	The proposed proprietary name / brand name	**Zentiva 10mg/ml Oral Suspension**
	Label Claim	Each ml contains:Sildenafil citrate as Sildenafil.....10mg
	Pharmacotherapeutic Group of (API)	d phosphodiesterase (PDE) inhibitors
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Sildenafil for Oral Suspension 10mg/ml of M/s NOVADOZ PHARMACEUTICALS LLC (USFDA Approved)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	1x112ml, 1x90ml, 1x1-As per SRO
	GMP status of the firm	18-09-2023: New DML
	Evidence of approval of manufacturing facility	18-09-2023: Dry powder suspension general section
	Name & address of API manufacturer	Rakshit Drugs Private Limited Add: Survey no.10/B, IDA, Gaddapotaram (v),Jinnaram Mandal, Sangareddy Dist., Telangana, India.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Sildenafil for Oral Suspension 10mg/ml: PE studies performed
	Detail of stability batches of drug product	3 batches: 155 bottles
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Biolabs and clearance certificate dated 19-05-2023
	Evaluation	Justify why CDP studies are not performed since FDA dissolution database specifies dissolution test for oral suspension. Response: Firm has submitted CDP studies result against Sildenafil citrate 10mg/ml Powder for Oral Suspension
	Shortcoming	
	Decision	Deferred for confirmation of consumption record of imported API from Bio-Labs along with verification of loan letter.

Sr. No	Title	Description
117	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(TTB-ANJ-H5QS, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	**Dexadron 4mg/1ml Injection**
	Label Claim	Each 1ml ampoule contains:Dexamethasone phosphate(as sodium).....4mg
	Pharmacotherapeutic Group of (API)	fluorinated steroid
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Decadron Injection USFDA Approved
	For generic drugs (me-too Status)	D.Dron 4mg/1ml Ianjection
	Proposed Pack Size	1mix25 Ampoules-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Ampoule & Vials SVP (steroid) Section
	Name & address of API manufacturer	Balaji steroids and hormones Pvt ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Decadron - Searle Pharma (PE performed)
	Detail of stability batches of drug product	3 batches : 3 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	03-05-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
118	Name, address of Manufacturing site.	**Highnoon Laboratories Ltd** 17.5 KM, Multan Road,**(000155)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(U1Y-SRR-9UNW, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-03,
	The proposed proprietary name / brand name	**FAVAIR-F 100MCG/62.5MCG/25MCG ROTACAPS**
	Label Claim	Each capsule contains:Fluticasone furoate....100mcgUmeclidinium (as bromide) ......62.5mcgVilanterol (as trifenatate) ......25mcgEach delivered dose contains:Fluticasone furoate....92mcgUmeclidinium (as bromide) ......55mcgVilanterol (as trifenatate) 22mcg
	Pharmacotherapeutic Group of (API)	adrenergics in combination with anticholinergics and inhaled corticosteroid
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	USFDA, (TRELEGY ELLIPTA)
	For generic drugs (me-too Status)	Not Applicable
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	GMP certifcate: Inspection date 12-06-2024
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	Aarti Pharmalabs Limited Unit – IV, Plot No: E – 50, 50/1 & 59/1, M.I.D.C., Tarapur, Taluka & District: Palghar, Pin-401 506 Maharashtra, India.,INKE, S.A. Área Industrial del Llobregat, C/ Argent, 1 08755 CASTELLBISBAL (Barcelona) SPAIN
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per zone II conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	TRELEGY ELLIPTA: PE studies performed
	Detail of stability batches of drug product	3 batches: 4000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	AD attested invoices submitted
	Evaluation	1. Submit evidence of approval of manufacturing facility / section approval letter from Licensig Division 2. The innovator's product contains 2 foil blister strips in which 1 strip contains fluticasone and the other strip contains rest of the two API, while your product contains all ingredients mixed in a single capsule. Clarify how your product can be considered equivalent or comparable to the reference product. 3. Submit compatibility studies of both drug substances, since the reference product do not have both drug substances mixed together in a single capsule or pouch. 4. Justify the assay limit 80% - 120% for the drug product. 5. Submit details of the device to be used along with the applied product. 6. Submit API stability study data as per Zone IV-A conditions
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
119	Name, address of Manufacturing site.	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan**(000619)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(UNW-NDJ-41BL, 2024-02-12)
	Detail of Fee Submitted	30000.0, 2023-12-11,
	The proposed proprietary name / brand name	**Tact Capsules**
	Label Claim	Each Capsule contains: Ceftibuten Dihydrate eq. to Ceftibuten 400mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too Status)	Xigiris Capsule by Wilshire
	Proposed Pack Size	5's-As per SRO
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	22-12-2020: Casule Cephalosporin section
	Name & address of API manufacturer	Danuka Lboratories Limited , 7Km Old Manesar Road, Village Mohammedpur Gurgaon , Haryana
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	As per refrigerating conditions
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xigris Capsule by Wilshire: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 2176 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	04-08-2021: AD clearaed invoice submitted
	Evaluation	1. Submit API specifications and analytical method from drug product manufacturer. 2. Submit drug substance verification studies from drug product manufacturer. 3. Submit GMP certificate of drug product manufacturer. 4. Submit evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting. 5. Clarify how micronized API used for suspension has been used in the manufacturing of capsule
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
120	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(VML-RG7-1TYD, 2024-10-08)
	Detail of Fee Submitted	30000.0, 2024-07-25,
	The proposed proprietary name / brand name	**Omesaq 20mg Capsule**
	Label Claim	Each Capsule Contains: Omeprazole (as enteric Coated Pellets).....20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US-FDA Approved
	For generic drugs (me-too Status)	Risek 20mg Capsule by Getz Pharma-Karachi
	Proposed Pack Size	2x7's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Capsule General Section
	Name & address of API manufacturer	Vision Pharmaceuticals (PVT) LTD. Plot No: 22-23, Kahuta Industrial Triangle, Kahuta Rd, Humak Islamabad
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Risek Capsule by Getz: PE studies performed
	Detail of stability batches of drug product	3 batches: 2000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	08-11-2023: Commercial invoice for 3kg pellets
	Evaluation	Submit CDP studies. Response: Firm has submitted CDP studies against Risek Capsule
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
121	Name, address of Manufacturing site.	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI**(000820)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(X4X-APH-RWYM, 2024-11-19)
	Detail of Fee Submitted	30000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Dotrine 40mg/2ml Ianjection**
	Label Claim	Each 2ml ampoule contains:Drotaverine HCl.....40mg
	Pharmacotherapeutic Group of (API)	Antispasmodic drug
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Approved in 3 European Countries
	For generic drugs (me-too Status)	spastop 40mg/2ml Injection
	Proposed Pack Size	2mlX25-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Liquid ampoule SVP (general) Section
	Name & address of API manufacturer	Punjab Chemicals and Crop Protection Ltd (PCCPL)Pharma division Alpha drug
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	No-Spa Injection Sanofi (PE performed)
	Detail of stability batches of drug product	3 batches : 5 L each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	12-02-2023 - clearance certificate
	Evaluation	
	Shortcoming	
	Decision	Approved .

Sr. No	Title	Description
122	Name, address of Manufacturing site.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad.**(000985)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(YDQ-GZQ-EA2Q, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-09-27,
	The proposed proprietary name / brand name	**Fungirex Capsule**
	Label Claim	Each Capsule Contains: Fluconazole.....150mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too Status)	Diflucan 150mg Capsules by Pfizer-Pakistan Ltd.
	Proposed Pack Size	1x1's-As per SRO
	GMP status of the firm	26-10-2023: New DML issued
	Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Capsule General Section
	Name & address of API manufacturer	Pioneer Laboratories India Private Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diflucan capsule of Pfizer: PE studies performed
	Detail of stability batches of drug product	3 batches: 2000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from Magns Pharma and clearance certificate dated 22-12-2023 submitted
	Evaluation	
	Shortcoming	
	Decision	Approved . Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
123	Name, address of Manufacturing site.	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan.**(000954)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(YRQ-TSS-B162, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-07-09,
	The proposed proprietary name / brand name	**Kezel 600mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: - Linezolid.....600mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	ZYVOX® (linezolid) 600mg tablets, USFDA approved
	For generic drugs (me-too Status)	Ecasil 600mg Tablet by Sami pharmaceuticals
	Proposed Pack Size	As per SRO.-As per SRO
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with Tablet General section
	Name & address of API manufacturer	Arene Life Sciences Pvt. Ltd. Plot No. 48, 49&50, 209,210, &211 Phase-II IDA, Pashamylaram Sangareddy India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ecasil Tablet of Sami Pharma: PE and CDP performed
	Detail of stability batches of drug product	3 batches: 1300 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Loan letter from linear pharma and invoice is submitted.
	Evaluation	1. Submit API specifications and analytical method from API manufacturer. Submitted by the firm 2. Submit API verification studies from drug product manufacturer Submitted by the firm 3. Submit complete HPLC chromatograms for stability studies. Complete stability study data of all the three batches for all time points is not submitted. 4. Submit BMR of stability batches Submitted by the firm
	Shortcoming	
	Decision	Deferred for submission of analytical record of stability study data of all batches along with raw data sheets and COA.

Sr. No	Title	Description
124	Name, address of Manufacturing site.	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan**(000619)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(Z49-DBN-DED3, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-06-20,
	The proposed proprietary name / brand name	**Foxi 1gm Injection**
	Label Claim	Each Vial Contains: Cefoxitin as sodium.....1gm
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Cefoxitin 1gm USFDA Approved
	For generic drugs (me-too Status)	Mefoxin Injection of Schazoo
	Proposed Pack Size	1s-As per SRO
	GMP status of the firm	Not submitted
	Evidence of approval of manufacturing facility	22-12-2020: Dry Powder Injection Cephalosporin section
	Name & address of API manufacturer	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefoxitin Injection of Fresenius Italy: PE Studies performed
	Detail of stability batches of drug product	3 batches: 1100 vials
	Documents for the procurement of API with approval from DRAP (in case of Improt)	05-08-2021: Commercial invoice cleared by AD I&E
	Evaluation	1. Submit API specifications and analytical method from drug product manufacturer. 2. Submit drug substance verification studies from drug product manufacturer. 3. Submit GMP certificate of drug product manufacturer.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
125	Name, address of Manufacturing site.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi**(000979)**
	Case Category	New License (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ZSM-U93-7SPY, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-21,
	The proposed proprietary name / brand name	**Itracol**
	Label Claim	Each capsule contains: Itraconazole pellets eq. to itraconazole 100mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Itracox by Maxitec
	Proposed Pack Size	12's,24's,48's,60's -As per SRO
	GMP status of the firm	27-10-2023: New DML issued
	Evidence of approval of manufacturing facility	27-10-2023: Capsule General Section
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23,Industrial Triangle,Kahuta Road,Islamabad-Pakistan
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Itrazox Capsule by Maxitech: PE and CDP performed
	Detail of stability batches of drug product	3 Batches: 2198 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Invoice dated 18-03-2023 of Shrooq Pharma is submitted
	Evaluation	Loan letter from Shrooq Pharma is required. Response: Firm has submitted loan letter from Shrooq Pharma dated 10-11-2023
	Shortcoming	
	Decision	Approved Registration letter shall be issued after verification of loan letter.

Sr. No	Title	Description
126	Name, address of Manufacturing site.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat**(000871)**
	Case Category	New Section (Dr. Muhmmad Haseeb Tariq)
	Application Form Dy. No / Tracking ID & date of submission	(ZVT-DJ6-HN6N, 2024-10-08)
	Detail of Fee Submitted	37000.0, 2024-09-09,
	The proposed proprietary name / brand name	**MIRTAGET 30MG TABLETS**
	Label Claim	Each Flm coated Tablet contains:MIRTAZAPINE 30mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	REMERON® (mirtazapine) Tablets F.D.A Approved
	For generic drugs (me-too Status)	Mitaz Tablet by Glitz
	Proposed Pack Size	30's-As per SRO
	GMP status of the firm	GMP certificate issued on the basis of inspection dated 22-08-2023
	Evidence of approval of manufacturing facility	Not submitted
	Name & address of API manufacturer	M/s. Almon industries Address: 408/409/410, Baleshwar City, Block A, Near Hathijan Circle, Ahmedabad, Gujarat, India
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	30 degree / 60% RH
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Detail of stability batches of drug product	3 batches: 1500 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Clearance certificate of Kanel pharma dated 19-10-2022 submitted.
	Evaluation	1. Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances. 2. Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3. 3. Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4. 4. Submit valid COA of reference standard used in the testing of drug product and drug substance 5. Submit API stability study data as per zone IV-A conditions. 6. Submit 6th month stability study data 7. Submit BMR of stability batches. 8. Submit evidence of approval of requisite manufacturing facility i.e. section approval letter from Licensing Division DRAP. 9. Submit pharmaceutical equivalence studies and comparative dissolution profile studies.
	Shortcoming	
	Decision	Deferred for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
127	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(11G-4EW-GNYD, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**FAMTROL BECLO**
	Label Claim	Each dry powder inhalation capsule contains: Beclomethasone dipropionate anhydrous……200mcg and formoterol fumarate dihydrate…..6mcg ; Equivalent to a delivered dose (the dose leaving the mouthpiece) of 158.8 micrograms of beclomethasone dipropionate anhydrous and 4.9 micrograms of formoterol fumarate dihydrate.
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Fostair NEXThaler 200 micrograms/6 micrograms, MHRA
	For generic drugs (me-too Status)	Foster Nexthaler DPI 200/6mcg, Manufacturer Chiesi Pharmaceutical (Pvt.) Ltd., Registration Number 095870
	Proposed Pack Size	7’s, 10’s, 14’s, 20’-As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	DPI Capsule (Steroid) section is approved dated 27-12-2023
	Name & address of API manufacturer	Aarti Pharmalabs Limited,AVIK PHARMACEUTICAL LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	48 months stability data is submitted for 3 batches according to zone IV-A for Beclomethasone. : 60 months stability data for 3 batches according to zoneIV-A is submitted for Formaoterol
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fostair PE studies have been performed against Nexthaler 200mcg/6mcg
	Detail of stability batches of drug product	3 months stability data is submitted for 3 batches. Batches: 4000DPI cap
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided
	Evaluation	Beclomethasone API Manufacturer: Plot No.: AVIK PHARMACEUTICAL LTD. A-1/8, IST Phase, Gujarat Industrial Development Corporation, City: Vapi, India API Lot Number: BMD/M/036/23 GMP certificate valid till 07-07-2026 Formoterol API Manufacturer: Aarti Pharmalabs Limited Plot No. D-53, phase II, MIDC Kalyanshil RD Dombivali (east) Thane Maharashtra State India API Lot Number: FF-23002(JM-01)-001 GMP certificate valid till 13-12-2025 Shortcomings: Please provide stability data till 6 months time point for FPP. (submitted) Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (the firm has submitted form 6, copies of invoices)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
128	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(4N6-S38-L9S3, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	**Indihale-MG**
	Label Claim	Each dry powder inhaler 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 114 mcg of indacaterol (as acetate), 58 mcg of glycopyrronium bromide equivalent to 46 mcg of glycopyrronium and 136 mcg of mometasone furoate
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Enerzair Breezhaler by Novartis Europharm Limited, Ireland
	For generic drugs (me-too Status)	Ultivair-M by Highnoon Laboratories Ltd
	Proposed Pack Size	7’s,10’s,14’s,20’s28-As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	DPI Capsule (Steroid) section is approved dated 27-12-2023
	Name & address of API manufacturer	MELODY HEALTHCARE PVT. LTD,MELODY HEALTHCARE PVT.LTD,VAMSI LABS LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data for indacaterol is submitted for 24months for Indacaterol, 60months according to zone IV-A for 3 batches for Mometasone & Glycopyrronium Bromide.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed aginst the reference product Enerzair breezhaler.
	Detail of stability batches of drug product	3 months data of 3 batches. Batch Size: 1000 DPI Cap
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	Indacaterol and Glycopyrronium Bromide API manufacturer: MELODY HEALTHCARE PVT. LTD. J-73, MIDC, Tarapur, Boisar Dist.– Palghar, 401 506, Maharashtra, India GMP certificate dated 13-04-2023 is submitted. Mometasone: API manufacturer: VAMSI LABS LTD A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra, India GMP certificate dated 22-02-2024 is submitted Shortcoming: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (form 6 and copies of inovices have been submitted) Provide stability data till 6th month time point. (submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
129	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(4Z1-SSE-2Y93, 2024-12-18)
	Detail of Fee Submitted	75000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Momehale**
	Label Claim	Each actuation contains: Mometasone Furoate.....100 mcg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ASMANEX HFA (Mometasone Furoate) 100 mcg inhalation aerosol by 3M Health care Ltd, Loughborough United Kingdom
	For generic drugs (me-too Status)	N.A
	Proposed Pack Size	120 actuation -As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	MDI (Metered dose Inhaler) Section is approved.
	Name & address of API manufacturer	Vamsi labs Ltd, A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	60 months data is submitted according to zone IV-A for 3 batches
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product ASMANEX® HFA 100 mcg
	Detail of stability batches of drug product	Stability data of 3 batches till 6th month time point is submitted, Batch Size: 60 canisters
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	VAMSI LABS LTD A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra, India API Lot No.: MSF-0030223 GMP certificate dated 22-02-2024 is submitted Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (form 6 and copy of iinvoice is submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
130	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(5L5-1GR-R279, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**FAMTROL BECLO**
	Label Claim	Each dry powder inhalation capsule contains: Beclomethasone dipropionate anhydrous.....100mcg , Formoterol fumarate dihydrate.....6mcg : This is equivalent to a delivered dose (the dose leaving the mouthpiece) of 81.9 micrograms ofbeclomethasone dipropionate anhydrous and 5.0 micrograms of formoterol fumarate dihydrate
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Fostair NEXThaler 100 micrograms/6 micrograms, MHRA Approved
	For generic drugs (me-too Status)	Foster Nexthaler DPI 100/6mcg, Manufacturer Chiesi Pharmaceutical (Pvt.) Ltd, Registration Number 095868
	Proposed Pack Size	7’s, 10’s, 14’s, 20’-As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	DPI Capsule (Steroid) section is approved dated 27-12-2023
	Name & address of API manufacturer	Aarti Pharmalabs Limited,AVIK PHARMACEUTICAL LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	48 months stability data is submitted for 3 batches according to zone IV-A for Beclomethasone. : 60 months stability data for 3 batches according to zoneIV-A is submitted for Formaoterol
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Fostair NEXThaler 100mcg/6mcg).
	Detail of stability batches of drug product	3 months stability data of 3 batches is submitted. Batch Size 4000 DPI Cap
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not provided
	Evaluation	Beclomethasone API Manufacturer: Plot No.: AVIK PHARMACEUTICAL LTD. A-1/8, IST Phase, Gujarat Industrial Development Corporation, City: Vapi, India API Lot Number: BMD/M/036/23 GMP certificate valid till 07-07-2026 Formoterol API Manufacturer: Aarti Pharmalabs Limited Plot No. D-53, phase II, MIDC Kalyanshil RD Dombivali (east) Thane Maharashtra State India API Lot Number: FF-23002(JM-01)-001 GMP certificate valid till 13-12-2025 Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (from 6 and copies of invoices have been submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
131	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(6L7-XAL-GP56, 2024-08-23)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Levapule**
	Label Claim	Each 3 mL unit-dose LDPE ampoule contains:0.31 mg of levalbuterol (as 0.36 mg of levalbuterol HCl)
	Pharmacotherapeutic Group of (API)	beta2-Adrenergic Agonist
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	US FDA approved as XOPENEX (Levalbuterol HCL) inhalation solution, for oral inhalation use
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -SOLUTION FOR INHALATION SECTION
	Name & address of API manufacturer	VAMSI LABS LTD An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India), Ph. No.: +91-217-2357274/75, Fax: +91-217-2357278
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xaponex -Akorn (PE performed)
	Detail of stability batches of drug product	2 batches : 5000 LDPE ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	100 gm procured via attested invoice dated 16-07-2021
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
132	Name, address of Manufacturing site.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat,**(000911)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(6U4-1VQ-HWJP, 2024-12-20)
	Detail of Fee Submitted	37000.0, 2024-10-21,
	The proposed proprietary name / brand name	**Betnogen-N Cream**
	Label Claim	Each gram of cream contains: Betamethasone as valerate .....1mg (0.1%w/w)Neomycin sulfate .....5mg (0.5% w/w)
	Pharmacotherapeutic Group of (API)	corticosteroid and antibiotics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Betnovate-N cream (MHRA approved).
	For generic drugs (me-too Status)	Betnovate-N cream
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	New DML w.e.f 13-02-2020
	Evidence of approval of manufacturing facility	Cream Section General - 14-02-2020
	Name & address of API manufacturer	MAHIMA LIFE SCIENCES PRIVATE LIMITED India,Sichuan Long March Pharmaceutical Co., Ltd China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	biozone-N (PE performed)
	Detail of stability batches of drug product	3 batches : 500 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	3 kg Betamethasone vide clearance certificate dated 10-06-2022 & neomycin
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
133	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(74P-44U-TXTV, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Bepule**
	Label Claim	Each 2mL LDPE ampoule contains: Beclometasone Dipropionate.....800mcg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Registered drug by EMA as CLENIL (BECLOMETASONE DIPROPIONATE) Inhalation suspension, for oral Inhalation use.
	For generic drugs (me-too Status)	Clenil Aerosol (Chiesi Pharmaceuticals (Pvt) Ltd.)
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Solution for Inhalation Section
	Name & address of API manufacturer	SHAKTI LIFESCIENCE Head office: 1004, Unique Tower, Off S.V. Road, Goregaon (W), Mumbai-400 062, India Tel: +91-22-28780912 Factory Address: Plot No. K-2 MIDC Tarapur, Dist. Palghar, Boisar-401 506
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Clenil - Chiesi (PE performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	0.50 kg via attested invoice dated 25-06-2021
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
134	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(853-6NV-JNJJ, 2024-07-31)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Ipranox**
	Label Claim	Each single 2.5 mL unit-dose LDPE vial contains: Ipratropium bromide monohydrate..... 0.5218 mg (equivalent to Ipratropium bromide 0.5 mg)
	Pharmacotherapeutic Group of (API)	Bronchodilators
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Registered drug by US FDA as Ipratropium bromide 0.02% inhalation solution, for oral inhalation use.
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 - Inhalation solution section
	Name & address of API manufacturer	VAMSI LABS LTD An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India), Ph. No.: +91-217-2357274/75, Fax: +91-217-2357278
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nephron Pharmaceuticals USA (PE performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	100 grams via attested invoice dated 16-07-2021
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
135	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(ELW-E4L-AR3R, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**FAMTROL BECLO**
	Label Claim	Each metered dose (ex-valve) contains: Beclomethasone dipropionate.....100mcg, formoterol fumarate dihydrate.....6mcg : This is equivalent to a delivered dose (ex-actuator) of 84.6 micrograms of beclomethasone dipropionate and 5.0 micrograms of formoterol fumarate dihydrate.
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Fostair 100 microgram/6 microgram per actuation pressurised inhalation solution, Chiesi Farmaceutici S.p.A., HPRA
	For generic drugs (me-too Status)	Foster Pressurized, Beclomethasone Dipropionate + Formoterol Fumarate Dihydrate 100mcg/6mcg, Chiesi Pharmaceutical (Pvt.) Ltd., Registration number: 066105
	Proposed Pack Size	120 actuations in 1 -As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	MDI (Metered dose Inhaler) Section is approved.
	Name & address of API manufacturer	Aarti Pharmalabs Limited,Avik Pharmaceutical Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	48 months stability data is submitted for 3 batches according to zone IV-A for Beclomethasone. : 60 months stability data for 3 batches according to zoneIV-A is submitted for Formaoterol
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Fostair 100 microgram/6 microgram per actuation pressurised inhalation solution.
	Detail of stability batches of drug product	6 months data is submitted of 3 batches. Batch Size: 500 cannister
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided
	Evaluation	Beclomethasone API Manufacturer: Plot No.: AVIK PHARMACEUTICAL LTD. A-1/8, IST Phase, Gujarat Industrial Development Corporation, City: Vapi, India API Lot Number: BMD/M/036/23 GMP certificate valid till 07-07-2026 Formoterol API Manufacturer: Aarti Pharmalabs Limited Plot No. D-53, phase II, MIDC Kalyanshil RD Dombivali (east) Thane Maharashtra State India API Lot Number: FF-23002(JM-01)-001 GMP certificate valid till 13-12-2025 Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (copies of invoices and form 6 are submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
136	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(H46-DDN-2U1L, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	**F-LINCO**
	Label Claim	Each 1ml Ampoule Contains:Lincomycin Hydrochloride Monohydrate eq. to Lincomycin.....300mg
	Pharmacotherapeutic Group of (API)	Anti-biotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	LINCOCIN INJECTION
	Proposed Pack Size	1ml x 5's-As per SRO
	GMP status of the firm	Fortune: New License w.e.f 22-02-2021 (issue date: 10-06-2021)
	Evidence of approval of manufacturing facility	Sterile Liquid Injection Ampoule (SVP) General is approved.
	Name & address of API manufacturer	Henan XinXiang Huaxing pharmaceutical factory, Liu village, Xinxiang city, Henan province.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	stability study data of 3 batches according to zoneIV-A till 36 months is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against Lincocin Injection (Batch: SKU 12986) by Pfizer.
	Detail of stability batches of drug product	Stability data of 3 batches till 6th month time point is submitted. Batch size: 1000ampoules
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 No. 3614 dated 15-11-2021 (5kg), Attested invoice ((dated 18-11-2021) No KF0810210859 dated 13-10-2021 for 5kg Lincomycin.
	Evaluation	API Manufacturer: Henan XinXiang Huaxing pharmaceutical factory, Liu village, Xinxiang city, Henan province. China API Lot Number: 210224082 GMP certificate No. HA20210115 valid till 29-11-2024 Shortcomings: Clarification regarding the filled volume is required since the innovator’s product is approved by USFDA as 2mL ampoule while you have mentioned 1mL ampoule is the online application.
	Shortcoming	
	Decision	Deferred Clarification regarding the filled volume is required since the innovator’s product is approved by USFDA as 2mL ampoule while you have mentioned 1mL ampoule is the online application.

Sr. No	Title	Description
137	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(M54-6VE-DSL3, 2024-09-18)
	Detail of Fee Submitted	37000.0, 2024-09-12,
	The proposed proprietary name / brand name	**F-FENAC**
	Label Claim	Each gm Gel Contains: Diclofenac Diethylamine 11.16mg eq. to Diclofenac Sodium.....10mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too Status)	Voltral Emulgel
	Proposed Pack Size	1's-As per SRO
	GMP status of the firm	Fortune: New License w.e.f 22-02-2021 (issue date: 10-06-2021)
	Evidence of approval of manufacturing facility	Cream / ointment (General) section is approved
	Name & address of API manufacturer	AARTI DRUGS LTD Plot No. G - 60, MIDC, Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of 3 batches is submitted till 48 months according to zone IV-A.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	not submitted
	Detail of stability batches of drug product	Stability data of 3 batches is submitted for 6 months. Batch Size: 100tubes
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Attested invoice (dated 18-11-2021) No. EXP/090008(20-21) dated 25.10.2021, Form 6 No. 3623 dated 18-11-2021.
	Evaluation	API Manufacturer: AARTI DRUGS LTD Plot No. G - 60, MIDC, Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. GMP certificate No. NEW-WHO_GMP/CERT/KD/103280/2022/11/37083 valid till 15-08-2025 API lot No. DDA/20110002 Shortcomings: Please provide details of the product (including batch number, expiry, manufacturer name) against which pharmaceutical equivalence studies are performed. Submitted.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
138	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(MGR-S9V-2XST, 2024-12-18)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	**FAMTROL BECLO**
	Label Claim	Each metered dose (ex-valve) contains: Beclomethasone dipropionate....100mcg , formoterol fumarate dihydrate.....6mcg : This is equivalent to a delivered dose (ex-actuator) of 177.7 micrograms ofbeclomethasone dipropionate and 5.1 micrograms of formoterol fumarate dihydrate.
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Fostair 200 microgram/6 microgram per actuation pressurised inhalation solution, Chiesi Farmaceutici S.p.A., HPRA
	For generic drugs (me-too Status)	Foster Pressurized, Beclomethasone Dipropionate + Formoterol Fumarate Dihydrate 200mcg/6mcg, Chiesi Pharmaceutical (Pvt.) Ltd., Registration number: 095871
	Proposed Pack Size	120 actuations in 1 -As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	MDI (Metered Dose Inhaler) Section is approved.
	Name & address of API manufacturer	Aarti Pharmalabs Limited,Avik Pharmaceutical Limited
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	48 months stability data is submitted for 3 batches according to zone IV-A for Beclomethasone. : 60 months stability data for 3 batches according to zoneIV-A is submitted for Formaoterol
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Fostair 200 microgram/6 microgram per actuation pressurised inhalation solution
	Detail of stability batches of drug product	6 months stability data of 3 batches is submitted. Batch Size: 500 cannisters
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Not provided.
	Evaluation	Beclomethasone API Manufacturer: Plot No.: AVIK PHARMACEUTICAL LTD. A-1/8, IST Phase, Gujarat Industrial Development Corporation, City: Vapi, India API Lot Number: BMD/M/036/23 GMP certificate valid till 07-07-2026 Formoterol API Manufacturer: Aarti Pharmalabs Limited Plot No. D-53, phase II, MIDC Kalyanshil RD Dombivali (east) Thane Maharashtra State India API Lot Number: FF-23002(JM-01)-001 GMP certificate valid till 13-12-2025 Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (form 6 and copies of invoices are submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
139	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(N4U-HBR-2BGU, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	**TRANXID**
	Label Claim	Each 5ml Ampoule Contains:Tranexamic Acid.....500mg
	Pharmacotherapeutic Group of (API)	anti-fibrinolytics
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	XED 500mg INJECTION BY INDUS PHARMA
	Proposed Pack Size	5ml x 5's & As per S-As per SRO
	GMP status of the firm	Fortune: New License w.e.f 22-02-2021 (issue date: 10-06-2021)
	Evidence of approval of manufacturing facility	Sterile Liquid Injection Ampoule (SVP) General is approved.
	Name & address of API manufacturer	Changzhou Yinsheng Pharmaceutical Co., Ltd. Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province,
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	stability data of 3 batches according to zone IV-A till 60 months is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted.
	Detail of stability batches of drug product	stability data of 03 batches for 6 months is submitted. Batch size: 1000 ampoule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Form 6 no. 3618 dated 18-11-2021, attested (18-11-2021) invoice no. KF2810210186 dated 28-10-2021 for 10kg Tranexamic acid
	Evaluation	API manufacturer: Changzhou Yinsheng Pharmaceutical Co., Ltd. Weitang Chemical Zone, Xinbei District, Changzhou, Jiangsu Province, 213033, China API lot number:F0022820179 GMP certificate No. JS20190680 valid till 20-06-2024 Shortcomings: Please provide details of the product (including batch number, expiry, manufacturer name) against which pharmaceutical equivalence studies are performed.
	Shortcoming	
	Decision	Deferred details of the product (including batch number, expiry, manufacturer name) against which pharmaceutical equivalence studies are performed.

Sr. No	Title	Description
140	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(PD7-BMY-62Y1, 2024-08-07)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Bepule**
	Label Claim	Each 1mL ampoule contains:Beclometasone Dipropionate.....400mcg(As per Innovator's Specifications.)
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered drug by EMA as CLENIL (BECLOMETASONE DIPROPIONATE) Inhalation suspension, for oral Inhalation use.
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Solution for Inhalation Section
	Name & address of API manufacturer	SHAKTI LIFESCIENCE Head office: 1004, Unique Tower, Off S.V. Road, Goregaon (W), Mumbai-400 062, India Tel: +91-22-28780912 Factory Address: Plot No. K-2 MIDC Tarapur, Dist. Palghar, Boisar-401 506, I
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Clenil - Chiesi (PE performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	0.50 kg via attested invoice dated 25-06-2021
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
141	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(PEW-SL3-4JXM, 2024-12-18)
	Detail of Fee Submitted	75000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Momehale**
	Label Claim	Each actuation contains: Mometasone Furoate.....200 mcg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ASMANEX HFA (Mometasone Furoate) 200 mcg inhalation aerosol by 3M Health care Ltd, Loughborough United Kingdom
	For generic drugs (me-too Status)	Not Applicable
	Proposed Pack Size	120 actuation -As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	MDI (Metered dose Inhaler) Section is approved.
	Name & address of API manufacturer	Vamsi labs Ltd, A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	60 months stability data is submitted according to zone IV-A for 3 batches
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been conducted agaisnt the referenc eproduct ASMANEX® HFA 200 mcg
	Detail of stability batches of drug product	6 months data of 3 batches is submitted. Batch size: 600 canisters
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	API manufacturer: VAMSI LABS LTD A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra, India API Lot No.: MSF-0030223 GMP certificate dated 22-02-2024 is submitted Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (form 6 and copy of invoice are submitted) Stability data till 6th month time point. (submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
142	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(PQS-ER1-2HA7, 2024-12-18)
	Detail of Fee Submitted	75000.0, 2024-11-20,
	The proposed proprietary name / brand name	**Indihale-M**
	Label Claim	Each dry powder inhaler capsule contains: Indacaterol (as Acetate)....150mcg Mometasone Furoate....80mcg : Each delivered dose (dose that leaves the mouthpiece of inhaler) contains: Indacaterol (as Acetate)..... 125mcg Mometasone Furoate.....62.5mcg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ATECTURA ® BREEZHALER 150mcg/80mcg, EMA Approved
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	7’s,10’s,14’s,20’s28-As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	DPI Capsule (Steroid) section is approved dated 27-12-2023
	Name & address of API manufacturer	MELODY HEALTHCARE PVT. LTD,VAMSI LABS LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data for indacaterol is submitted for 24months and 60months according to zone IV-A for 3 batches for Indacaterol and Mometasone respectively.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product Actectura Breezehaler/
	Detail of stability batches of drug product	3 months data is submitted for 3 batches. Batch size: 1000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not provided.
	Evaluation	Indacaterol: API manufacturer: MELODY HEALTHCARE PVT. LTD. J-73, MIDC, Tarapur, Boisar Dist.– GMP certificate dated 13-04-2023 is submitted. Mometasone: API manufacturer: VAMSI LABS LTD A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra, India GMP certificate dated 22-02-2024 is submitted Form 6 dated 12-12-2023 for Indacaterol (25g) and Mometasone (25g), Invoice Number EXP/236/23-24 dated 11-12-2023 for mometasone is submitted. and Invoice number MBR234/GEP00241 dated 26-02-2024 is submitted. Shortcomings: Please provide documents confirming procurement of APIs including invoice, Form 6, clearance certificate. (from 6 and copies of invoices are submitted) Provide stability data of the applied product till 6th months time point. (submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
143	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(PUY-E8G-VM1X, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-08-12,
	The proposed proprietary name / brand name	**Umenium**
	Label Claim	Each Capsule contains 74.2mcg umeclidinium bromide equivalent to umeclidinium .....62.5mcgEach single inhalation provides a delivered dose (the dose leaving the mouthpiece ofthe inhaler) of 55 micrograms umeclidinium
	Pharmacotherapeutic Group of (API)	anticholinergics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Registered drug by US FDA (INCRUSE ELLIPTA)
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Dry powder for inhalation section
	Name & address of API manufacturer	Inke, S.A. Area Industrial del Llobregat C/Argent, 1 08755 Castellbisbal, Barcelona- Spain
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	INCRUSE ELIPTA GlaxoSmithKline (PE performd)
	Detail of stability batches of drug product	02 batches of each 5000 capsules.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	documents available attested invoice dated 17-09-2021
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
144	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(RSB-VUJ-XA6V, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Levapule**
	Label Claim	Each 3 mL unit-dose LDPE ampoule contains:0.63 mg of levalbuterol (as 0.73 mg of levalbuterol HCl)(As per USP Specifications.)
	Pharmacotherapeutic Group of (API)	beta2-Adrenergic Agonist
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered drug by US FDA as XOPENEX (Levalbuterol HCL) inhalation solution, for oral inhalation use.
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Solution for Inhalation Section
	Name & address of API manufacturer	VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India),
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xaponex -Akorn (PE performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API clearance is submitted with approval from DRAP.
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
145	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi**(000351)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(TT2-B49-9MJ6, 2024-12-18)
	Detail of Fee Submitted	75000.0, 2024-11-20,
	The proposed proprietary name / brand name	**Indihale-M**
	Label Claim	Each dry powder inhaler capsule contains: Indacaterol (as Acetate)....150mcg Mometasone Furoate...160mcg : Each delivered dose (dose that leaves the mouthpiece of inhaler) contains: Indacaterol (as Acetate)-------- 125mcg Mometasone Furoate----------127.5mcg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	ATECTURA ® BREEZHALER 150mcg/160mcg, EMA Approved.
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	7’s,10’s,14’s,20’s28-As per SRO
	GMP status of the firm	Genix: GMP certificate dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023
	Evidence of approval of manufacturing facility	DPI Capsule (Steroid) section is approved dated 27-12-2023
	Name & address of API manufacturer	MELODY HEALTHCARE PVT. LTD,VAMSI LABS LTD
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data for indacaterol is submitted for 24months and 60months according to zone IV-A for 3 batches for Indacaterol and Mometasone respectively.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted agaisnt the reference product Artectura Breezhaler.
	Detail of stability batches of drug product	3 months stability data of 03 batches is submitted. Batch size: 1000 Capsule
	Documents for the procurement of API with approval from DRAP (in case of Improt)	not submitted.
	Evaluation	Indacaterol: API manufacturer: MELODY HEALTHCARE PVT. LTD. J-73, MIDC, Tarapur, Boisar Dist.– Palghar, 401 506, Maharashtra, India GMP certificate dated 13-04-2023 is submitted. Mometasone: API manufacturer: VAMSI LABS LTD A-14, A-15, A-31, A-32 and A-33 MIDC area, Chincholi, Solapur-413255, Maharashtra, India GMP certificate dated 22-02-2024 is submitted Shortcomings: Stability data till 6th months time point for FPP. (submitted) Documents confirming procurement of API. (form 6 and copies of invoices are submitted)
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
146	Name, address of Manufacturing site.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi**(000924)**
	Case Category	New License (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(V7T-QS1-XXLV, 2024-08-05)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	**VOMITA**
	Label Claim	Each 4ml Ampoule Contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron.....8mg
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	ZOFRAN INJECTION
	Proposed Pack Size	4ml x 5's-As per SRO
	GMP status of the firm	Fortune: New License w.e.f 22-02-2021 (issue date: 10-06-2021)
	Evidence of approval of manufacturing facility	Sterile Liquid Injection Ampoule (SVP) General is approved.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	stability data of 3 batches is submitted according to zone IV-A till 60 months.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed agaisnt Vomita Injection
	Detail of stability batches of drug product	Stability data of 03 batches is submitted. Batch Size: 1000 amp.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	The firm has submitted copy of form 6 no. 3644 dated 18/11/2021, attested invoice no. 009/2591 from DRAP Karachi dated 15/11/2021 is submitted for Ondansetron (4KG).
	Evaluation	API manufacturer: Anugraha Chemicals, No. D-47, D-48, D-49, D-50 & C-63 & C-63 KSSIDC Industrial Estate Doddaballapur, India GMP certificate No. DCD/SPL-1/CR-03/2023-24 dated 15-11-2023 API Lot number: AOND-21001 Shortcomings: Please provide detail of the product (Batch Number, expiry, name of manufacturer etc) against which the pharmaceutical equivalence studies have been performed.
	Shortcoming	
	Decision	Deferred detail of the product (Batch Number, expiry, name of manufacturer etc) against which the pharmaceutical equivalence studies have been performed.

Sr. No	Title	Description
147	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(W9X-A23-DZET, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Ipranox-S**
	Label Claim	Each 2.5 ml single dose unit LDPE Vial contains 500 micrograms Ipratropium bromide (as 520 micrograms Ipratropium bromide monohydrate) , 3 mg Albuterol sulfate (corresponds to 2.5mg Albuterol base)
	Pharmacotherapeutic Group of (API)	Bronchodilator Combination
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too Status)	Combihale 0.5mg/2.5mg (Hudson Pharma (Pvt) Ltd.)
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Solution for Inhalation Section
	Name & address of API manufacturer	VAMSI LABS LTD An A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India), Ph. No.: +91-217-2357274/75, Fax: +91-217-2357278,VAMSI LABS LTD An 14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India), Ph. No.: +91-217-2357274/75, Fax: +91-217-2357278
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A (60 months for both APIS)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Combihale -husdon (PE Performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each. Stability data til 6th month time point is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Documents attested submitted
	Evaluation	
	Shortcoming	
	Decision	Approved Registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
148	Name, address of Manufacturing site.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila**(000856)**
	Case Category	New Section (Farooq Aslam)
	Application Form Dy. No / Tracking ID & date of submission	(WRX-7SQ-1ASV, 2024-07-31)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Levapule**
	Label Claim	Each 3 mL unit-dose LDPE ampoule contains:1.25 mg of levalbuterol (as 1.44 mg of levalbuterol HCl)
	Pharmacotherapeutic Group of (API)	beta2-Adrenergic Agonist
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	Registered drug by US FDA as XOPENEX (Levalbuterol HCL) inhalation solution, for oral inhalation use.
	For generic drugs (me-too Status)	N/A
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	25-10-2023: additional section approved
	Evidence of approval of manufacturing facility	25-10-2023 -Solution for Inhalation Section
	Name & address of API manufacturer	VAMSI LABS LTD An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (India), Ph. No.: +91-217-2357274/75, Fax: +91-217-2357278
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xaponex -Akorn (PE performed)
	Detail of stability batches of drug product	02 batches of 5000 containers each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Documents submitted for procurement and attested.
	Evaluation	
	Shortcoming	
	Decision	Approved Registration Board noted the fact that current title of the section i.e., "Solution for Inhalation" has been granted for the manufacturing facilities intended for the production of anaesthetic solutions while the instant formulation is not intended for anaesthesia purpose, hence Board decided that registration letter will be issued after revision of title of the section of "Solution for Inhalation" from Licensing Division.

Sr. No	Title	Description
149	Name, address of Manufacturing site.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore**(000872)**
	Case Category	New Section (Saima Hussain)
	Application Form Dy. No / Tracking ID & date of submission	(76V-9YQ-6L7L, 2024-10-08)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	**Sonoin l0mg Soft Gelatin Capsule**
	Label Claim	Each soft capsule contains: Isotretinoin 10mg
	Pharmacotherapeutic Group of (API)	Retinoid for treatment of acne
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Roaccutane 10 mg soft capsules (MHRA Approved)
	For generic drugs (me-too Status)	Oratane 10mg soft gelatin capsule (082469)-Crystolite Pharmaceuticals (Pvt.) Ltd
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Name & address of API manufacturer	-
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Oratane soft gelatin capsule of M/s. Crystollite
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Submitted
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
150	Name, address of Manufacturing site.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road**(000616)**
	Case Category	New Section (Saima Hussain)
	Application Form Dy. No / Tracking ID & date of submission	(GZJ-8LR-E6JN, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-05-27,
	The proposed proprietary name / brand name	**CefSure 500mg Injection**
	Label Claim	Each combination pack contains:Vial:Ceftazidime Pentahydrate (with Sodium Carbonate)Eq. to Ceftazidime ……500mg/vialAmpoule:Water for injection….5mL(USP Specifications)
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	UK MHRA
	For generic drugs (me-too Status)	Fortum(010078) GSK
	Proposed Pack Size	1's (Vial)-As per SRO,5's (Vial)-As per SRO
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Name & address of API manufacturer	Qilu Antibiotics Pharmaceutical Co., Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence against Fortum 500mg Injection of M/s. GSK
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Submitted
	Evaluation	3.2.S.4.1-3.2.S.4.2 Submit the specification and detailed analytical procedure of drug substance used by drug product manufacturer. 3.2.S.4.3 Provide analytical method validation report performed by drug product manufacturer. 3.2.S.4.4 Provide batch analysis report of drug substance performed by the drug product manufacturer. 3.2.S.5 Provide certificate of analysis of reference standard /working standard used for testing of the product. 3.2.S.7 Submit stability data of drug substance performed at zone IV-a conditions. 3.2.P.2.2.1 & 3.2.P.5.1 Justify for not including the test of Sodium carbonate while establishing the pharmaceutical equivalence against the reference product. Further, the said test is also not included in the finished product specification and the specification complied while performing the stability study of drug product, when the USP monograph of Ceftazidime for Injection recommend the test of sodium carbonate in their official monograph.. 3.2.P.5.4 Justify for not performing the test of particulate matter in Injections while conducting the batch analysis of drug product. 3.2.P.8.2 l Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. l Documents for the procurement of API with approval from DRAP (in case of import). 3.2.P.8.3 Justify for not performing the sterility test, bacterial endotoxin test, particulate matter in Injections test and the LOD test while conducting the stability study of drug product, when these tests are included in the USP official monograph of ceftazidime for injection. 2.3.R.1.1 please furnished the calculations regarding the quantity of active per vial considering the moisture and sodium carbonate factor, since the attached BMR only reflects the total quantity of active ingredients that was dispensed for trial batch. company hasn't read this reply yet.
	Shortcoming	
	Decision	Deferred . Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
151	Name, address of Manufacturing site.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore**(000872)**
	Case Category	New Section (Saima Hussain)
	Application Form Dy. No / Tracking ID & date of submission	(HAL-VUN-EQP3, 2024-10-08)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	**Sonoin 20mg Soft Gelatin Capsule**
	Label Claim	Each soft capsule contains: lsotretinoin 20mg
	Pharmacotherapeutic Group of (API)	Retinoid for treatment of acne
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Roaccutane 20 mg soft capsules (MHRA Approved)
	For generic drugs (me-too Status)	Arynoin 20mg soft gelatin capsule (090128)-Mass Pharma (Pvt.) Ltd
	Proposed Pack Size	As Per SRO-As per SRO
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Name & address of API manufacturer	-
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Oratane soft gelatin capsule of M/s. Crystollite
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Submitted
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
152	Name, address of Manufacturing site.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road**(000616)**
	Case Category	New Section (Saima Hussain)
	Application Form Dy. No / Tracking ID & date of submission	(LG6-B3L-EWWY, 2024-07-04)
	Detail of Fee Submitted	30000.0, 2024-05-20,
	The proposed proprietary name / brand name	**CefSure 250mg Injection (IV/IM)**
	Label Claim	Each combination pack contains:Vial:Ceftazidime Pentahydrate (with Sodium Carbonate)Eq. to Ceftazidime .....250mg/vialAmpoule:Water for injection....5mL(USP Specifications)
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	UK MHRA
	For generic drugs (me-too Status)	Fortum (GSK) (Reg # 015819))
	Proposed Pack Size	1's (Vial)-As per SRO
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Name & address of API manufacturer	Qilu Antibiotics Pharmaceutical Co., Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence against Fortum 250mg Injection of M/s. GSK
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Submitted
	Evaluation	3.2.S.4.1-3.2.S.4.2 Submit the specification and detailed analytical procedure of drug substance used by drug product manufacturer. 3.2.S.4.3 Provide analytical method validation report performed by drug product manufacturer. 3.2.S.4.4 Provide batch analysis report of drug substance performed by the drug product manufacturer. 3.2.S.5 Provide certificate of analysis of reference standard /working standard used for testing of the product. 3.2.S.7 Submit stability data of drug substance performed at zone IV-a conditions. 3.2.P.2.2.1 & 3.2.P.5.1 Justify for not including the test of Sodium carbonate while establishing the pharmaceutical equivalence against the reference product. Further, the said test is also not included in the finished product specification and the specification complied while performing the stability study of drug product, when the USP monograph of Ceftazidime for Injection recommend the test of sodium carbonate in their official monograph.. 3.2.P.5.4 Justify for not performing the test of particulate matter in Injections while conducting the batch analysis of drug product. 3.2.P.8.2 l Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. l Documents for the procurement of API with approval from DRAP (in case of import). 3.2.P.8.3 Justify for not performing the sterility test, bacterial endotoxin test, particulate matter in Injections test and the LOD test while conducting the stability study of drug product, when these tests are included in the USP official monograph of ceftazidime for injection. 2.3.R.1.1 please furnished the calculations regarding the quantity of active per vial considering the moisture and sodium carbonate factor, since the attached BMR only reflects the total quantity of active ingredients that was dispensed for trial batch. company hasn't read this reply yet.
	Shortcoming	
	Decision	Deferred . Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
153	Name, address of Manufacturing site.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road**(000616)**
	Case Category	New Section (Saima Hussain)
	Application Form Dy. No / Tracking ID & date of submission	(N1Z-Y4B-6497, 2024-08-09)
	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	**CefSure 1g Injection (IV/IM)**
	Label Claim	Each vial contains:Ceftazidime Pentahydrate (with Sodium Carbonate)Eq. to Ceftazidime 1g/vial
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	UK MHRA
	For generic drugs (me-too Status)	Fortum (GSK) (Reg # 015819))
	Proposed Pack Size	1's (Vial)-As per SRO
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted
	Name & address of API manufacturer	Qilu Antibiotics Pharmaceutical Co., Ltd.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence against Fortum 1g Injection of M/s. GSK
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Submitted
	Evaluation	3.2.S.4.1-3.2.S.4.2 Submit the specification and detailed analytical procedure of drug substance used by drug product manufacturer. 3.2.S.4.3 Provide analytical method validation report performed by drug product manufacturer. 3.2.S.4.4 Provide batch analysis report of drug substance performed by the drug product manufacturer. 3.2.S.5 Provide certificate of analysis of reference standard /working standard used for testing of the product. 3.2.S.7 Submit stability data of drug substance performed at zone IV-a conditions. 3.2.P.2.2.1 & 3.2.P.5.1 Justify for not including the test of Sodium carbonate while establishing the pharmaceutical equivalence against the reference product.Further, the said test is also not included in the finished product specification and the specification complied while performing the stability study of drug product, when the USP monograph of Ceftazidime for Injection recommend the test of sodium carbonate in their official monograph.. 3.2.P.5.4 Justify for not performing the test of particulate matter in Injections while conducting the batch analysis of drug product. 3.2.P.8.2 l Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. l Documents for the procurement of API with approval from DRAP (in case of import). 3.2.P.8.3 Justify for not performing the sterility test, bacterial endotoxin test, particulate matter in Injections test and the LOD test while conducting the stability study of drug product, when these tests are included in the USP official monograph of ceftazidime for injection. 2.3.R.1.1 please furnished the calculations regarding the quantity of active per vial considering the moisture and sodium carbonate factor, since the attached BMR only reflects the total quantity of active ingredients that was dispensed for trial batch. company hasn't read this reply yet.
	Shortcoming	
	Decision	Deferred . Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No	Title	Description
154	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(33Q-M9Z-LJS4, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Emprolim-90% Oral Powder**
	Label Claim	Each 100 gram contains: Amprolium HCl..... 90 gram (USP Specifications)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Hanster-90% Water Soluble Powder (Reg. No. 102218) by Dhaans Pharma (Pvt.) Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
155	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(4VQ-7U8-XZ5E, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Silinex 20 Oral Liquid**
	Label Claim	Each ml contains: Silymarin ..... 21mg Vitamin E.....15mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Hepatocare Oral Suspension (Reg. No. 062167) by Attabak Pharmaceutical Industries
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Deferred Referred to Sub-committee on veterinary drugs.

Sr. No	Title	Description
156	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(61J-9SW-8WR8, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Bromo Ruth 5% Oral Liquid**
	Label Claim	Each ml contains: Bromhexine HCl ..... 50mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Hexbro-50 Oral Liquid (Reg. No. 102241) by Dhaans Pharma (Pvt.) Ltd.
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
157	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(7YU-4J5-TLJS, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Mintohexine 2/4 Oral Liquid**
	Label Claim	Each ml contains: Bromhexine HCl ..... 20mg Menthol ..... 40mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Bromithol 20/40 Oral Liquid (Reg. No. 118387) by Acme Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
158	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(9ZY-64G-PJMM, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Prelox 10Oral Liquid**
	Label Claim	Each ml contains: Pefloxacin Methanesulfonate 139.6mg eq. to Pefloxacin..... 100mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Pefloxkam-10 Solution (Reg. No. 120589) by M.A. Kamil Farma (Pvt.) Limited
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
159	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(26B-EX5-Y82Q, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Ruthstin-60 Oral Powder**
	Label Claim	Each gram contains: Colistin Sulphate..... 351.8 mg (6MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acmecol 60 Oral Powder (Reg. No. 116967) by Acme Pharmaceuticals
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	calculation in grammage is not correct, fee for correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
160	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(AXZ-PB3-RS54, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Enrohexine 20/1 Oral Liquid**
	Label Claim	Each ml contains: Enrofloxacin ..... 200mg Bromhexine HCl ..... 10mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Bromoflox Oral Solution (Reg. No. 073905) by Mylab Pvt. Ltd.
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
161	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(DX8-LJ4-N1HH, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Emprolim-50% Oral Powder**
	Label Claim	Each 100 gram contains: Amprolium HCl..... 50 gram (USP Specifications)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acmepro-50% Water Soluble Powder (Reg. No. 117042) by Acme Pharmaceuticals
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
162	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(EWZ-H8J-1PY3, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Ruthstin-50 Oral Powder**
	Label Claim	Each gram contains: Colistin Sulphate..... 263.16 mg (5MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acmecol 50 Oral Powder (Reg. No. 116962) by Acme Pharmaceuticals
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	fee required for grammage correction.
	Shortcoming	
	Decision	Approved Fee required for grammage correction in composition (colistin).

Sr. No	Title	Description
163	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(GNW-GDS-638M, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Lincoruth 11% Oral Powder**
	Label Claim	Each 1000 gram contains: Lincomycin as HCl.....110 gm (USP Specifications)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Linc-Hans 11% Powder (Reg. No. 102212) by Dhaans Pharma (Pvt.) Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
164	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(J3H-818-GHYZ, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Neo Ruth 72% Oral Powder**
	Label Claim	Each 100 gram contains: Neomycin Sulphate..... 72 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Neomycin-72 Water Soluble Powder (Reg. No. 029669) by Farm Aid Group
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
165	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(M16-VY4-RAHM, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Floruth 25% Oral Liquid**
	Label Claim	Each 100ml contains: Florfenicol ..... 25gram Colistin Sulphate.....2.632gram (50MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Florotin-25 Liquid (Reg. No. 093840) by Aptly Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	fee required for colistin grammage correction.
	Shortcoming	
	Decision	Approved Fee required for colistin grammage correction.

Sr. No	Title	Description
166	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(MB1-8ZN-5ZTM, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**N-Florox Oral Powder**
	Label Claim	Each gram contains: Oxytetracycline HCl..... 300 mg Florfenicol..... 100 mg Neomycin Sulphate..... 150 mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Insha-Flor Powder (Reg. No. 103854) by Inshal Pharmaceutical Industries
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
167	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(3JU-V5L-QXU1, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Neoxystin 30% Oral Powder**
	Label Claim	Each 100 gram contains: Oxytetracycline HCl..... 30 gram Neomycin Sulphate..... 25 gram Colistin Sulphate.....0.029 gram (0.55MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acme NOC 30/25/0.55 Water Soluble Powder (Reg. No. 117041) by Acme Pharmaceuticals
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	fee required for colistin grammage correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
168	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(MYQ-NXE-JT6X, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Neo Ruth 70% Oral Powder**
	Label Claim	Each 100 gram contains: Neomycin Sulphate..... 70 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Neo-Aid Powder (Reg. No. 093827) by Farm Aid Group
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
169	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(N6S-SWX-9B5U, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Mintohexine 4/4 Oral Liquid**
	Label Claim	Each ml contains: Bromhexine HCl ..... 50mg Menthol ..... 40mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Mentovet 50/40 Oral Liquid (Reg. No. 103897) by Dhaans Pharma (Pvt.) Ltd.
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
170	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(P9B-RGU-XRM5, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Ruth Oxonic Oral Liquid**
	Label Claim	Each ml contains: Oxolinic Acid ..... 100mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Aceoxol Oral Liquid (Reg. No. 117036) by Acme Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
171	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(3V8-G8H-JZ13, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Enrostin 25% Oral Liquid**
	Label Claim	Each ml contains: Enrofloxacin ..... 250mg Colistin Sulphate ..... 26.32mg (0.5MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acmecoliflox 25/50 Oral Liquid (Reg. No. 117020) by Acme Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
172	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(SAD-1YV-4S2J, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Lincoruth 44% Oral Powder**
	Label Claim	Each 1000 gram contains: Lincomycin as HCl.....440 gm (USP Specifications)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Linc-Hans 44% Powder (Reg. No. 102214) by M/s Dhaans Pharma (Pvt.) Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
173	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(TUH-445-2G8M, 2024-12-30)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Bromo Ruth 10% Oral Liquid**
	Label Claim	Each ml contains: Bromhexine HCl ..... 100mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	ET Bromhexine Oral Liquid (Reg. No. 112312) by Eterna Pharma (Pvt.) Ltd. AJK.
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
174	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(TWZ-7AS-P2BV, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Tilco-Ruth Oral Liquid**
	Label Claim	Each ml contains: Tilmicosin as Phosphate ..... 250mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Martil Liquid (Reg. No. 093772) by Aptly Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
175	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(4WQ-ZJ3-HRR3, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Enrostin 20% Oral Liquid**
	Label Claim	Each liter contains: Enrofloxacin ..... 200 gram Colistin Sulphate ..... 26.32 gram (500MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Senrox-Plus Oral Liquid (Reg. No. 081324) by Sanna Laboratories
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Application is complete
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
176	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(W7B-DPV-V6M8, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Enrohexine 20/5 Oral Liquid**
	Label Claim	Each ml contains: Enrofloxacin ..... 200mg Bromhexine HCl ..... 50mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Rofl Liquid (Reg. No. 101976) by Inshal Pharmaceutical Industries
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
177	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(WZ2-UXR-RHR5, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Ruth-Lysonex**
	Label Claim	Each gram contains: Lysozyme (as HCl) (JP).....220mg (22%) Vitamin E (USP).....5mg (0.5%) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Vitozyme Powder (Reg. No. 049622) by Selmore Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	application is complete.
	Shortcoming	
	Decision	Deferred Referred to Sub-committee on veterinary drugs.

Sr. No	Title	Description
178	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(5E5-P1J-YXRQ, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Spirahexine Oral Powder**
	Label Claim	Each Kg contains: Lincomycin HCl ..... 50 gram Spectinomycin HCl ..... 75 gram Spiramycin Adipate ..... 25 gram Bromhexine HCl ..... 5 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Brolin-S Oral Powder (Reg. No. 102027) by Leads Pharma (Pvt.) Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Fee for salt form correction is required.
	Shortcoming	
	Decision	Approved Fee required for salt form correction in composition.

Sr. No	Title	Description
179	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(73P-2A1-SAJM, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**CRD Ruth 30 Oral Powder**
	Label Claim	Each 1000 gram contains: Tylosin Tartrate..... 100 gram Doxycycline Hyclate..... 200 gram Colistin Sulphate..... 25.26 gram (480MIU) Bromhexine HCl..... 5 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Emeria Shell Powder (Reg. No. 080515) by Inshal Pharmaceutical Industries
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Available generic salt form of DOXYCYCLINE HCL while applied DOXYCYCLINE hyclate, fee is required for salt form correction as per generic.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
180	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(9SE-VLJ-AYHA, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Floxiprim-S Oral Liquid**
	Label Claim	Each ml contains: Enrofloxacin ..... 75mg Sulphamethoxypyridazine ..... 75mg Sulphamethazine ..... 50mg Trimethoprim ..... 25mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Ensulprim Liquid (Reg. No. 093773) by Aptly Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	application is complete.
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
181	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(DE4-YGZ-DJA4, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Cinivit Oral Powder**
	Label Claim	Each gram contains: Acetylsalicylic Acid……67mg Vitamin C……200mg (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Sali-C Powder (Reg. No. 043537) by Selmore Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Acetylsalicylic Acid and Vitamin C containing formulations are under review of Sub-committee.
	Shortcoming	
	Decision	Deferred Referred to sub-committee on veterinary drugs.

Sr. No	Title	Description
182	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(DZN-1VH-QT82, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**CRD Ruth 60 Oral Powder**
	Label Claim	Each 100 gram contains: Tylosin Tartrate..... 20 gram Doxycycline Hyclate..... 40 gram Colistin Sulphate..... 2.632 gram (50MIU) Bromhexine HCl..... 1 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Fludoxyt-400 Powder (Reg. No. 103851) by Inshal Pharmaceutical Industries
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Fee required for salt form and colistin grammage correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
183	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(J1Z-3N1-NERH, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**CRD Ruth 10/20 Oral Powder**
	Label Claim	Each 1000 gram contains: Tylosin Tartrate..... 100 gram Doxycycline Hyclate..... 200 gram Colistin Sulphate..... 21 gram (400MIU) Bromhexine HCl..... 3 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Resbro Oral Water Soluble Powder (Reg. No. 092174) by Sanna Laboratories
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Fee required for salt form and colistin grammage correction
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
184	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(JD9-N1H-HATY, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**CRD Ruth 20/40 Oral Powder**
	Label Claim	Each 1000 gram contains: Tylosin Tartrate..... 100 gram Doxycycline Hyclate..... 200 gram Colistin Sulphate..... 21 gram (400MIU) Bromhexine HCl..... 3 gram (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Resbro Oral Water Soluble Powder (Reg. No. 092174) by Sanna Laboratories
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Applied Doxycycline Hyclate while generic is Doxycycline HCL fee required for salt form correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
185	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(USW-HU3-G4V7, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Floruth 23% Oral Liquid**
	Label Claim	Each 100ml contains: Florfenicol ..... 23gram Colistin Sulphate.....2.632gram (50MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Florotin-23 Liquid (Reg. No. 093839) by Aptly Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Fee required for colistin grammage correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
186	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(W6J-VQ7-UB8P, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Enrostin 10% Oral Liquid**
	Label Claim	Each ml contains: Enrofloxacin ..... 100mg Colistin Sulphate ..... 27.37mg (0.52MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acmecoliflox 10/52 Oral Liquid (Reg. No. 117022) by Acme Pharmaceuticals
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Fee required for colistin grammage correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
187	Name, address of Manufacturing site.	**Ruth Pharmaceutical** 5-km, Bhati Mansoor Road Ghakhar, Tehseel Wazirabad,District Gujranwala**(000997)**
	Case Category	New License (Sarfraz Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(YRT-Y84-LJGS, 2024-12-31)
	Detail of Fee Submitted	37000.0, 2024-12-26,
	The proposed proprietary name / brand name	**Neoxystin 20% Oral Powder**
	Label Claim	Each 100 gram contains: Oxytetracycline HCl..... 20 gram Neomycin Sulphate..... 20 gram Colistin Sulphate.....0.029 gram (0.55MIU) (As per Innovator's Specification)
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	NA
	For generic drugs (me-too Status)	Acme NOC 20/20/0.55 Water Soluble Powder (Reg. No. 117040) by Acme Pharmaceuticals
	Proposed Pack Size	100gram, 250gram, 50-De-Controlled
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	fee required for colistin grammage correction.
	Shortcoming	
	Decision	Approved Firm shall submit fee of pre-registration variation i.e., Rs. 37,000/- for correction correction /standardization of composition as per SRO 496 (I)/2023 dated 17-04-2023.

Sr. No	Title	Description
188	Name, address of Manufacturing site.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore**(000576)**
	Case Category	New Section (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(5AP-42R-DDS5, 2024-10-29)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Neufocus 40mg Capsule**
	Label Claim	Each Capsule contains: Atomoxetine as Hydrochloride 40mg
	Pharmacotherapeutic Group of (API)	N06BA Centrally acting sympathomimetic.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too Status)	Moxitine Capsule 40mg by CCL pharma.
	Proposed Pack Size	28's-As per SRO
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 14-04-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	Capsule (General) section (second floor) approved vide letter No. F. 1-3/2003-Lic (Vol-III) dated 30-04-2022.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both Real time & accelerated stability data of the drug substance as per zone IVb condition is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against Attentra 40mg capsule, B. No. 23AM001 manufactured by M/s Genetics Pharma.
	Detail of stability batches of drug product	03 batches of 1500 capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of commercial invoice No. 2220193 dated 27-10-20 mentioning 0.5kg of Atomoxetine attested by DRAP, Lahore dated 05-11-2020.
	Evaluation	Your application is found deficient for the following; Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from drug substance shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.
	Shortcoming	
	Decision	Deferred For the following Observations; Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from drug substance shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.

Sr. No	Title	Description
189	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(A4D-7TW-JDUH, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-12-06,
	The proposed proprietary name / brand name	**Starcipro Tablet**
	Label Claim	Each film coated tablet Contains Ciprofloxacin as Hydrochloride ..... 250mg.
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA approved.
	For generic drugs (me-too Status)	Novidat 250mg Tablet by M/s Sami pharmaceuticals.
	Proposed Pack Size	1 x 10's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	CITI pharma Pvt Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of drug substance for one batch from drug substance manufacturers as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Novidat 250mg Tablet, Batch No. FHM033, Mfg. date 07-24 manufactured by M/s Sami Pharma.
	Detail of stability batches of drug product	03 batches of 600 tablets each is manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Drug substance is locally purchased.
	Evaluation	Your application is evaluated and found deficient for the following; • COA of the drug substance from drug product manufacturer used in trial batches shall be submitted. • COA of the working standard used shall be submitted. • Stability study data of drug substance for two batches shall be submitted. • Complete six month stability data shall be submitted. • Purchase invoice shall be submitted. Firm has submitted the following documents in response to deficiencies; • COA of the drug substance, COA of the working standard, Stability study summary sheets of the drug substance from drug substance manufacturer and purchase invoice from the drug substance manufacturer mentioning different APIs.
	Shortcoming	
	Decision	Approved Registration letter will be issued after submission of stability data of six month time point.

Sr. No	Title	Description
190	Name, address of Manufacturing site.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan**(000999)**
	Case Category	New License (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(BSB-32U-1R2V, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-12-06,
	The proposed proprietary name / brand name	**Starcipro Tablet**
	Label Claim	Each film coated tablet contains Ciprofloxacin as hydrochloride 500mg
	Pharmacotherapeutic Group of (API)	J01MA Fluoroquinolones.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	USFDA approved.
	For generic drugs (me-too Status)	Novidat 500mg Tablet
	Proposed Pack Size	1 x 10's-As per SRO
	GMP status of the firm	Firm is newly licensed unit, DML issued on 02-12-2024 in 302nd meeting of CLB on the basis of inspection conducted on 12-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) section approved vide letter No. F. 3-1/2021-Lic dated 02-12-2024.
	Name & address of API manufacturer	CITI pharma Pvt Ltd
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability data of one batch of drug substance from drug substance manufacturers as per Zone Iva submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP studies are performed against Novidat 500mg Tablet, Batch No. FIM136, Mfg. date 08-24 manufactured by M/s Sami Pharma.
	Detail of stability batches of drug product	03 batches of 600 tablets each is manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Drug substance is locally purchased.
	Evaluation	Your application is evaluated and found deficient for the following; • COA of the drug substance from drug product manufacturer used in trial batches shall be submitted. • COA of the working standard used shall be submitted. • Stability study data of drug substance for two batches shall be submitted. • Complete six month stability data shall be submitted. • Purchase invoice shall be submitted. Firm has submitted the following documents in response to deficiencies; • COA of the drug substance, COA of the working standard, Stability study summary sheets of the drug substance from drug substance manufacturer and purchase invoice from the drug substance manufacturer mentioning different APIs.
	Shortcoming	
	Decision	Approved • Registration letter will be issued after submission of stability data of six month time point.

Sr. No	Title	Description
191	Name, address of Manufacturing site.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore**(000576)**
	Case Category	New Section (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(E5D-W6Q-M6N4, 2024-10-09)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Neufocus 25mg Capsule**
	Label Claim	Each Capsule contains: Atomoxetine as Hydrochloride 25mg
	Pharmacotherapeutic Group of (API)	N06BA Centrally acting sympathomimetic.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too Status)	Moxitine Capsule 25mg by CCL pharma
	Proposed Pack Size	28's-As per SRO
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 14-04-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	Capsule (General) section approved vide letter No. F. 1-3/2003-Lic (Vol-III) dated 04-06-2022.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both Real time & accelerated stability data of the drug substance as per zone IVb condition is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against Attentra 25mg capsule, B. No. 22AN004 manufactured by M/s Genetics Pharma.
	Detail of stability batches of drug product	03 batches of 1500 capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of commercial invoice No. 2220193 dated 27-10-20 mentioning 0.5kg of Atomoxetine attested by DRAP, Lahore dated 05-11-2020.
	Evaluation	Your application is found deficient for the following; Section 1.5.2 has mentioned the label claim with mentioning salt form. Clarification shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from drug substance shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.
	Shortcoming	
	Decision	Deferred For the following Observations; Section 1.5.2 has mentioned the label claim with mentioning salt form. Clarification shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from both drug substance and drug product manufacturer shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.

Sr. No	Title	Description
192	Name, address of Manufacturing site.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT**(000941)**
	Case Category	New License (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(NBU-W3U-PXYV, 2024-12-19)
	Detail of Fee Submitted	37000.0, 2024-11-27,
	The proposed proprietary name / brand name	**Pantoera 40mg Injection**
	Label Claim	Each vial contains: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too Status)	Product: Zopent 40mg Injection Manufacturer: Hilton Pharma Karachi
	Proposed Pack Size	1s-De-Controlled
	GMP status of the firm	New DML issued dated 14-09-2021.
	Evidence of approval of manufacturing facility	Dry Powder Injection General section approved vide letter No. F. 1-42/2011-Lic dated 16-09-2021.
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Address: Plot # 22-23, Industrial Triangle, Kahutta Road, Islamabad-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both Real time & accelerated stability data of the drug substance as per zone IVa condition is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are performed against Zopent 40mg Injections, B. No. ZPG014 manufactured by M/s Hilton Pharma
	Detail of stability batches of drug product	03 batches of 2892 injection each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	API is locally purchased and invoice submitted.
	Evaluation	
	Shortcoming	
	Decision	Approved

Sr. No	Title	Description
193	Name, address of Manufacturing site.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore**(000576)**
	Case Category	New Section (Shahid Nawaz)
	Application Form Dy. No / Tracking ID & date of submission	(NW9-J3E-J9VQ, 2024-10-31)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Neufocus 10mg Capsule**
	Label Claim	Each Capsule Contains: Atomoxetine as HCl 10mg
	Pharmacotherapeutic Group of (API)	N06BA Centrally acting sympathomimetic.
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too Status)	Moxitine Capsule 10mg by CCL pharmaceutical.
	Proposed Pack Size	28's-As per SRO
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 14-04-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	Capsule (General) section approved vide letter No. F. 1-3/2003-Lic (Vol-III) dated 04-06-2022.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Both Real time & accelerated stability data of the drug substance as per zone IVb condition is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against Attentra 10mg capsule, B. No. 22AT001 manufactured by M/s Genetics Pharma.
	Detail of stability batches of drug product	03 batches of 1500 capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	copy of commercial invoice No. 2220193 dated 27-10-2020 mentioning 0.5kg of Atomoxetine attested by DRAP, Lahore dated 05-11-2020.
	Evaluation	Your application is found deficient for the following; Section 1.5.2 has mentioned the label claim with mentioning salt form. Clarification shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from both drug substance and drug product manufacturer shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.
	Shortcoming	
	Decision	Deferred For the following Observations; Section 1.5.2 has mentioned the label claim with mentioning salt form. Clarification shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Drug substance manufacturer has claimed USP specifications for the drug substance while the analytical method is different from USP monograph. Clarification shall be submitted. Specifications and analytical method for the drug substance from drug product manufacturer shall be submitted. Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. COA of the drug substance used in the trial batches from both drug substance and drug product manufacturer shall be submitted. Complete real time stability data for the drug substance till claimed shelf life shall be submitted.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td rowspan="19">194</td><td>Name, address of Manufacturing site.</td><td>Levon Pharmaceuticals Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura(000976)</td></tr>
<tr><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(1PS-B6Z-3GGE, 2024-09-24)</td></tr>
<tr><td>Detail of Fee Submitted</td><td>30000.0,
2024-05-09,</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Roklar 500mg Capsule</td></tr>
<tr><td>Label Claim</td><td>Each capsule contains: Cefaclor (as Monohydrate) ... 500mg</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>J01DC04: Second-generation cephalosporins</td></tr>
<tr><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>CECLOR 500mg Capsules, USFDA. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**</td></tr>
<tr><td>For generic drugs (me-too Status)</td><td>Ceclor 500mg Capsule of M/s AGP Limited.</td></tr>
<tr><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td>GMP status of the firm</td><td>New License w.e.f. 25-10-2023</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Capsule (Cephalosporin) Section has been submitted.</td></tr>
<tr><td>Name & address of API manufacturer</td><td>Pharmagen</td></tr>
<tr><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical Equivalence and CDP conducted against Ceclor 500mg Capsule.</td></tr>
<tr><td>Detail of stability batches of drug product</td><td>03 Batches, 900 Capsules each.</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Local purchase from M/s Pharmagen Ltd., Lahore.</td></tr>
<tr><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP Certificate valid for three years from the date of inspection (11-07-2024) have been submitted.</td></tr>
</table></td></tr>
<tr><td>Shortcoming</td><td></td></tr>
<tr><td>Decision</td><td>Approved</td></tr>
</table>

Sr. No	Title	Description
195	Name, address of Manufacturing site.	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan**(000986)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(1G9-BAX-2YPQ, 2024-11-11)
	Detail of Fee Submitted	30000.0, 2024-08-01,
	The proposed proprietary name / brand name	**NEMOVATE N**
	Label Claim	Each gm contains: Betamethasone Valerate ... 0.1% w/w Neomycin Sulfate ... 0.5% w/w
	Pharmacotherapeutic Group of (API)	D07CC01: Corticosteroids, potent, combinations with antibiotics
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Betamethasone valerate/Neomycin sulphate 1 mg/5 mg/g Cream, EMA Approved.
	For generic drugs (me-too Status)	Betnovate N Cream of M/s GlaxoSmithKline Pakistan Ltd.
	Proposed Pack Size	20 g-As per SRO
	GMP status of the firm	New License w.e.f. 26-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Cream/Ointment (General) Section has been submitted.
	Name & address of API manufacturer	1- MAHIMA LIFE SCIENCES PRIVATE LIMITED, Address, 705, 4TH FLOOR, ONKAR BHAWAN, BHAGIRATH PALACE, CHANDNI CHOWK, NEW DELHI, INDIA - 110 006,2- Sichuan Long March Pharmaceutical Co., Ltd. 448 Changqing Road, Leshan,Sichuan 614000, People’s Republic China
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturers.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Betnovate cream of M/s GlaxoSmithKline Pakistan Ltd.
	Detail of stability batches of drug product	03 Batches, 5Kgs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of Loan letter for 800gm API (each) from Derma Techno Pharma, Lahore has been submitted. Clearance documents for Import are not provided.
	Evaluation	1) BETAMETHASONE VALERATE: Please provide valid GMP of API Manufacturer. 2) 3.2. P.2.2.1 It has been mentioned that Pharmaceutical Equivalence has been conducted against Betnovate Cream, which is Betamethasone Valerate 0.1% w/w only (without Neomycin Sulfate). Please justify. Also provide evidence of Reference pack used for Pharmaceutical Equivalence. 3) 3.2. P.5.1 Specification does not include Tests for Neomycin. Please justify. 4) Please provide evidence of Import of relevant Batches of APIs, along with DRAP I&E Clearance of the said consignments. 5) CHROMATOGRAMS, RAW DATA SHEETS, COA etc. are submitted for 6th Month Accelerated Studies Only. 6) Audit Trail Reports of HPLC Testing have not been submitted. 7) Batch Manufacturing Records / Trail Manufacturing Records have not been submitted.
	Shortcoming	
	Decision	Deferred Submission of response to the following deficiencies: - 1) BETAMETHASONE VALERATE: Please provide valid GMP of API Manufacturer. 2) 3.2. P.2.2.1 It has been mentioned that Pharmaceutical Equivalence has been conducted against Betnovate Cream, which is Betamethasone Valerate 0.1% w/w only (without Neomycin Sulfate). Please justify. Also provide evidence of Reference pack used for Pharmaceutical Equivalence. 3) 3.2. P.5.1 Specification does not include Tests for Neomycin. Please justify. 4) Please provide evidence of Import of relevant Batches of APIs, along with DRAP I&E Clearance of the said consignments. 5) CHROMATOGRAMS, RAW DATA SHEETS, COA etc. are submitted for 6th Month Accelerated Studies Only. 6) Audit Trail Reports of HPLC Testing have not been submitted. 7) Batch Manufacturing Records / Trail Manufacturing Records have not been submitted.

Sr. No	Title	Description
196	Name, address of Manufacturing site.	**Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura**(000976)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(5RX-YU5-V4NR, 2024-10-23)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	**Leedox 250mg Capsule**
	Label Claim	Each Capsule contains: Cefadroxil (as monohydrate) ... 250mg
	Pharmacotherapeutic Group of (API)	J01DB05: First-generation cephalosporins
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	DURICEF 250mg Capsules, USFDA (Discontinued)
	For generic drugs (me-too Status)	Stoxil Capsules 250mg of M/s Wnsfeild Pharmaceuticals (046789).
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Capsule (Cephalosporin) Section has been submitted.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not provided, firm have mentioned in Section 3.2. P.2.2.1 that Cefadroxil 250mg Capsule is not Available of any brand in market.
	Detail of stability batches of drug product	03 Batches, 900 Capsules each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Local purchase from M/s Pharmagen Ltd., Lahore.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Please provide valid RRA Status of applied strength. The mentioned strength is discontinued in USFDA. 2) Please provide valid GMP of API Manufacturer. 3) Pharmaceutical Equivalence and Comparative Dissolution Profile have not been submitted. Firm have mentioned in Section 3.2. P.2.2.1 that Cefadroxil 250mg Capsule is not Available of any brand in market.
	Shortcoming	
	Decision	Deferred 1. Valid RRA Status of applied strength. 2. Valid GMP of API Manufacturer. 3. Pharmaceutical Equivalence and Comparative Dissolution Profile against Innovator / Reference Product.

Sr. No	Title	Description
197	Name, address of Manufacturing site.	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan**(000986)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(J8S-YPZ-XP1Y, 2024-08-16)
	Detail of Fee Submitted	30000.0, 2024-07-08,
	The proposed proprietary name / brand name	**NEMOVATE**
	Label Claim	Each gm contains: BETAMETHASONE VALERATE eq. to BETAMETHASONE ... 1mg
	Pharmacotherapeutic Group of (API)	D07AC01: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	Betamethasone 0.1% w/w Cream, MHRA approved.
	For generic drugs (me-too Status)	Betnovate Cream 0.1% w/w of M/s GlaxoSmithKline Pakistan Ltd.
	Proposed Pack Size	20 g-As per SRO
	GMP status of the firm	New License w.e.f. 26-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Cream / Ointment Section (General) has been submitted.
	Name & address of API manufacturer	MAHIMA LIFE SCIENCES PRIVATE LIMITED, Address, 705, 4TH FLOOR, ONKAR BHAWAN, BHAGIRATH PALACE, CHANDNI CHOWK, NEW DELHI, INDIA - 110 006
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Betnovate Cream 0.1% w/w.
	Detail of stability batches of drug product	03 Batches, 5Kgs each
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Copy of Loan letter for 100gm API from Derma Techno Pharma, Lahore has been submitted. Clearance documents for Import are not provided.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Please provide valid GMP of API Manufacturer. 2) Please provide evidence of Import of relevant batch of API along with DRAP (I&E) Clearance of consignment. 3) CHROMATOGRAMS, RAW DATA SHEETS, COA etc. are submitted for 6th Month Accelerated Studies Only. 4) Audit Trail Reports of HPLC Testing have not been submitted. 5) Batch Manufacturing Records / Trail Manufacturing Records have not been submitted.
	Shortcoming	
	Decision	Deferred 1) Valid GMP of API Manufacturer. 2) Evidence of Import of relevant batch of API along with DRAP (I&E) Clearance of consignment. 3) CHROMATOGRAMS, RAW DATA SHEETS, COA etc. are submitted for 6th Month Accelerated Studies Only. 4) Audit Trail Reports of HPLC Testing. 5) Batch Manufacturing Records / Trail Manufacturing Records.

Sr. No	Title	Description
198	Name, address of Manufacturing site.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura,**(000956)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(M2L-1L3-YJP8, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	**Artham Dry Suspension 15mg/90mg (30ml)**
	Label Claim	Each 5ml of reconstituted suspension contains: Artemether ... 15mg Lumefantrine ... 90mg
	Pharmacotherapeutic Group of (API)	P01BF01: ANTIMALARIALS
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Could not be confirmed from WHO or USFDA
	For generic drugs (me-too Status)	ARCEVA 15mg+90mg / 5ml Dry Suspension of M/s SAMI Pharmaceuticals Pvt. Ltd.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License w.e.f. 28-04-2022
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Oral Dry Powder Suspension Section (General) has been submitted.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against ARCEVA 15mg+90mg / 5ml Dry Suspension of M/s SAMI Pharmaceuticals Pvt. Ltd.
	Detail of stability batches of drug product	03 Batches, 100 Bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Could not be confirmed from submitted documents.
	Evaluation	Following deficiencies / shortcomings have been communicated to the applicant: 1) RRA status could not be confirmed from WHO / USFDA (as mentioned). Please provide evidence of RRA status for applied dosage form and strengths. 2) 3.2.P.5 Finished Product Specifications have been claimed 'As per Innovator' and 'In-house', whereas the applied formulation is available in International Pharmacopia. Please provide justification for not adopting Pharmacopeal specifications. 3) Please provide valid GMP of API Manufacturer. 4) Please provide evidence of Borrowing of API (endorsed by Importer) along with legible copy of DRAP I&E Clearance for Import.
	Shortcoming	
	Decision	Deferred 1. Provide evidence of RRA status for applied dosage form and strengths. 2. 3.2.P.5 Finished Product Specifications have been claimed 'As per Innovator' and 'In-house', whereas the applied formulation is available in International Pharmacopia. Please provide justification for not adopting Pharmacopeial specifications. 3) Provide valid GMP of API Manufacturer. 4) Provide evidence of Borrowing of API (endorsed by Importer) along with legible copy of DRAP I&E Clearance for Import.

Sr. No	Title	Description
199	Name, address of Manufacturing site.	**Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura**(000976)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(NW9-6DA-M849, 2024-10-21)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	**RINOGEN 125mg/5ml Dry Powder for Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Cefalexin monohydrate equivalent to cefalexin base ... 125mg
	Pharmacotherapeutic Group of (API)	J01DB01: First-generation cephalosporins
	Reference to Finished product specifications	United States Pharmacopeia
	The status in reference regulatory authorities	KEFLEX 125mg/5ml for Oral Suspension, USFDA **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too Status)	Keflex 125mg/5ml Suspension of M/s AGP Limited.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Dry Powder for Suspension (Cephalosporin) Section has been submitted.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against KEFLEX 125mg/5ml Suspension
	Detail of stability batches of drug product	03 Batches, 100 Bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Local purchase from M/s Pharmagen Ltd., Lahore.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Label claim needs to be corrected as 'Each 5ml of reconstituted suspension contains: Cefalexin monohydrate equivalent to cefalexin base ... 125mg'. 2) Please provide valid GMP of API Manufacturer.
	Shortcoming	
	Decision	Approved Registration Letter will be issued after submission of: - 1. Fee for Pre-registration variation / correction of label claim. 2. Valid GMP of API Manufacturer.

Sr. No	Title	Description
200	Name, address of Manufacturing site.	**Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura**(000976)**
	Case Category	New License (Tahir Waqas)
	Application Form Dy. No / Tracking ID & date of submission	(PUM-4LV-V9MM, 2024-10-08)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	**NELRAX 125mg/5ml Dry Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: CEPHRADINE .....125mgBP Specification
	Pharmacotherapeutic Group of (API)	J01DB09: First-generation cephalosporins.
	Reference to Finished product specifications	British Pharmacopeia
	The status in reference regulatory authorities	VELOSEF '125' For Oral Suspension. USFDA (Discontinued)
	For generic drugs (me-too Status)	Velosef 125mg/5ml Dry powder suspension by GSK Pharma.
	Proposed Pack Size	As per SRO-As per SRO
	GMP status of the firm	New License w.e.f. 25-10-2023
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Capsule (Cephalosporin) Section has been submitted.
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against Velocef 125mg/5ml Dry powder suspension
	Detail of stability batches of drug product	03 Batches, 150 Bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Improt)	Local purchase from M/s Citi Pharma, Lahore.
	Evaluation	Following deficiencies have been communicated to the applicant: 1) Please provide valid RRA Status of applied strength. The mentioned strength is discontinued in USFDA. 2) Please provide summary of quantities of FPP utilized and further required for Stability Studies till claimed shelf life. (Submitted)
	Shortcoming	
	Decision	Deferred 1. Evidence of RRA Status of applied strength and dosage form.

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td rowspan="19">201</td><td>Name, address of Manufacturing site.</td><td>Levon Pharmaceuticals Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura(000976)</td></tr>
<tr><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(VGJ-H2N-GG62, 2024-08-22)</td></tr>
<tr><td>Detail of Fee Submitted</td><td>30000.0,
2024-05-09,</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>RINOGEN 250mg/5ml Dry Powder for Suspension</td></tr>
<tr><td>Label Claim</td><td>Each 5ml of reconstituted suspension contains: Cefalexin monohydrate equivalent to cefalexin base ... 250mg</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>J01DB01: First-generation cephalosporins</td></tr>
<tr><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>KEFLEX 250mg/5ml for Oral Suspension, USFDA **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**</td></tr>
<tr><td>For generic drugs (me-too Status)</td><td>Keflex 250mg/5ml Suspension of M/s AGP Limited.</td></tr>
<tr><td>Proposed Pack Size</td><td>As per SRO-As per SRO</td></tr>
<tr><td>GMP status of the firm</td><td>New License w.e.f. 25-10-2023</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Dry Powder for Suspension (Cephalosporin) Section has been submitted.</td></tr>
<tr><td>Name & address of API manufacturer</td><td></td></tr>
<tr><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Not submitted</td></tr>
<tr><td>Detail of stability batches of drug product</td><td>03 Batches, 100 Bottles each.</td></tr>
<tr><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Local purchase from M/s Pharmagen Ltd., Lahore.</td></tr>
<tr><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant.
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Label claim needs to be corrected as 'Each 5ml of reconstituted suspension contains: Cefalexin monohydrate equivalent to cefalexin base ... 250mg'</td><td>Firm have submitted revised label claim as:
Each 5ml of reconstituted suspension contains: Cephalexin monohydrate equivalent to cephalexin base ... 250 mg</td></tr>
<tr><td>2.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP Certificate valid for three years from the date of inspection (11-07-2024) has been submitted.</td></tr>
<tr><td>3.</td><td>Pharmaceutical Equivalence Study with Reference / Innovator / Comparator Product have not been submitted.</td><td>Pharmaceutical Equivalence Study with Keflex 250mg/5ml Dry Powder for Suspension have been submitted.</td></tr>
</table></td></tr>
<tr><td>Shortcoming</td><td></td></tr>
<tr><td>Decision</td><td>Approved
Registration letter will be issued after submission of prescribed Fee for Pre-registration variation / correction of label claim.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Title</th><th>Description</th></tr>
<tr><td>202</td><td>Name, address of Manufacturing site.</td><td>Levon Pharmaceuticals Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura(000976)</td></tr>
<tr><td></td><td>Case Category</td><td>New License (Tahir Waqas)</td></tr>
<tr><td></td><td>Application Form Dy. No / Tracking ID & date of submission</td><td>(ZTJ-SA3-V7NA, 2024-08-22)</td></tr>
<tr><td></td><td>Detail of Fee Submitted</td><td>30000.0,
2024-05-09,</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Rinogen 250mg Capsule</td></tr>
<tr><td></td><td>Label Claim</td><td>Each Capsule contains: Cefalexin monohydrate equivalent to cefalexin base ... 250mg</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>J01DB01: First-generation cephalosporins</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Keflex Capsules 250mg, MHRA approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too Status)</td><td>Keflex 250mg capsule of M/s AGP LIMITED.</td></tr>
<tr><td></td><td>Proposed Pack Size</td><td>As per SRO.-As per SRO</td></tr>
<tr><td></td><td>GMP status of the firm</td><td>New License w.e.f. 25-10-2023</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Section approval letter from Licensing Division for Capsule (Cephalosporin) Section has been submitted.</td></tr>
<tr><td></td><td>Name & address of API manufacturer</td><td>Pharmagen Limited. Kot Nabi Bakhsh wala,34 K.M. Ferozepur road, Lahore ,Punjab.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Stability Studies conducted on Zone IV by Drug Substance Manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Not submitted</td></tr>
<tr><td></td><td>Detail of stability batches of drug product</td><td>03 Batches, 1200 Capsules each.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP (in case of Improt)</td><td>Local purchase from M/s Pharmagen Ltd., Lahore.</td></tr>
<tr><td></td><td>Evaluation</td><td>Following deficiencies have been communicated to the applicant:
<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response of the firm</th></tr>
<tr><td>1.</td><td>Label claim needs to be corrected as: 'Each Capsule contains: Cefalexin monohydrate equivalent to cefalexin base ... 250mg'</td><td>Firm have submitted revised label claim as follows.
Each Capsule contains:
Cephalexin monohydrate equivalent to Cephalexin base ... 250mg</td></tr>
<tr><td>2.</td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile have not been submitted.</td><td>Firm have submitted Pharmaceutical Equivalence and Comparative Dissolution Profile Study conducted against Keflex 250mg Capsules.</td></tr>
<tr><td>3.</td><td>Please provide valid GMP of API Manufacturer.</td><td>Copy of GMP Certificate valid for three years from the date of inspection (11-07-2024) has been submitted.</td></tr>
</table></td></tr>
<tr><td></td><td>Shortcoming</td><td></td></tr>
<tr><td></td><td>Decision</td><td>Approved
Registration Letter will be issued after submission of prescribed Fee for Pre-registration variation / correction of label claim.</td></tr>
</table>

a. Pharmaceutical Evaluation Cell (PEC)

Agenda of Mr. Ammar Ashraf Awan

Case no.: 01 Applications of Form 5F by way of contract manufacturing

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gallop Water Sciences.** **Plot No. 404, Sunder Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 6332 dated 25-02-2021 Rs.20,000/- dated 01-01-2020 & 30,000/- dated 27-01-2021
	The proposed proprietary name / brand name	**Gee-Cefax 100mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Cefixime as Trihydrate…100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Cefixime suspension (USFDA Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Cefspan Suspension by Barret Hodgson
	Detail of stability batches of drug product	Stability data of three batches shall be submitted.
	Document for procurement of API	Drug substance from Pharmagen has been used
Evaluation by PEC^{II}: Firm has submitted data for in-use stability studies of reconstituted suspension. Mass Pharmaceuticals has been granted renewal of DML dated 14-10-2021 including Dry powder suspension cephalosporin section.		
Decision: Approved.		
2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gallop Water Sciences.** **Plot No. 404, Sunder Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 6331 dated 25-02-2021 Rs.20,000/- dated 01-01-2020 & 30,000/- dated 27-01-2021
	The proposed proprietary name / brand name	**Gee-Cefax 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefixime (Trihydrate)…400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Cefixime 400mg capsule (MHRA Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	In-House
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Cefspan capsules
	Detail of stability batches of drug product	Stability data of three commercial batches is submitted
	Document for procurement of API	Invoice form Pharmagen submitted
Evaluation by PEC^{II}: Mass Pharmaceuticals has been granted renewal of DML dated 14-10-2021 including Capsule cephalosporin section.		
Decision: Approved		
3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 6330 dated 25-02-2021 Rs.20,000/- dated 01-01-2020 & 30,000/- dated 27-01-2021
	The proposed proprietary name / brand name	**Cef-AX 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefixime as Trihydrate…400mg
	Pharmacotherapeutic Group of (API)	Antibiotic

	The status in reference regulatory authorities	Cefixime 400mg capsule (MHRA Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	In-House
	Detail of stability batches of drug product	Submitted against Cefspan capsules
	Document for procurement of API	Stability data of three commercial batches is submitted
Evaluation by PEC^{II}: Mass Pharmaceuticals has been granted renewal of DML dated 14-10-2021 including Capsule cephalosporin section.		
Decision: Approved.		
4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 6329 dated 25-02-2021 Rs.20,000/- dated 01-01-2020 & 30,000/- dated 27-01-2021
	The proposed proprietary name / brand name	**Cef-AX 100mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Cefixime as Trihydrate…100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Cefixime suspension (USFDA Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Cefspan Suspension by Barret Hodgson
	Detail of stability batches of drug product	Stability data of three batches shall be submitted.

	Document for procurement of API	Drug substance from Pharmagen has been used
Evaluation by PEC^{II}: Firm has submitted data for in-use stability studies of reconstituted suspension. Mass Pharmaceuticals has been granted renewal of DML dated 14-10-2021 including Dry powder suspension cephalosporin section.		
Decision: Approved.		

Application of Finished drug product import applied on Form 5A

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Medics Medical System.** **F-597, F-Block, Satellite Town, Rawalpindi, Pakistan**
	Name, address of MA Holder in country of origin	M/s Hainan Hailing Chemipharma Corporation Ltd. No. 281, Nanhai Avenue, Haikou, Hainan 570311, China
	Name, address of Manufacturing site.	M/s Hainan Hailing Chemipharma Corporation Ltd. No. 281, Nanhai Avenue, Haikou, Hainan 570311, China
	Country of origin	China
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5A Dy.No 13123 dated 06-03-2019 Rs100,000/- dated 05-03-2019
	The proposed proprietary name / brand name	**Salbact**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone Sodium Eq. Cefoperazone…500mg Sulbactam Sodium Eq. To Sulbactam…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Approved by PMDA of Japan
	For generic drugs (me-too status)	2Sum of M/s Sami
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	In-House
	Detail of stability batches of drug product	Stability data of three batches submitted as per Zone IV conditions at accelerated 6 month and long term 36 months

	Details of certification	COPP Original Legalized COPP no. 20180059 issued by Hainan Food and Drug Administration valid till 20-09-2020 declares free sale status in exporting country as well as GMP of the drug product manufacturer. Firm has submitted legalized copy of GMP certificate no. HI20180032 issued by Hainan FDA valid till 17-09-2023. Letter of Authorization : Firm has submitted sole distribution agreement legalized.
Evaluation by PEC^{II}: Valid COPP and GMP certificate shall be submitted		
Decision: Approved as per policy of inspection of manufacturer abroad. Following shall be submitted before issuance of registration letter: • **Original valid legalized CoPP.** • **Valid GMP certificate of drug product manufacturer.** • **Analytical record including chromatograms and raw data sheets for the drug product stability studies.**		

Case no.: 02 Deferred applications

6.	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	Gemnil 1g Injection Lyophilized Powder for Injection
	Diary No. Date of R& I & fee	Dy.No. 5588 dated: 07/02/2019 Rs.20,000/-
	Composition	Each Vial Contains: Gemcitabine as HCL…..…1gm
	Pharmacological Group	Antineoplastic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	GEMZAR (gemcitabine) for injection, Lyophilized powder (200mg/via & 1gm/vial) by M/s Lilly USA, LLC, USFDA Approved.
	Me-too Status	ONCOGEM 1gm injection by M/s AJ MIRZA PHARMA (PVT) LTD., (Imported) Reg. No. 45672
	GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13th June, 2017. • Tablet (oncology) • Capsule (oncology) • Liquid vial SVP (oncology) • Liquid Ampoule SVP (Onclology)

		• Dry powder vial (oncology) • Capsule (Ceph) • Dry [powder for oral suspension (ceph) • Dry Powder vial (ceph) • Dry Powder vial (Ceph)
	Remarks of the Evaluator.	
	Decision of 322nd Meeting: Registration Board discussed that the applied formulation is approved in reference regulatory authorities as Lyophilized Powder for Injection as well as Solution for Injection. Considering the submission from the applicant that they had applied for solution for injection, the Board deferred the case for confirmation of applied dosage form from the initially submitted dossier	
	Firm's response: Firm vide its letter no. Rotex/20/184 dated 07-03-2020 has submitted that "we have applied Gemnil 1gm injection & Gemnil 200mg as liquid injection (solution for injection) to be manufactured in our approved Liquid vial SVP (Oncology) section. The reference product approved in TGA is a solution for injection of 26.3ml vial & 5.3ml for 1gm and 200mg injection respectively.	
	Decision: Deferred for presentation of the case by company's representative along with relevant documents in upcoming Registration Board meeting.	
7.	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	Gemnil 200mg Injection Powder for Injection
	Diary No. Date of R& I & fee	Dy.No. 5600 dated: 07/02/2019 Rs.20,000/-
	Composition	Each Vial Contains: Gemcitabine as HCL…..…200mg
	Pharmacological Group	Antineoplastic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	GEMZAR (gemcitabine) for injection, Lyophilized powder (200mg/via & 1gm/vial) by M/s Lilly USA, LLC, USFDA Approved.
	Me-too Status	ONCOGEM 200mg injection by M/s AJ MIRZA PHARMA (PVT) LTD., (Imported) Reg. No. 45671
	GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13th June, 2017. • Tablet (oncology) • Capsule (oncology) • Liquid vial SVP (oncology) • Liquid Ampoule SVP (Onclology) • Dry powder vial (oncology) • Capsule (Ceph) • Dry [powder for oral suspension (ceph) • Dry Powder vial (ceph) • Dry Powder vial (Ceph)
	Remarks of the Evaluator.	

	Decision of 322nd Meeting: Registration Board discussed that the applied formulation is approved in reference regulatory authorities as Lyophilized Powder for Injection as well as Solution for Injection. Considering the submission from the applicant that they had applied for solution for injection, the Board deferred the case for confirmation of applied dosage form from the initially submitted dossier	
	Firm's response: Firm vide its letter no. Rotex/20/184 dated 07-03-2020 has submitted that "we have applied Gemnil 1gm injection & Gemnil 200mg as liquid injection (solution for injection) to be manufactured in our approved Liquid vial SVP (Oncology) section. The reference product approved in TGA is a solution for injection of 26.3ml vial & 5.3ml for 1gm and 200mg injection respectively.	
	Decision: Deferred for presentation of the case by company's representative along with relevant documents in upcoming Registration Board meeting.	
8.	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	OCTERO 0.05mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.05mg
	Diary No. Date of R& I & fee	Diary No:8686, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)50mcg injection, solution by M/s Novartis Pharmaceuticals Corporation **(USFDA Approved)**
	Me-too status	Sandostatin 0.05mg injection by Novartis (Reg. No. 013473)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents (M-275). Deferred for clarification of origin of API whether biological source or synthetic (M-287). Registration Board deferred the case for further delibration regarding source of API (M-289).
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted that API source is BCN peptides, SPAIN and Octreotide produced by BCN peptides is claimed as synthetic origin material. (Declaration from BCN peptides, Spain and Certificate of analysis of is attached herewith).
	Decision of 295th meeting: Registration Board deferred the case for confirmation of source of API whether biological or synthetic.	
	Firm's response: Firm has submitted that their source of API is synthetic.	

	Decision: Deferred for submission of documents pertaining to characterization and quality & clinical profile of drug substance along with evidence of regulatory approval status of the drug substance manufacturer by relevant regulatory authority of country of origin.	
9.	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	OCTERO 0.1mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.1mg
	Diary No. Date of R& I & fee	Diary No:8685, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)100mcg injection, solution by M/s Novartis Pharmaceuticals Corporation (USFDA Approved)
	Me-too status	Sandostatin 0.1mg injection by Novartis (Reg. No. 013472)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents (M-275). Deferred for clarification of origin of API whether biological source or synthetic (M-287). Registration Board deferred the case for further delibration regarding source of API (M-289).
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted that API source is BCN peptides, SPAIN and Octreotide produced by BCN peptides is claimed as synthetic origin material. (Declaration from BCN peptides, Spain and Certificate of analysis of is attached herewith).
	Decision of 295th meeting: Registration Board deferred the case for confirmation of source of API whether biological or synthetic.	
	Firm's response: Firm has submitted that their source of API is synthetic.	
	Decision: Deferred for submission of documents pertaining to characterization and quality & clinical profile of drug substance along with evidence of regulatory approval status of the drug substance manufacturer by relevant regulatory authority of country of origin.	
10.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Ointment
	Composition	Each Gram of Ointment Contains: Fluocinolone Acetonide…0.25mg Clioquinol…3mg
	Diary No. Date of R & I & fee	Dy. No. 13556; 07.03.2019

		PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Ointment 0.025/3%. MHRA approved
	Me-too status	Synalar C Ointment. Reg. No. 30865
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision of 296th meeting: Deferred for consideration on its turn.	
	Firm's response: Case is presented for consideration of Board please.	
	Decision: Approved with Innovator's specifications. Firm shall submit fee of pre-registration variation in specifications i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
11.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Cream
	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide…0.25mg Clioquinol…3mg
	Diary No. Date of R & I & fee	Dy. No. 13557; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Cream 0.025/3%. MHRA approved
	Me-too status	Synalar C Cream. Reg. No. 30866
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision of 296th meeting: Deferred for consideration on its turn.	
	Firm's response: Case is presented for consideration of Board please.	
	Decision: Approved with Innovator's specifications. Firm shall submit fee of pre-registration variation in specifications i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
12.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex 0.025% Cream
	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide…0.25mg
	Diary No. Date of R & I & fee	Dy. No. 13562; 07.03.2019

		PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synlar Cream 0.025%. USFDA approved
	Me-too status	Dermolone Cream 0.025%. Reg. No. 41891
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision of 296th meeting: Deferred for consideration on its turn.	
	Firm's response: Case is presented for consideration of Board please.	
	Decision: Approved.	
13.	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Fetrex Gel 0.025%
	Composition	Each Gm of Gel Contains: Fluocinolone Actonide 0.25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13561 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	043445; "DERMOLONE GEL 0.025%" "VEGA."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision of 327th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Firm has referred to Synalar Gel of M/s Reig Jofre UK Limited approved by MHRA of UK	
	Decision: Approved.	

Agenda of Dr. Haseeb Tariq

14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	GMP status of drug product manufacturer	Firm has submitted copy of GMP certificate dated 20-06-2022 based on inspection conducted on 13-06-2022.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1178: 13-01-2023
	Details of fee submitted	PKR 30,000/- : 05-12-2022
	The proposed proprietary name / brand name	**AXALOR-D Syrup 0.5mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Desloratadine……0.5mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	New antial syrup by Sami
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	Morepen Laboratories Limited. Village Masulkhana, Parwanoo, Distt Solan, Parwanoo, Himachal Pradesh, 173220, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Neo-Antial syrup of Sami
	Details of stability studies of drug product	2L each / 3 batches
Evaluation by PEC[3]:		
Decision: Approved.		
15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	GMP status of drug product manufacturer	Firm has submitted copy of GMP certificate dated 17-08-2022 based on inspection conducted on 16-08-2022.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 30844: 31-10-2022
	Details of fee submitted	PKR 75,000/- : 24-10-2022
	The proposed proprietary name / brand name	**Ginza-B 30gm Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of Cream Contains: Benzoyl Per-Oxide…30mg Tretinoin…1mg
	Pharmacotherapeutic Group of (API)	Topical antibiotic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	TWYNEO USFDA Approved.

	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	**Benzoyl peroxide**: Cambrex Karlskoga Sweden **Tretinoin:** Chongqing Huapont Pharm Co Ltd China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against TWYNEO Cream from USFDA
	Details of stability studies of drug product	500 Tubes each / 2 batches
Evaluation by PEC[3]:		
Decision: Approved.		
16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of drug product manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29755: 20-10-2022
	Details of fee submitted	PKR 30,000/- : 22-04-2022
	The proposed proprietary name / brand name	**Tacrogen 0.1% w/w Ointment**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Tacrolimus as Monohydrate…1mg
	Pharmacotherapeutic Group of (API)	Agents for dermatitis, excluding corticosteroids
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Acroli Ointment of Shrooq Pharma
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Crolimus ointment of Valor
	Details of stability studies of drug product	500 Tubes each / 3 batches
Evaluation by PEC[3]:		
• Fee for change of title of DML is required.		
Decision: Approved. Firm shall fee for change of title of the applicant, before issuance of registration letter.		
17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swat Pharmaceuticals. Saidu Sharif, Swat, Pakistan**

	Name, address of Manufacturing site.	M/s Swat Pharmaceuticals. Saidu Sharif, Swat, Pakistan
	GMP status of drug product manufacturer	Not submitted
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29097: 13-10-2022
	Details of fee submitted	PKR 30,000/- : 08-04-2022
	The proposed proprietary name / brand name	**Panaset 6 Plus 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension Contains: Paracetamol…250mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Panadol Suspension by GSK
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Details of stability studies of drug product	
Evaluation by PEC[3]:		
• Updated status of DML is required • Evidence of section approval letteris required. • Complete Module 3 as per CTD guidance document is required.		
Decision: Deferred for following: • **Confirmation of validity of DML of the applicant form Licensing Division.** • **Evidence of section approval letter for required manufacturing facility from Licensing Division** • **Complete Module 3 as per CTD guidance document.**		

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Agenda of Mr. M. Tahir Waqas

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

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 27735 dated 28-11-2023
	Details of fee submitted	PKR 75,000/- dated 16-11-2023 Challan / Receipt # 08962900851
	The proposed proprietary name / brand name	**TOLVAMARK 15mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Tolvaptan … 15mg
	Pharmacotherapeutic Group of (API)	C03XA01, other diuretics, Vasopressin antagonists
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tolvaptan 15mg Tablets, MHRA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	As per SRO
	GMP Status of the Firm	Copy of GMP Certificate issued dated 23-11-2021 based on inspection dated 11-11-2021 (valid for a period of 2 years from the date of inspection) has been submitted.
	Evidence of Approval of Manufacturing Facility	Copy of DML is enclosed.
	Stability Studies of Drug Substance	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against SAMSCA 15mg Tablet of Otsuka Pharmaceutical Co., Ltd., Batch No. D19031202, Expiry Date: 08-2024.
	Detail of Stability Batches of Drug Product	03 Batches, 1200 Tablets each.
	Document for Procurement of API (Import)	Copy of Form-6 (License to Import for Test / Analysis) 0.5 Kgs and Commercial Invoice No. KSDS2205129 dated 08th June 2022.

Evaluation by PEC (XXI):

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

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till Sep – 2023, and issued by Chonngqing Medicine Center for Economic Development which is not the relevant authority for issuance of GMP.	
ii.	1.3.5 Please provide Section approval letter from Licensing Division.	
iii.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate was valid till 11 – 2023.	
iv.	Please provide evidence of I&E (DRAP) approval / clearance for Invoice No. KSDS2205129 dated 08th June 2022.	
v.	Please provide evidence of Reference / Innovator's pack used for Pharmaceutical equivalence and CDP.	

Decision: Approved.
Registration letter will be issued after submission of: -

i. Valid GMP of API Manufacturer issued by relevant authority.

ii.	**Valid GMP status of drug product manufacturer.**	
iii.	**Documents confirming release of drug substance from custom authorities i.e., clearance certificate or good declaration/airway bill.**	
19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 27736 dated 28-11-2023
	Details of fee submitted	PKR 75,000/- dated 16-11-2023 Challan / Receipt # 92054497746
	The proposed proprietary name / brand name	**TOLVAMARK 30mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Tolvaptan … 30mg
	Pharmacotherapeutic Group of (API)	C03XA01, other diuretics, Vasopressin antagonists
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tolvaptan 30mg Tablets, MHRA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	As per SRO
	GMP Status of the Firm	Copy of GMP Certificate issued dated 23-11-2021 based on inspection dated 11-11-2021 (valid for a period of 2 years from the date of inspection) has been submitted.
	Evidence of Approval of Manufacturing Facility	Copy of DML is enclosed.
	Stability Studies of Drug Substance	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against SAMSCA 30mg Tablet of Otsuka Pharmaceutical Co., Ltd., Batch No. D13251202, Expiry Date: 06-2024.
	Detail of Stability Batches of Drug Product	03 Batches, 1200 Tablets each.
	Document for Procurement of API (Import)	Copy of Form-6 (License to Import for Test / Analysis) 0.5 Kgs and Commercial Invoice No. KSDS2205129 dated 08th June 2022.

Evaluation by PEC (XXI):

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

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till Sep – 2023, and issued by Chonngqing Medicine Center for Economic Development which is not the relevant authority for issuance of GMP.	
ii.	1.3.5 Please provide Section approval letter from Licensing Division.	

iii.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate was valid till 11 – 2023.	
iv.	Please provide evidence of I&E (DRAP) approval / clearance for Invoice No. KSDS2205129 dated 08th June 2022.	
v.	Please provide evidence of Reference / Innovator's pack used for Pharmaceutical equivalence and CDP.	

Decision: Approved.

Registration letter will be issued after submission of: -

i. **Valid GMP of API Manufacturer issued by relevant authority.**
ii. **Valid GMP status of drug product manufacturer.**
Documents confirming release of drug substance from custom authorities i.e., clearance certificate or good declaration/airway bill.

Agenda Item No. 02: Deferred applications of previous meetings

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 966 dated 11 JAN 2023
	Details of fee submitted	PKR 30,000/- dated 29-12-2022 Challan Number: 72592320068
	The proposed proprietary name / brand name	**MARK INSTA 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole … 20mg Sodium Bicarbonate (as Buffer) … 1680mg
	Pharmacotherapeutic Group of (API)	A02BC01, Proton Pump Inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA 20mg Sachet of M/s Getz Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Decision of 339th Meeting: Registration Board deferred the case for submission of reply to the cited shortcomings.

Evaluation by PEC (XXI):

Sr. No.	Shortcomings	Firm's response

i.	Please provide approval for Change of Title to "M/s Axis Pharmaceuticals" since in the enclosed DML / Section Approval Letters the name of firm has been mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd."	Copy of DML of M/s Axis Pharmaceuticals has been submitted.
ii.	Please provide valid GMP Certificate of API Manufacturer issued by relevant Regulatory Authority of Country of Origin. The enclosed certificate was valid till 05-2023.	Submitted
iii.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	Firm has submitted that Sodium Bicarbonate has been used as excipient to maintain pH of the drug product & accordingly mentioned on label claim as per innovator.
iv.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	The firm has submitted that the product was developed in year 2022 and monograph for Omeprazole is unavailable since 2020 (USP-43), therefore Innovator's Specifications were claimed.
v.	Please provide Stability Study Data (Accelerated and Real Time) along with supporting documents for 6th Month Testing Interval.	Submitted.

Decision of 340th meeting: Registration Board deferred the case for submission of data as required in point (iii) and (iv) of above cited shortcomings.

In response to decision of 340th Meeting, the firm have submitted as follows:

Sr. No.	Shortcomings	Firm's response in 340th Meeting	Firm's Response
i.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	Firm has submitted that Sodium Bicarbonate has been used as excipient to maintain pH of the drug product & accordingly mentioned on label claim as per innovator.	Firm have now submitted that they have quantitatively added sodium bicarbonate according to innovator's formulation, where it was mentioned as buffer. They have now revised their formulation and updated sodium bicarbonate as an API to ensure compliance with innovator (revised formulation is submitted). They have further stated that they have already tested and reported the

			sodium bicarbonate content in the drug product at the finished stage and during stability studies both accelerated and real time. Furthermore, the firm have submitted information on 3.2.S Drug Substance for Sodium Bicarbonate from Hebei Huachen Pharmaceutical Co., Ltd., GMP Certificate valid till 22-04-2023.
ii.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	The firm has submitted that the product was developed in year 2022 and monograph for Omeprazole is unavailable since 2020 (USP-43), therefore Innovator's Specifications were claimed.	Same as before.

Decision: Approved.

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 967 dated 11 JAN 2023
	Details of fee submitted	PKR 30,000/- dated 29-12-2022 Challan Number: 5432137667
	The proposed proprietary name / brand name	**MARK INSTA 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole … 40mg Sodium Bicarbonate (as Buffer) … 1680mg
	Pharmacotherapeutic Group of (API)	A02BC01, Proton Pump Inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA 40mg Sachet of M/s Getz Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Decision of 339th Meeting: Registration Board deferred the case for submission of reply to the cited shortcomings.

Evaluation by PEC (XXI):

Sr. No.	Shortcomings	Firm's response
i.	Please provide approval for Change of Title to "M/s Axis Pharmaceuticals" since in the enclosed DML / Section Approval Letters the name of firm has been mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd."	Copy of DML of M/s Axis Pharmaceuticals has been submitted.
ii.	Please provide valid GMP Certificate of API Manufacturer issued by relevant Regulatory Authority of Country of Origin. The enclosed certificate was valid till 05-2023.	Submitted
iii.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	Firm has submitted that Sodium Bicarbonate has been used as excipient to maintain pH of the drug product & accordingly mentioned on label claim as per innovator.
iv.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	The firm has submitted that the product was developed in year 2022 and monograph for Omeprazole is unavailable since 2020 (USP-43), therefore Innovator's Specifications were claimed.
v.	Please provide Stability Study Data (Accelerated and Real Time) along with supporting documents for 6th Month Testing Interval.	Submitted.

Decision of 340th meeting: Registration Board deferred the case for submission of data as required in point (iii) and (iv) of above cited shortcomings.

In response to decision of 340th Meeting, the firm have submitted as follows:

Sr. No.	Shortcomings	Firm's response in 340th Meeting	Firm's Response
i.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	Firm has submitted that Sodium Bicarbonate has been used as excipient to maintain pH of the drug product & accordingly mentioned on label claim as per innovator.	Firm have now submitted that they have quantitatively added sodium bicarbonate according to innovator's formulation, where it was mentioned as buffer. They have now revised their formulation and updated sodium bicarbonate as an API to ensure compliance with innovator (revised

			formulation is submitted). They have further stated that they have already tested and reported the sodium bicarbonate content in the drug product at the finished stage and during stability studies both accelerated and real time. Furthermore, the firm have submitted information on 3.2.S Drug Substance for Sodium Bicarbonate from Hebei Huachen Pharmaceutical Co., Ltd., GMP Certificate valid till 22-04-2023.
ii.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	The firm has submitted that the product was developed in year 2022 and monograph for Omeprazole is unavailable since 2020 (USP-43), therefore Innovator's Specifications were claimed.	Same as before.
Decision: Approved.			

Agenda of Mr. Shahrukh

22.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name +Dosage Form + Strength	Dlans 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) …..…30mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	Form-5 Dy.No 8088 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	**DEXILANT** ® Capsule, USFDA approved.

	Me-too status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remarks of the Evaluator	Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Dlans 30mg Capsules		
Manufacturer of API	**M/s Surge laboratories 10-K.m Faisalabad road bikhi district Pakistan**		
API Lot No.	DXZ-22-DDR-003		
Description of Pack (Container closure system)	2*7 tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	DL001	DL002	DL003
Batch Size	700 capsule	700 capsule	700 capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	11-02.2022	12-02.2022	16-02.2022
No. of Batches	03		
Date of Submission	Dy. No. 33954 dated 24-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer ref.no 182/2019 dated 04-07-19 valid for 3 years
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Surge laboratories locally purchased
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Protocols followed for conduction of stability study shall be submitted.	
6.	Method used for analysis of Finished Product shall be submitted.	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Record of comparative dissolution data shall be submitted.	

10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

23.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name +Dosage Form + Strength	Dlans 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……..…60mg (Source of pellets Vision Pharma)
	Diary No. Date of R& I & fee	Form-5 Dy.No 8089 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	PPI. ATC Code: A02BC06 .
	Type of Form	Form 5.
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1x10's, 3x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulator Authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	Me-too status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086977)
	GMP status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remarks of the Evaluator	Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Dlans 60mg Capsules
Manufacturer of API	**M/s Surge laboratories 10-K.m Faisalabad road bikhi district Pakistan**
API Lot No.	DXZ-22-DDR-003
Description of Pack (Container closure system)	2*7 tablets in Alu-Alu blister pack.
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 09 months Accelerated: 06 months
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)

Batch No.	DL001	DL002	DL003
Batch Size	700 capsule	700 capsule	700 capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	11-02.2022	12-02.2022	16-02.2022
No. of Batches	03		
Date of Submission	Dy. No. 33954 dated 24-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided
3	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4	Stability study data of API from API manufacturer	Not submitted.
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer ref.no 182/2019 dated 04-07-19 valid for 3 years
6	Documents for the procurement of API with approval from DRAP (in case of import).	Surge laboratories locally purchased
7	Protocols followed for conduction of stability study	Not submitted.
8	Method used for analysis of FPP	submitted.
9	Drug-excipients compatibility studies (where applicable)	Not submitted.
10	Complete batch manufacturing record of three stability batches.	Not submitted.
11	Record of comparative dissolution data (where applicable)	Not submitted.
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.

13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3	Stability study data of API from both API manufacturer shall be submitted.	
4	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5	Protocols followed for conduction of stability study shall be submitted.	
6	Method used for analysis of Finished Product shall be submitted.	
7	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8	Complete batch manufacturing record of three stability batches shall be submitted..	
9	Record of comparative dissolution data shall be submitted.	
10	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
11	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

24.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd, 124/1- Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Kanlif-M 150/500
	Composition	Each tablet contains: Canagliflozin…150 Metfrormin…500
	Diary No. Date of R& I & fee	Form-5D Dy.No 19630 dated 31-10-2017 Rs.50,000/- dated 31-10-2017
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	INVOKAMET (50mg/500mg, 50mg/1000mg, 150mg/500mg, 150mg/1000mg) film coated tablets USFDA Approved

	Me-too status		
	GMP status		
	Remarks of the Evaluator		
STABILITY STUDY DATA			
Drug	Kanlif-M 150/500		
Manufacturer of API			
API Lot No.			
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%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

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.	Registration Board approved Kanlif-M Tablet 50/500mg & Kanlif-M Tablet 50/1000mg with Innovator's specifications in 320th meeting of RB
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Protocols followed for conduction of stability study shall be submitted.	
6.	Method used for analysis of Finished Product shall be submitted.	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Record of comparative dissolution data shall be submitted.	
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

25.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd, 124/1- Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Kanlif-M 150/1000

	Composition	Each tablet contains: Canagliflozin…150 Metfrormin…1000
	Diary No. Date of R& I & fee	Form-5D Dy.No 19630 dated 31-10-2017 Rs.50,000/- dated 31-10-2017
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5.
	Finished product Specifications	Not provided
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	INVOKAMET (50mg/500mg, 50mg/1000mg, 150mg/500mg, 150mg/1000mg) film coated tablets USFDA Approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Kanlif-M 150/1000		
Manufacturer of API			
API Lot No.			
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%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches			
Date of Submission			

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.	Registration Board approved Kanlif-M Tablet 50/500mg & Kanlif-M Tablet 50/1000mg with Innovator's specifications in 320th meeting of RB

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Protocols followed for conduction of stability study shall be submitted.	
6.	Method used for analysis of Finished Product shall be submitted.	

7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Record of comparative dissolution data shall be submitted.	
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

26.	Name and address of manufacturer / Applicant	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Onset 4mg Tablet
	Composition	Each Orodispersible Tablet Contains: Ondansetron As Hcl…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 59 dated 01-01-2019 Rs.20,000/- dated 01-01-2019
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS
	Type of Form	Form 5.
	Finished product Specifications	USP
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Zofran Melt 4mg tablet USFDA Approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Onset 4mg Tablet		
Manufacturer of API	**Anugraha chemicals (As per COA)**		
API Lot No.			
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%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3,4, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	OND4-TR002	OND4-TR003	OND4-TR004
Batch Size	1000	1000	1000
Manufacturing Date	12-2018	06-2019	06-2019

Date of Initiation	19-12-2018	30-07-2019	29-07-2019
No. of Batches	3		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Not Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Submitted against reference product ZOFRAN MELT 4mg in all 3 medium
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 stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
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)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm

1	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required.	
2	Stability study data of API from API manufacturer	
3	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
4	Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl	

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

27.	Name and address of manufacturer / Applicant	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Onset 8mg Tablet
	Composition	Each Orodispersible Tablet Contains: Ondansetron As Hcl…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 60 dated 01-01-2019 Rs.20,000/- dated 01-01-2019
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS
	Type of Form	Form 5.
	Finished product Specifications	USP
	Pack size & Demanded Price	
	Approval status of product in Reference Regulator Authorities	Zofran Melt 8mg tablet USFDA Approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Onset 4mg Tablet		
Manufacturer of API	**Anugraha chemicals (As per COA)**		
API Lot No.			
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 ℃ ± 2 ℃ / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3,4, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	OND4-TR002	OND4-TR003	OND4-TR004
Batch Size	1000	1000	1000
Manufacturing Date	12-2018	06-2019	06-2019
Date of Initiation	19-12-2018	30-07-2019	29-07-2019

No. of Batches	3
Date of Submission	

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Submitted against reference product ZOFRAN MELT 4mg in all 3 medium
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 stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm.
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)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm

1	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required.	
2	Stability study data of API from API manufacturer	
3	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
4	Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl	

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

Agenda of Ms. Maham Misbah

Case no. 01 Registration applications of drugs for which stability study data is submitted

a. New cases/ Verification of stability study data/ Exemption from onsite verification of stability data

28.	Name and address of manufacturer/ Applicant	**Genetics Pharmaceuticals Pvt. Ltd.**
	Brand Name + Dosage Form + Strength	Trint 10mg Tablet
	Composition	Each film-coated tablet contains: Vortioxetine hydrobromide eq. to Vortioxetine …..10mg
	Diary No. Date of R & I & fee	Dy. No. 18932 dated: 24/10/2017 Rs. 50,000 dated: 24/10/2017
	Pharmacological Group	Antidepressant of the serotonin modulator and stimulator (SMS) class
	Type of Form	Form-5D
	Finished product Specification	In-House
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Trintellix 10mg Tablet, USFDA Approved
	Me-too status	Vorneu Tablet 20mg by M/s Hilton Pharma (Pvt) Limited Registration No. 107779 Vorneu Tablet 10mg by M/s Hilton Pharma (Pvt) Limited Registration No. 107777 107778 Vorneu Tablet 15mg 107776 Vorneu Tablet 5mg
	GMP status	Valid

STABILITY STUDY DATA

Drug	Vortioxetine HBr
Manufacturer of API	M/s Lianyungang Jari Pharmaceutical Co., Ltd, Add # 18, Zhenua Road, Lianyungang, Jinagsu province, China
API Lot No.	20210802
Description of Pack	Alu-PVC Blister 10's

(Container closure system)			
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 months Real Time: 06 months		
Frequency	Real Time: 0,3,6 (06months) Accelerated: 0,1,2,3,4,6 (06 months)		
Batch No.	RD-GP-5D-VX-22010	RD-GP-5D-VX-22011	RD-GP-5D-VX-22012
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	06/2022	06/2022	06/2022
Date of Initiation	30/06/2022	30/06/2022	30/06/2022
No. of Batches	03		
Date of Submission	Dy No. 39632 dt 30-Dec-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection report of their product "Dextom 30mg and 60mg Capsule", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML available Dated: 07-10-2020 valid till 06-10-2025
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no. 21YX0084L DATED: 11/10/2021 ATTESTED BY DRAP
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Submitted against Brintellex 10mg (B#2705602) of Lundbeck Denmark

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 Batches 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:

Decision: Approved.

29.	Name and address of manufacturer/ Applicant	**Genetics Pharmaceuticals Pvt. Ltd.**
	Brand Name + Dosage Form + Strength	Trint 20mg Tablet
	Composition	Each film-coated tablet contains: Vortioxetine hydrobromide eq. to Vortioxetine …..20mg
	Diary No. Date of R & I & fee	Dy. No. 18934.dated: 24/10/2017 Rs. 50,000 dated: 24/10/2017
	Pharmacological Group	Antidepressant of the serotonin modulator and stimulator (SMS) class
	Type of Form	Form-5D
	Finished product Specification	In-House
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Trintellix 20mg Tablet, USFDA Approved
	Me-too status	Vorneu Tablet 20mg by M/s Hilton Pharma (Pvt) Limited Registration No. 107779
	GMP status	

STABILITY STUDY DATA

Drug	Vortioxetine		
Manufacturer of API	M/s Lianyungang Jari Pharmaceutical Co., Ltd, Add # 18, Zhenua Road, Lianyungang, Jinagsu province, China		
API Lot No.	20210802		
Description of Pack (Container closure system)	Alu-PVC Blister 10's		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 months Real Time: 06 months		
Frequency	Real Time: 0,3,6 (06months) Accelerated: 0,1,2,3,4,6 (06 months)		
Batch No.	RD-GP-5D-XE-22013	RD-GP-5D-XE-22014	RD-GP-5D-XE-22015
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	07/2022	07/2022	07/2022
Date of Initiation	05/07/2022	05/07/2022	05/07/2022
No. of Batches	03		

Date of Submission	Dy No. 39633 dt 30-Dec-2022

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection report of their product "Dextom 30mg and 60mg Capsule", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	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	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML available Dated: 07-10-2020 valid till 06-10-2025
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice no. 21YX0084L DATED: 11/10/2021 Attested By DRAP
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	N/A
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Yes, against Brintellex 20mg (B#2705580), Lundbeck Denmark
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of 03 Batches 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:

Decision: Approved.

30.	Name, address of Applicant / Marketing Authorization Holder	**M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Jexma Tablets 5mg
	Composition	Each Film Coated tablet contains:

		Vortioxetine……5mg.
	Dy. No. and date of submission	Dy. No. 1007 dated 02-10-2015
	Details of fee submitted	PKR 50,000/-:0501989 dated 30-11-2015
	Pharmacotherapeutic Group of (API)	Antidepressant
	Type of Form	Form 5-D
	Reference to Finished product specifications	As per Innovators Specs
	Proposed Pack size & Demanded MRP	10's, 20's & 30's ; As per DPC/SRO
	The status in reference regulatory authorities	Product is registered and being marketed in Denmark as **Brintellix** by Lundbeck.
	Me-too status	Not Available
	GMP status of the Finished product manufacturer	GMP certificate issued 03-09-2024

STABILITY STUDY DATA

Manufacturer of API	Lianyungang Jari Pharmaceutical Co.,Ltd **Address:** No.18,Zhenhua Road,Lianyungang.		
API Lot No.	20200610		
Description of Pack (Container closure system)	Alu-Alu blister (2x7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1411-L	NPD-T-1436-P	NPD-T-1437-P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	05-04-2021	08-09-2021	08-09-2021
Date of Initiation	22-09-2021	22-09-2021	22-09-2021
No. of Batches	03		
Date of submission	Dy No. 8502 dt 01-04-2022		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to their product Apixaban Tablets 5mg which was approved in 295th Meeting of Registration Board held on 08th – 11th June 2020. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copy of COA of Vortioxetine (Batch# 20200610) from Lianyungang Jari Pharmaceutical Co., Ltd is submitted.

Copy of COA of Vortioxetine (Batch# 20200610) from M/s. Martin Dow Limited 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>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</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>Copy GMP Certificate of Lianyungang Jari Pharmaceutical Co., Ltd. valid upto 11-04-2024 is submitted</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 (invoice# 20YX2038B Dated: 06-08-2020 cleared by DRAP Karachi office dated 18-08-2020.</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</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch no.</th><th>Batch size</th><th>Mfg. date</th></tr>
<tr><td>NPD-T-1411-L</td><td>5000 tablets</td><td>05-04-2021</td></tr>
<tr><td>NPD-T-1436-P</td><td>5000 tablets</td><td>08-09-2021</td></tr>
<tr><td>NPD-T-1437-P</td><td>5000 tablets</td><td>08-09-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>CDP has been performed against Brintellix by Lundbeck, 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.</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:</td></tr>
<tr><td colspan="3">Decision: Approved. Label claim shall be change as follows along with submission of requisite fee:
“Each film coated tablet contains:</td></tr>
</table>

Vortioxetine as Hydrobromide… 5mg"		
31.	Name and address of manufacturer / Applicant	**M/s Helix Pharma (Pvt)., Ltd.** **Hakimsons House, A-56, S.I.T.E, Karachi.**
	Brand Name +Dosage Form + Strength	TAFILU Ophthalmic Solution 0.0015%
	Composition	Each ml of Ophthalmic Solution contains: Tafluprost ……0.015mg
	Diary No. Date of R& I & fee	Form-5D Dy. No 12386 dated 17-08-2017 Rs.50,000/- dated 17-08-2017 DS No. 0610823 duplicate
	Pharmacological Group	Prostaglandin Analogs. It lowers pressure in the eye by increasing the flow of natural eye fluids out of the eye.
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	5ml ,8ml & 10ml ; As per SRO / PRC
	Approval status of product in Reference Regulator Authorities	USFDA approval for ZIOPTAN™ (tafluprost ophthalmic solution) 0.0015%
	Me-too status	N/A
	GMP status	Routine GMP Inspection conducted on 07/03/2024 GMP Compliance Certificate dated: 24/07/2024
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Manufacturer of API	M/s CENTURY PHARMACEUTICALS LIMITED– INDIA.		
API Lot No.	Tafluprost ; 08773001-TFP		
Description of Pack (Container closure system)	LDPE Bottle.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0,1,2,3,6 months Real Time : 0,3,6,9 months		
Batch No.	TR 079	TR 080	TR 081
Batch Size	3000 ml (600 bottles)	3000 ml (600 bottles)	3000 ml (600 bottles)
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	20-07-2021	20-07-2021	20-07-2021
No. of Batches	03		
Date of Submission	28530 dt 07/10/2022		

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	The firm has referred the DRB 307th meeting Minutes for approval of new molecule "C-ZYN Ophthalmic Solution 0.24% (Cetirizine)" which was approved on basis of product specific inspection. The said DRB Meeting minutes has mentioned that: • The HPLC is 21CFR Compliant. • Audit trail on the testing reports of "C-ZYN Ophthalmic Solution 0.24% (Cetirizine)" were available. Adequate monitoring & control are available for stability chamber. The firm has installed software for recording temperature/Humidity of the chamber (for real time stability software V5.7T Thermo, India & Accelerated Stability studies, software is Logit Chrt; Technoman; Pakistan) & the data can been verified for 01 year.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	• **API CoA** from API manufacturer as well as Finished Product Manufacturer submitted • **Reference standards and impurity standards:** Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	The firm has submitted method used for analysis of API along with COA. (Both Helix & API manufacturer)
4.	Stability study data of API from API manufacturer	Submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s CENTURY PHARMACEUTICALS LIMITED– INDIA. Copy of DML issued by Food and Drug Control Administration, India is submitted Validity: 31-12-2026
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Tafluprost** : ADC (Karachi) issued license to import API "Tafluprost" from CENTURY PHARMACEUTICALS LIMITED– INDIA. Dated:04/09/2018 is submitted.
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 has submitted that "we manufactured lab scale batches of our applied products by using same formulation of innovator's product
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	N/A
12.	Data of 03 batches will be supported by attested respective documents like	Submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

Decision: Approved.

32.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name +Dosage Form + Strength	Cefspan Max Suspension 500mg/5ml
	Composition	Each 5ml Contains: Cefixime…500mg
	Diary No. Date of R& I & fee	Dy.No 14756 dated 07-03-2019 Rs.50,000/- DS No. 0826810 (Duplicate)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5D
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	10ml, 20ml/ As per DPC/SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Not available .
	GMP status	Copy of certificate of GMP generated against inspection conducted on 06/12/2021 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (PVT.) Limited		
API Lot No.	22 CF1-10057		
Description of Pack (Container closure system)	High density polyethylene (HDPE) plastic bottle with induction seal and white propylene cap		
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 (month) Real Time: 0,3,6 (month)		
Batch No.	EXP-S-531	PLT- S-09	PLT-S-10
Batch Size	(100 bottles)	(100 bottles)	(100 bottles)

Manufacturing Date	04-11-2022	07-11-2022	08-11-2022
Date of Initiation	28-11-2022	28-11-2022	28-11-2022
No. of Batches	03		
Date of Submission of stability data	Dy No. Dated 26-12-2022 & 24-03-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term,24 Months** (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. 180/2022-DRAP (K) issued by DRAP on the basis of inspection conducted on 07-10-2022 is submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not applicable as the excipients used by the applicant and innovator are same.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Not Applicable
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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	Submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator[xxiii]:

Sr. No.	Observations
i.	Valid GMP certificate of applicant shall be submitted.
ii.	Stability study data of API from API manufacturer shall be submitted for long term storage conditions at 36 month time point.
iii.	Stability studies data of finished product is submitted for three months only. Stability studies data shall be submitted for 6 months' time point at both accelerated and real time conditions for all three batches along with supporting data.

Decision: Deferred for submission of following:

- **Valid GMP certificate of applicant,**
- **Stability study data of API from API manufacturer for long term storage conditions at 36 month time point,**
- **Stability studies reports for 6 month time point at both accelerated and real time conditions for all three batches along with supporting data.**

33.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name +Dosage Form + Strength	Emglif-M XR Tablet 10mg/1000mg
	Composition	Each Extended Release Tablet Contains: Empagliflozin…10mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No 34139 dated 15-10-2018 Rs.50,000/- dated 15-10-2018 DS No. 0798044 (Duplicate)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's ,28's 30's/ As per PRC
	Approval status of product in Reference Regulator Authorities	Synjardy XR 10mg/1000mg Tablet approved by USFDA
	Me-too status	Empoli Plus XR 10mg + 1000mg Tablet Reg. No. 110030 by M/s SAMI
	GMP status	Copy of certificate of GMP dated 13-06-2023 is submitted.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin + Metformin hydrochloride:
API Lot No.	Not submitted.
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 6 months

	Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21SB-070-01	21SB-071-02	21SB-072-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	25-01-2021	25-01-2021	25-01-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. Dated 22-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Not Submitted
4.	Stability study data of API from API manufacturer	Empagliflozin:The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 24 Months** (40°C ± 2°C &70±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.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not required.
10.	Complete batch manufacturing record of three stability batches.	Submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product against the reference product.
12.	Data of 03 batches will be supported by attested respective documents like	Submitted

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
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[xxiii]:

Sr. No.	Observations
i.	In CDP report, name of innovator product and its manufacturer shall be submitted.
ii.	Stability study data of Metformin API from API manufacturer shall be submitted.
iii.	Certificate of Analysis of APIs from both API Manufacturer and Finished Product Manufacturer for the API lots used in the manufacturing of stability batches shall be submitted.
iv.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
vi.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
vii.	Label claim shall be changed as per already registered product as follows along with submission of requisite fee: Each film coated tablet contains: Empagliflozin (as immediate release coating)…5 mg Metformin hydrochloride (as extended release core)….1000 mg

Decision: Deferred for submission of response to above-mentioned shortcomings.

34.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name +Dosage Form + Strength	Emglif-M XR Tablet 25mg/1000mg
	Composition	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy.No 34141 dated 15-10-2018 Rs.50,000/- dated 15-10-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's ,28's 30's/ As per PRC
	Approval status of product in Reference Regulator Authorities	Synjardy XR 25mg/1000mg Tablet approved by USFDA
	Me-too status	Empoli Plus XR 25mg + 1000mg Tablet Reg. No. 110029 by M/s SAMI
	GMP status	Copy of certificate of GMP dated 13-06-2023 is submitted.

STABILITY STUDY DATA			
Manufacturer of API	Empagliflozin + Metformin hydrochloride:		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	21SB-073-01	21SB-074-02	21SB-075-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	19-01-2021	19-01-2021	19-01-2021
No. of Batches	03		
Date of Submission of stability data	Dy No. Dated 22-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
i.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
ii.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
iii.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Not Submitted
iv.	Stability study data of API from API manufacturer	Empagliflozin:The firm has submitted copy of **accelerated, 06 Months** (30°C ± 2°C & 70±5%RH) & **long term, 24 Months** (40°C ± 2°C &70±5%RH) stability study reports of 03 batches.
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
vi.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
vii.	Protocols followed for conduction of stability study	Submitted
viii.	Method used for analysis of FPP	Submitted

ix.	Drug-excipients compatibility studies (where applicable)	Not required.
x.	Complete batch manufacturing record of three stability batches.	Submitted
xi.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the reference product against the reference product.
xii.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
xiii.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
xiv.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[xxiii]:

Sr. No.	Observations
i.	In CDP report, name of innovator product and its manufacturer shall be submitted.
ii.	Stability study data of Metformin API from API manufacturer shall be submitted.
iii.	Certificate of Analysis of APIs from both API Manufacturer and Finished Product Manufacturer for the API lots used in the manufacturing of stability batches shall be submitted.
iv.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
v.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
vi.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.

Decision: Deferred for submission of response to above-mentioned shortcomings.

35.	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	Mirabron XR 50mg Tablet
	Composition	Each film coated tablet contains: Mirabegron…..50mg
	Diary No. Date of R & I & fee	Dy. No. 1041 dated 25-06-2014 Rs. 20,000/- dated 25-06-2014
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	Innovator specs.
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 50 mg (mirabegron extended-release film-coated tablet), USFDA approved.
	Me-too status	Mirabet Tablet 50mg, Reg# 090503, CCL Pharmaceuticals, Lahore.

	GMP status	Copy of certificate of GMP generated against inspection conducted on ----------is submitted.

STABILITY STUDY DATA			
Drug	Mirabegron		
Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co. Ltd.		
API Lot No.	MRB210401		
Description of Pack (Container closure system)	Alu Alu blister in unit carton		
Stability Storage Condition	Accelerated: 40±2°C, 75% ±5% RH Long Term: 30±2°C, 75% ±5% RH		
Time Period	6 months		
Frequency	0, 3 and 6		
Batch No.	22PD-0232-29-SB	22PD-0233-30-SB	22PD-0234-31-SB
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	June-22	June-22	June-22
Date of Initiation	30th- June-2022	30th- June-2022	30th- June-2022
No. of Batches	3 Batches		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Details**
	Reference of previous approval of applications with stability study data of the firm.	Firm has submitted reference of previous approval of a product specific inspection for Empagmin XR Tablet inspection is conducted on 5-12-2019 and the case was approved in the 293 meeting
	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted the COAs of API batch number MRB210401 tested by both the API manufacturer and the finished product manufacturer
	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Firm has submitted the method used for the analysis of API from API Manufacturer and from the Finished Product Manufacturer
	Stability study data of API from API manufacturer	Firm has submitted the stability data of the 3 batches of API from the API Manufacturer at both accelerated and real time conditions. The accelerated stability data is conducted at 40±2ºC, RH 75%±5% and the long term stability data is conducted at 30±2ºC, RH 65%±5%
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted the copy of GMP Certificate Issued by the Peoples Republic of China valid till 29-5-2024

	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted the commercial invoice cleared on 14-7-2021. The invoice is cleared by Assistant Director of DRAP Karachi
	Protocols followed for conduction of stability study	Firm has submitted the stability study protocol
	Method used for analysis of FPP	Form has submitted the method used for the analysis of finished drug product
	Drug-excipients compatibility studies (where applicable)	Firm has submitted the undertaking that they have used the excipients as used by the innovator product
	Complete batch manufacturing record of three stability batches.	Firm has submitted the BMRs of 3 stability batches
	Record of comparative dissolution data (where applicable)	Firm has submitted the CDP of their product against the reference product Mibega XR Tablet in 3 dissolution mediums
	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted the stability data of 3 batches with respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted the 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)	Firm has submitted the Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator:		
Decision: Approved.		
36.	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	Mirabron XR 25mg Tablet
	Composition	Each film coated tablet contains: Mirabegron…..25mg
	Diary No. Date of R & I & fee	Dy. No. 1039 dated 25-06-2014 Rs. 20,000/- dated 25-06-2014
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	Innovator specs.
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 21's, 28's, 30's, 56's, 84's 100's and 122's
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 25 mg (mirabegron extended-release film-coated tablet), USFDA approved.
	Me-too status	Mirabet Tablet 25mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	Copy of certificate of GMP generated against inspection conducted on ----------is submitted.
STABILITY STUDY DATA		

Drug	Mirabegron		
Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co. Ltd.		
API Lot No.	MRB210401		
Description of Pack (Container closure system)	Alu Alu blister in unit carton		
Stability Storage Condition	Accelerated: 40±2°C, 75% ±5% RH Long Term: 30±2°C, 75% ±5% RH		
Time Period	6 months		
Frequency	0, 3 and 6		
Batch No.	22PD-0380-17-SB	22PD-0381-18-SB	22PD-0382-19-SB
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	June-22	June-22	June-22
Date of Initiation	30th- June-2022	30th- June-2022	30th- June-2022
No. of Batches	3 Batches		
Date of Submission	02-06-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	• Firm has submitted reference of previous approval of a product specific inspection for Empagmin XR Tablet inspection is conducted on 5-12-2019 and the case was approved in the 293 meeting
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted the COAs of API batch number MRB210401 tested by both the API manufacturer and the finished product manufacturer
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Firm has submitted the method used for the analysis of API from API Manufacturer and from the Finished Product Manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted the stability data of the 3 batches of API from the API Manufacturer at both accelerated and real time conditions. The accelerated stability data is conducted at 40±2ºC, RH 75%±5% and the long term stability data is conducted at 30±2ºC, RH 65%±5%
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted the copy of GMP Certificate Issued by the Peoples Republic of China valid till 29-5-2024
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted the commercial invoice cleared on 14-7-2021. The invoice is cleared by Assistant Director of DRAP Karachi
7.	Protocols followed for conduction of stability study	Firm has submitted the stability study protocol

8.	Method used for analysis of FPP	Form has submitted the method used for the analysis of finished drug product
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted the undertaking that they have used the excipients as used by the innovator product
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted the BMRs of 3 stability batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted the CDP of their product against the reference product Mibega XR Tablet in 3 dissolution mediums
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 the stability data of 3 batches with 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.	Firm has submitted the Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted the Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator:		
Decision: Approved.		

37.	Name and address of manufacturer/ Applicant	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Brand Name + Dosage Form + Strength	Gabra 25mg ER tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Mirabegron…25mg
	Diary No. Date of R & I & fee	Dy.No 22430 dated 27-06-2018 Rs.50,000/- dated 27-06-2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5-D
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 25 mg (mirabegron extended-release film-coated tablet), USFDA approved.
	Me-too status	Mirabet Tablet 25mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	Copy of certificate of GMP generated against inspection conducted on 12-10-2022 is submitted.

STABILITY STUDY DATA	
Drug	Mirabegron
Manufacturer of API	Jiangsu Yongun Pharmaceutical Co. Ltd. No. 18, 237, Provincial Road, Economic Development Zone, Jiangsu, China.
API Lot No.	2100-202105001

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, 12 (months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	27-07-2020	27-07-2020	27-07-2020
No. of Batches	03		
Date of Submission	12201 dated 19-05-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
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	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The Firm has submitted copy of DML **Valid up to 06-12-2025**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Commercial Invoice (invoice no.ZY21060901G/W). Firm has also submitted Form 6 for import of 300gm API issued by AD(I&E), DRAP dated 23-06-2021.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (As per Innovator's Formulation)
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches.

11.	Record of comparative dissolution data (where applicable)	Firm has submitted Comparative dissolution study against Mibega 25mg XR Tablet.
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.	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
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 (real time and accelerated)

Remarks of Evaluator:

Sr. No.	Shortcomings
i.	ADC attested invoice for import of raw material shall be submitted.
ii.	Stability study data- of API from API manufacturer shall be submitted.
iii.	The manufacturer name and registration number of reference product against which CDP was performed shall be submitted.

Decision: Deferred for submission of response to above-mentioned shortcomings.

b. Deferred cases/ Verification of stability study data/ Exemption from onsite verification of stability data

38.	Name and address of manufacturer/ Applicant	**M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industrial Estate, Hattar**
	Brand Name + Dosage Form + Strength	Idyll 10mg tabelts
	Composition	Each film coated tablet contains: Vortioxetine as Hydrobromide… 10mg
	Diary No. Date of R & I & fee	Dy.No. 36306 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 5mg (USFDA Approved)
	Me-too status	Brintellix 10mg Tablet by M/s Lundbeck.
	GMP status	GMP inspection of the unit was conducted on 03-03-2022. Based on the inspection report, the firm was operating at a satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit Stability studies along with requisite documents
	Decision of 293rd meeting of RB:	**Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.**

STABILITY STUDY DATA

Drug	Vortioxetine Hydrobromide
Manufacturer of API	Lianyungang Jari Pharmaceutical

API Lot No.	20210501		
Description of Pack (Container closure system)	Alu-Alu blister 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)		
Batch No.	TID004	TID005	TID006
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	20-07-2021	20-07-2021	20-07-2021
No. of Batches	03		
Date of Submission	33400 dated 21-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
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	The firm has submitted copy of **Accelerated stability studies** (40°C ± 2°C & 75±5% RH) for **06 Months** & **Long-Term on Zone IV-B** (30°C ± 2°C & 75±5% RH) for 24 **months** of 03 batches.
5.		The Firm has submitted copy of DML of manufacturer "Lianyungang Jari Pharmaceuticals " **Valid up to 06-12-2025**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Form 6 dated 09-06-2021 issued by AD (I&E) DRAP for 700g of Vortioxetine hydrobromide.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols followed for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.
9.	Drug-excipients compatibility studies (where applicable)	N/A (As per Innovator's Formulation)

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches.
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

39.	Name and address of manufacturer/ Applicant	**M/s Navegal Lahoratories.** **41/1-A-2, Phase -1, Industeial Estate, Hattar**
	Brand Name + Dosage Form + Strength	Idyll 20mg tabelts
	Composition	Each film coated tablet contains: Vortioxetine as Hydrobromide… 20mg
	Diary No. Date of R & I & fee	Dy.No. 36307 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX Tablet 20mg (USFDA Approved)
	Me-too status	Brintellix 20mg Tablet by M/s Lundbeck.
	GMP status	GMP inspection of the unit was conducted on 03-03-2022. Based on the inspection report, the firm was operating at a satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit Stability studies along with requisite documents
	Decision of 293rd meeting of RB:	**Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.**

STABILITY STUDY DATA

Drug	Vortioxetine Hydrobromide
Manufacturer of API	Lianyungang Jari Pharmaceutical
API Lot No.	20210501
Description of Pack (Container closure system)	Alu-Alu blister 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: 12 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 12 (months)		
Batch No.	TID007	TID008	TID009
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	20-07-2021	20-07-2021	20-07-2021
No. of Batches	03		
Date of Submission	33399 dated 21-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Details
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
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	The firm has submitted copy of **Accelerated stability studies** (40°C ± 2°C & 75±5% RH) for **06 Months** & **Long-Term on Zone IV-B** (30°C ± 2°C & 75±5% RH) for 24 **months** of 03 batches.
5.		The Firm has submitted copy of DML of manufacturer "Lianyungang Jari Pharmaceuticals " **Valid up to 06-12-2025**
6.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Form 6 dated 09-06-2021 issued by AD (I&E) DRAP for 700g of Vortioxetine hydrobromide.
7.	Protocols followed for conduction of stability study	The firm has submitted protocols followed for conduction of stability studies.
8.	Method used for analysis of FPP	The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of finished product.
9.	Drug-excipients compatibility studies (where applicable)	N/A (As per Innovator's Formulation)
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record for all batches.
11.	Record of comparative dissolution data (where applicable)	Not submitted 1.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms,	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the

	Raw data sheets, COA, summary data sheets etc.	stability studies.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Observations
i.	ADC attested invoice for import of raw material shall be submitted.
ii.	Complete stability studies data shall be submitted as decided in 293rd meeting of RB

Decision: Deferred for submission of following:

- **ADC attested invoice for import of raw material shall be submitted.**
- **Complete stability studies data as decided in 293rd meeting of RB.**

40.	**Name and address of manufacturer / Applicant**	**M/s Wnsfeild Pharma plot no. 122, Block-a, Phase-v, Industrial Estate Hattar**
	Brand Name +Dosage Form + Strength	Denset 2mg Tablet
	Composition	Each Tablet Contains: Dienogest…….2mg
	Diary No. Date of R& I & fee	Dy. No.14565 dated 07-03-2019, Rs: 20,000/- dated 07-03-2019
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished product Specifications	Not submitted
	Pack size & Demanded Price	2 x 10's
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Not submitted; not available in database
	GMP status	GMP certificate issued based upon inspection conducted on 03-04-2023.
	Remarks of evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of requisite manufacturing facility / section approval from Licensing Division.
	Decision of 323rd meeting of RB:	Deferred for following submissions:

		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm 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. • Evidence of requisite manufacturing facility / section approval from Licensing Division. • Reference of finished product specifications.

STABILITY STUDY DATA

Manufacturer of API	M/s SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA		
API Lot No.	Deinogest: DNG/921005		
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%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0,3, 6 (months)		
Batch No.	DG-01	DG-02	DG-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	28-05-2022	28-05-2022	28-05-2022
No. of Batches	03		
Date of Submission of stability data	Dy No.39575 Dated 30-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (DNG/921005) of API (Dienogest) from M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA and M/S Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar

3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of APIs from both API Manufacturer and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Dienogest: Firm has submitted copy of GMP certificate dated 17-10-2022 in the name of M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA issued by FDA GUJARAT INDIA. Valid till 16-10-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	For Dienogest: The firm has submitted copy of invoice No. FHPL/20210901 dated 14-03-2022 from exporter M/S SWATI SPENTOSE PVT .LTD A-1/2111, PHASE III , G.I.D.C.-VAPI ,GUJARAT -396 195 , INDIA, for import of 12gs of DIENOGEST (Batch No. 921005) in name of M/s Wnsfeild Pharmaceuticals Hattar. Form-6 issued by AD (I&E) DRAP Peshawar dated 27-04-2022 is also submitted
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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[xxiii]:
Applicant shall submit the following:

Sr. No.	Observations/Shortcoming
i.	Tablet (steroidal hormone) section was granted vide letter dated 13-01-2019 but is not included in the list of sections renewed vide letter dated 11-06-2024. Applicant shall justify and submit evidence of requisite manufacturing facility / section approval from Licensing Division, DRAP.
ii.	Reference of finished product specifications shall be submitted.
iii.	Stability study data of API from API manufacturer
iv.	Drug-excipients compatibility studies (where applicable)
v.	Complete batch manufacturing record of three stability batches.

vi.	Record of comparative dissolution data (where applicable)	
Decision: Deferred for submission of response to above mentioned shortcomings.		
41.	**Name and address of manufacturer/ Applicant**	**M/s WNSFEILD PHARMA PLOT NO. 122, BLOCK-A, PHASE-V, INDUSTRIAL ESTATE HATTAR**
	Brand Name + Dosage Form + Strength	Mirabegron 25mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Mirabegron…….25mg
	Diary No. Date of R & I & fee	Dy. No.41830 dated 07-12-2018 , Fee Rs: 20,000/- dated 06-12-2018 vide deposit slip No.
	Pharmacological Group	Beta-3 adrenergic agonists. (Relaxing the bladder muscles to prevent urgent, frequent, or uncontrolled urination)
	Type of Form	Form 5D
	Finished product Specification	Innovator
	Pack size & Demanded Price	20's (2×10's); As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 25 mg (mirabegron extended-release film-coated tablet), USFDA approved.
	Me-too status	Mirabet Tablet 25mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	GMP certificate issued based upon inspection conducted on 03-04-2023.
	Decision of 295th meeting of RB	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, or else application on form-5D along with differential fee.

STABILITY STUDY DATA

Drug	Mirabegron		
Manufacturer of API	Not submitted.		
API Lot No.	Not submitted.		
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, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	MB-01	MB-02	MB-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	19-06-2021	19-06-2021	19-06-2021
No. of Batches	03		
Date of Submission	2941 dated 31-01-2022		

42.	**Name and address of manufacturer/ Applicant**	**M/s WNSFEILD PHARMA PLOT NO. 122, BLOCK-A, PHASE-V, INDUSTRIAL ESTATE HATTAR**
	Brand Name + Dosage Form + Strength	Mirabegron 50mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Mirabegron…….50mg
	Diary No. Date of R & I & fee	Dy. No.41831 dated 07-12-2018 , Fee Rs: 20,000/- dated 06-12-2018 vide deposit slip No.
	Pharmacological Group	Beta-3 adrenergic agonists. (Relaxing the bladder muscles to prevent urgent, frequent, or uncontrolled urination)
	Type of Form	Form 5D
	Finished product Specification	Innovator
	Pack size & Demanded Price	20's (2×10's); As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ 25 mg (mirabegron extended-release film-coated tablet), USFDA approved.
	Me-too status	Mirabet Tablet 25mg, Reg# 090378, CCL Pharmaceuticals, Lahore.
	GMP status	GMP certificate issued based upon inspection conducted on 03-04-2023.
	Decision of 295th meeting of RB	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, or else application on form-5D along with differential fee.

STABILITY STUDY DATA

Drug	Mirabegron		
Manufacturer of API	Not submitted.		
API Lot No.	Not submitted.		
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, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	MB-04	MB-05	MB-06
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	21-06-2021	21-06-2021	21-06-2021
No. of Batches	03		
Date of Submission	2942 dated 31-01-2022		

Remarks of Evaluator:

Sr. No.	Observations

i.	Complete Stability study data is required as per the guidelines approved in 293rd meeting of Registration Board.

Decision: Deferred for submission of submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.

Agenda of Mr. Waqar Ahmed

43.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd. 158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam Tablet 10mg
	Composition	Each Film coated tablet contains: Brivaracetam ….10mg
	Diary No. Date of R& I & fee	From-5 Dy. No.4071 dated 26-05-2017 Rs. 50,000/- dated 26-05-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Brivatam 10mg Tablet by M/s CCL Pharmaceuticals
	GMP status	Submitted. Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).

STABILITY STUDY DATA			
Drug	Bricetam Tablet 10mg		
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India		
API Lot No.	BVMU011		
Description of Pack (Container closure system)	1x10's Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003

Batch Size	1000	1000	1000
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	11-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8 is submitted. The values of f2 factor are in acceptable range.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

44.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd.** **158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam 10mg/ml Oral Solution
	Composition	Each ml contains: Brivaracetam ….10mg
	Diary No. Date of R& I & fee	From-5 Dy. No.4071 dated 26-05-2017 Rs. 50,000/- dated 26-05-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets, 10mg/ml oral solution).** USFDA approved.
	Me-too status	Brivatam 10mg/ml oral solution by M/s CCL Pharmaceuticals
	GMP status	Submitted.

		Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).

STABILITY STUDY DATA			
Drug	Bricetam Tablet 10mg		
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India		
API Lot No.	BVMU011		
Description of Pack (Container closure system)	Amber color plastic bottle packed in a card box unit.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 Bottles	1000 Bottles	1000 Bottles
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	04-01-2023	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	11-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	submitted.

8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8 is submitted. The values of f2 factor are in acceptable range.
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.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

45.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd.** **158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam Tablet 25mg
	Composition	Each Film coated tablet contains: Brivaracetam ….25mg

	Diary No. Date of R& I & fee	From-5 Dy. No.4071 dated 26-05-2017 Rs. 50,000/- dated 26-05-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Brivatam 25mg Tablet by M/s CCL Pharmaceuticals
	GMP status	Submitted. Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).

STABILITY STUDY DATA

Drug	Bricetam Tablet 25mg		
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India		
API Lot No.	BVMU011		
Description of Pack (Container closure system)	1x10's Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000	1000	1000
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	11-04-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8 is submitted. The values of f2 factor are in acceptable range.
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.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	

2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

46.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd.** **158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam Tablet 50mg
	Composition	Each Film coated tablet contains: Brivaracetam ….50mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 15392 dated 18-09-2017 Rs.50,000/- dated 18-09-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Brivatam 50mg Tablet by M/s CCL Pharmaceuticals
	GMP status	Submitted. Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).

STABILITY STUDY DATA

Drug	Bricetam Tablet 50mg
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India
API Lot No.	BVMU011
Description of Pack (Container closure system)	1x10's Alu-Alu blister pack.
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 06 months Accelerated: 06 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000	1000	1000
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	12-06-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH

		6.8 is submitted. The values of f2 factor are in acceptable range.
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.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

47.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd.** **158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam Tablet 75mg
	Composition	Each Film coated tablet contains: Brivaracetam ….75mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 15392 dated 18-09-2017 Rs.50,000/- dated 18-09-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Brivatam 75mg Tablet by M/s CCL Pharmaceuticals

	GMP status	Submitted. Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).	
STABILITY STUDY DATA			
Drug	Bricetam Tablet 75mg		
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India		
API Lot No.	BVMU011		
Description of Pack (Container closure system)	1x10's Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000	1000	1000
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	12-06-2023		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	**Documents to Be Provided**	**Status**	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted	
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.	

7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8 is submitted. The values of f2 factor are in acceptable range.
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.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	
2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

48.	Name and address of manufacturer / Applicant	**M/s. Amarant Pharmaceuticals (Pvt) Ltd.** **158-D, Toro Gadap road, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Bricetam Tablet 100mg

	Composition	Each Film coated tablet contains: Brivaracetam ….100mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 15392 dated 18-09-2017 Rs.50,000/- dated 18-09-2017
	Pharmacological Group	Anti-Epileptic / Anticonvulsants ATC Code: N03AX .
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulator Authorities	**BRIVIACT (Brivaracetam) Tablets (10mg, 25mg, 50mg, 75mg & 100mg Tablets).** USFDA approved.
	Me-too status	Brivatam 100mg Tablet by M/s CCL Pharmaceuticals
	GMP status	Submitted. Certificate No. 23/2023-DRAP (K), Dated, 01-03-2023. (Valid for 02 years).

STABILITY STUDY DATA

Drug	Bricetam Tablet 100mg		
Manufacturer of API	M/s. JPR Labs Private Ltd., Plot No. 74/A, J.N, Pharmacity, Thanam Vilage, Parawada (M), Visakhapatnam, India		
API Lot No.	BVMU011		
Description of Pack (Container closure system)	1x10's Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000	1000	1000
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		
Date of Submission	12-06-2023		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#BVMU011) of API from M/s JPR Labs Pvt. Ltd., India and M/s M/s Amarant Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer submitted
4.	Stability study data of API from API manufacturer	Submitted as per zone IV-A
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs control administration, Government of Andrapradesh India valid upto 19-04-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.
7.	Protocols followed for conduction of stability study	submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not Submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted. Report of comparative dissolution performed against Brivace 10mg tablet by M/s Hilton Pharma in Buffer pH 1.2, acetate buffer pH 4.5, phosphate buffer pH 6.8 is submitted. The values of f2 factor are in acceptable range.
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.	Not Submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted	

2.	Complete batch manufacturing record of three stability batches shall be submitted.	
3.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
4.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
5.	Drug-excipients compatibility studies shall be submitted	
6.	Submit valid GMP certificate of **M/s. Amarant Pharmaceuticals (Pvt) Ltd.**	

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

49.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Brand Name +Dosage Form + Strength	Emgly 10mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…..10mg
	Diary No. Date of R& I & fee	From-5 Dy. No. 180 dated 03-02-2017 50,000/- dated 02-02-2017
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size & MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years).
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Emgly 10mg Tablet
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.
API Lot No.	D86-200401
Description of Pack (Container closure system)	3x10's, Alu-Au Blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (months)

	Real Time: 0, 3, 6, (months)		
Batch No.	PLT-T-137	PLT-T-138	PLT-T-139
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	03.2021	03.2021	03.2021
No. of Batches	03		
Date of Submission	Dy. No. 31022 dated 01-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Empagliflozin) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd. Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)**
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	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
4.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
5.	Complete batch manufacturing record of three stability batches shall be submitted..	
6.	Record of comparative dissolution data shall be submitted.	
7.	Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	
8.	Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point)	
9.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

50.	Name and address of manufacturer / Applicant	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Brand Name +Dosage Form + Strength	Emgly 25mg Tablet
	Composition	Each film coated tablet contains: Empagliflozin…..25mg
	Diary No. Date of R& I & fee	From-5 Dy. No. 179 dated 03-02-2017 50,000/- dated 02-02-2017
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size & MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company

		Limited, Karachi. (Reg. No. 093089)
	GMP status	Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years).
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Emgly 25mg Tablet		
Manufacturer of API	Chifeng Arker Pharmaceutical Technology Co. Ltd. Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China.		
API Lot No.	D86-200401		
Description of Pack (Container closure system)	3x10's, Alu-Au Blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	PLT-T-1074		
Batch Size	2000 Tablets		
Manufacturing Date	02-2021		
Date of Initiation	03.2021		
No. of Batches	01		
Date of Submission	Dy. No. 31022 dated 01-11-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Empagliflozin) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd. Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)**
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	Not submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
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.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
4.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
5.	Complete batch manufacturing record of three stability batches shall be submitted..	
6.	Record of comparative dissolution data shall be submitted.	
7.	Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd.	
8.	Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point). Also provide complete 03 batches data.	

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

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

51.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Gliem 25mg Tablets
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38602 dated 23-11-2018 Rs.20,000/- dated 23-11-2018
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Gliem 25mg Tablets		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
No. of Batches	03		
Date of Submission	29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches, along with chromatograms.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	

4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
6.	Method used for analysis of Finished Product shall be submitted.	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Record of comparative dissolution data shall be submitted.	

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

52.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 15768 dated 07-03-2019 Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Empxin 10mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size			

Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s **Winlet Pharmaceuticals.**	

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

53.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 15769 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)

	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Empazin 25mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		
Date of Submission	29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.

9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
14.	Submit valid GMP certificate of M/s **Winlet Pharmaceuticals.**	

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

54.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Valoglif 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13743 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Valoglif 10mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	05-2022	05-2022	05-2022
No. of Batches	03		
Date of Submission	29-12-2022.		

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.	N/A

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Drug product analytical procedure submitted including Assay & Dissolution test
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Drug product analytical procedure submitted including Assay & Dissolution test
9.	Drug-excipients compatibility studies (where applicable)	Submitted for binary combinations of drug with each excipient
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted against Diampa tablet of Getz pharma in three dissolution medium of pH 1.2 4.5 and 6.8
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	

6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Submit valid GMP certificate of M/s Valor Pharmaceuticals.	

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

55.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Valoglif 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13742 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Jardiance tablets (USFDA Approved)
	Me-too status	Emsyn 25mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Valoglif 25mg Tablet		
Manufacturer of API	**Not submitted**		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**1x10's, PVC foil.**		
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.	Trial 01	Trial 02	Trial 03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	05-2022	05-2022	05-2022
No. of Batches	03		
Date of Submission	29-12-2022.		

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.	N/A
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Drug product analytical procedure submitted including Assay & Dissolution test
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Drug product analytical procedure submitted including Assay & Dissolution test
9.	Drug-excipients compatibility studies (where applicable)	Submitted for binary combinations of drug with each excipient
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Submitted against Diampa tablet of Getz pharma in three dissolution medium of pH 1.2 4.5 and 6.8
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	

4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Submit valid GMP certificate of M/s Valor Pharmaceuticals.	

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

Agenda of Ms. Najia Saleem

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

a. Duplicate dossiers with photocopies of R&I receiving (to be verified from R&I DRAP) and with incomplete evidence for fee challans and R&I receiving

56.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Foxin 50mg capsule
	Composition	Each capsule contains Etifoxine HCl…50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 28834 dated 01-01-2020; Rs.12000/- dated 01-01-2020, (**original**) R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Anxiolytic (benzoxazine)
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	12's, 24's;As per SRO
	RRA status	ANSM France approved
	Me-too status	Glitifox 50 mg Capsules of M/s Glitz Pharma, Islamabad. (078083)
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	**Capsule (General) section** confirmed vide letter No. F. 1-29/2001-Lic (M-215) dated 11-05-2009 **Shortcomings:** No evidence of Rs. 8000/- and initial application submission in DRAP is attached.
	Decision: Approved. Registration Board further decided that registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.**	
57.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Senox forte tablet

	Composition	Each film coated tablet contains: Secnidazole…1000mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 28834 dated 01-01-2020; Rs.12000/- dated 01-01-2020, (**original**) Rs.8000/- dated 08-11-2010 (photocopy challan only) **R&I receiving is not attached**
	Pharmacological Group	Anti-amoebic & anti-infective
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2's, 4's;As per SRO
	RRA status	ANSM France approved
	Me-too status	Secnidal Tablets 500mgof M/s sanofi-aventis Pakistan Limited. (010299)
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	The firm has **revised** its request to following label claim **Each film coated tablet contains:** **Secnidazole…500mg** Tablet (General) section confirmed from copy of DML **Shortcomings:** No evidence of initial application submission in DRAP is attached.
	Decision: Approved. Registration Board further decided that registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **Submission of fee Rs. 37,000/- for pre-approval variation in formulation (strength) and FPP Specifications.**	
58.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Zopic 1mg tablet
	Composition	Each film coated tablet contains: Eszopiclone…1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 30984 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (**original**) Dy. No. Nil, dated 04-01-2011; Rs.8000/- dated 04-01-2011 (photocopy) to be verified from concerned section
	Pharmacological Group	Benzodiazepine related drugs
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10's;As per SRO
	RRA status	USFDA approved
	Me-too status	Clonexa 1mg Tablet of M/s Atco Laboratories Limited, Karachi. (058428)
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	**Tablet (General) section** confirmed from copy of DML **In-charge R&I section DRAP Remarks:**

		"No record found in R&I section as dossier was received in section concerned instead of R&I section"
	Decision: Approved. Registration Board further decided that registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
59.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Zopic 2mg tablet
	Composition	Each film coated tablet contains: Eszopiclone…2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 30985 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (**original**) Dy. No. Nil, dated 04-01-2011; Rs.8000/- dated 04-01-2011 (photocopy) to be verified from concerned section
	Pharmacological Group	Benzodiazepine related drugs
	Finished product Specifications	USP specs
	Pack size & Demanded Price	10's;As per SRO
	RRA status	USFDA approved
	Me-too status	Clonexa 2mg Tablet of M/s Atco Laboratories Limited, Karachi. (058429)
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	**Tablet (General) section** confirmed from copy of DML **In-charge R&I section DRAP Remarks:** "No record found in R&I section. Moreover, dossier was directly submitted in section instead of R&I section"
	Decision: Approved. Registration Board further decided that registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
60.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Sabilax Sachet
	Composition	Each Sachet contains: Vigabatrin….500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 30986 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (**original**) Rs.8000/- dated 27-11-2010 (photocopy challan only) **R&I receiving is not attached**
	Pharmacological Group	Anti-epileptic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO;As per SRO

	RRA status	USFDA approved
	Me-too status	Hasteraz 500mg Sachet of M/s Hamaz Pharmaceuticals (Pvt) Ltd.(110995)
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	**Sachet section** confirmed vide letter No. F. 1-29/2001-Lic (M-215) dated 11-05-2009 **Shortcomings:** No evidence of initial application submission in DRAP is attached.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.**	
61.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Dipro 500mg tablet
	Composition	Each extended release tablet contains: Divalproex sodium eq. to valproic acid…500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier**) Dy. No. 28837 dated 01-01-2020; Rs.12000/- dated 01-01-2020, (**original**) Dy. No. nil dated 22-12-2010 Rs.8000/- dated 22-12-2010 (photocopy) to be verified
	Pharmacological Group	Anti-epileptic
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO;As per SRO
	RRA status	USFDA approved
	Me-too status	Epival of M/s Abbott
	GMP status	GMP certificate dated 15-12-2023 based upon evaluation conducted on 01-12-2023
	Remarks of the Evaluator	**Tablet (General) section** confirmed from copy of DML
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
62.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Aprazole 40 mg tablets
	Composition	Each enteric coated tablet contains: Pantoprazole (as Sodium Sequihydrate)……40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14059 dated 30-12-2024 **intimation dated 16-11-2020** Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified

		R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	20's; As per SRO
	RRA status	USFDA approved
	Me-too status	Zopent of M/s Hilton
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.**	
63.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Piroxiderm-S Liquid (topical liquid)
	Composition	Each ml contains: Ciclopirox Olamine ....15mg Salicylic acid……30mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14056 dated 30-12-2024, **intimation dated 12-12-2019** Dy. No. nil dated 03-06-2011; Rs.8000/- dated 03-06-2011, (photocopy) to be verified Dy. No. nil dated 22-01-2019; Rs. 12,000/- dated 22-01-2019, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Antidandruff
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Cilox-S Lotion of M/s Valor Pharmaceuticals, Islamabad 072899
	GMP status	
	Remarks of the Evaluator	**The firm has requested to consider the case against decision of 179th meeting of DRAP Authority.**
	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.	
64.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Mupical cream
	Composition	Each gram contains: Mupirocin as calcium……20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14050 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**

	Pharmacological Group	Broad spectrum antibiotic
	Finished product Specifications	BP specs
	Pack size & Demanded Price	10gm; As per SRO
	RRA status	USFDA approved
	Me-too status	Bactogen Cream of M/s Biogen Pharma
	GMP status	
	Remarks of the Evaluator	**Shortcoming:** No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.**	
65.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Acnetek gel 0.1% w/w
	Composition	Each gram contains: Adapalene …..1mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14051 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Anti-Acne
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	15gm; As per SRO
	RRA status	USFDA approved
	Me-too status	Axadap 0.1% Gel of M/s Akhsah Pharmaceuticals (Pvt) Ltd Rawat (119182)
	GMP status	
	Remarks of the Evaluator	**Shortcoming:** No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.**	
66.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linopril -5 mg Tablets
	Composition	Each film coated tablet contains: Lisinopril Dihydrate eq. to Lisinopril Anhydrous …..5mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14052 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	ACE inhibitors
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x14; As per SRO
	RRA status	Zestril (USFDA approved)
	Me-too status	Lisnoguf-5 Tablet of M/s Gulf Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Shortcoming:** • No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached. • **Uncoated tablet in RRA**
	Decision: Approved as uncoated tablet. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation.**	
67.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linopril -10 mg Tablets
	Composition	Each film coated tablet contains: Lisinopril Dihydrate eq. to Lisinopril Anhydrous …..10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14061 dated 30-12-2024 and **intimation dated 16-11-2020** Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	ACE inhibitors
	Finished product Specifications	USP specs
	Pack size & Demanded Price	2x14; As per SRO
	RRA status	Zestril (USFDA approved)
	Me-too status	Lisnoguf-10 Tablet of M/s Gulf Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Shortcoming:** • No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached. • **Uncoated tablet in RRA**
	Decision: Approved as uncoated tablet. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.**	

	• **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation.**	
68.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ethycol 500mcg Tablet
	Composition	Each film coated tablet contains: Mecobalamin ….500mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14060 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Vitamin
	Finished product Specifications	JP specs
	Pack size & Demanded Price	10's; As per SRO
	RRA status	PMDA approved
	Me-too status	Methycobal
	GMP status	
	Remarks of the Evaluator	**Shortcoming:** • No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached. • **Sugar coated tablet in RRA**
	Decision: Approved as sugar coated tablet. Registration Board further decided that Registration letter shall be issued after the following: • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation of formulation in line with reference product.**	
69.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Rubonac gel
	Composition	Each gram contains: Diclofenac Diethylamine …..10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14058 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	NSAID
	Finished product Specifications	BP specs
	Pack size & Demanded Price	20gm; As per SRO
	RRA status	MHRA approved
	Me-too status	Disof Gel 1% of M/s Reliance Pharma
	GMP status	
	Remarks of the Evaluator	**Shortcomings:**

		Correction of label claim as per reference product along with fee
	Decision: Approved as per following label claim: **Each gram contains:** **Diclofenac Diethylamine eq. to Diclofenac Sodium …. 1%** **. Registration Board further decided that Registration letter shall be issued after the following:** • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change in label claim.**	
70.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Dermolimus 0.1% Ointments
	Composition	Each gram contains: Tacrolimus ….0.1%w/w
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14057 dated 30-12-2024 and **intimation dated 16-11-2020** and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Immunomodulator
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	10gm; As per SRO
	RRA status	MHRA approved (Tacrolimus as monohydrate 1mg/g)
	Me-too status	Tacrus Ointment of M/s Shrooq Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** Correction of label claim as per reference product along with fee
	Decision: Approved as per following label claim: **Each gram contains:** **Tacrolimus as Monohydrate …. 0.1%w/w.** **Registration Board further decided that Registration letter shall be issued after the following:** • **Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.** • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 37000/- for pre-approval change in label claim.**	
71.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Quit tablets 375/20mg
	Composition	Each delayed release bilayer tablet contains: Naproxen (acid resistant granules) ….375mg Esomeprazole as Magnesium ….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D (**Duplicate dossier)** Dy. No. 25148 dated 25-09-2020 Rs. 5000/- dated 25-09-2020 (original)

		Dy. No. 1679 dated 19-01-2011; Rs.15000/- dated 19-01-2011, (photocopy) **verified from R&I DRAP** Dy. No. 37069 dated 20-12-2022 **Rs. 12,000/- dated 15-12-2022**
	Pharmacological Group	NSAID/ PPI
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved
	Me-too status	Eznepo of M/s Wnsfeild
	GMP status	
	Remarks of the Evaluator	**Stability data not submitted, differential fee Rs. 12000/- deposited after the deadline** As per manufacturing method firm has manufactured bilayer tablet while RRA approved formulation is Core Coated.
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
72.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Quit tablets 500/20mg
	Composition	Each delayed release bilayer tablet contains: Naproxen (acid resistant granules) ….500mg Esomeprazole as Magnesium ….20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5D (**Duplicate dossier)** Dy. No. 25149 dated 25-09-2020 Rs. 5000/- dated 25-09-2020 (original) Dy. No. 1679 dated 19-01-2011; Rs.15000/- dated 19-01-2011, (photocopy) to be verified Dy. No. 37070 dated 20-12-2022 **Rs. 12,000/- dated 15-12-2022**
	Pharmacological Group	NSAID/ PPI
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved
	Me-too status	Eznepo of M/s Wnsfeild
	GMP status	
	Remarks of the Evaluator	**Stability data not submitted, differential fee Rs. 12000/- deposited after the deadline** As per manufacturing method firm has manufactured bilayer tablet while RRA approved formulation is Core Coated.
	Decision: Registration Board considered the fact that applied formulation required submission of drug product stability data for which the cut–off submission date decided by Authority was 30-06-2023, as notified vide notification No. F.15-1/2022-PEC dated 18-10-2024 and since firm has not submitted drug product stability data till date, hence, Board decided to reject the instant application.	
73.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd, 44-Industrial Triangle Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	Tramalgia capsule 50mg
	Composition	Each capsule contains: Tramadol HCl ….50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. nil dated 07-03-2019 Rs. 20000/- dated 06-03-2019 (**photocopy**) to be verified
	Pharmacological Group	Centrally acting opioid analgesic
	Finished product Specifications	BP specs
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	RRA status	MHRA approved
	Me-too status	Tomogex 50mg Capsule of M/s Axis Pharmaceuticals (115418)
	GMP status	
	Remarks of the Evaluator	Clarification regarding applied dosage form was sought vide letter No. F. 1-1/2017/PEC-DRAP (AD PEC-VI) dated 19-12-2019 since **the dosage form written on fee challan is tablet** while that mentioned on form-5 is capsule. In response the firm had submitted application dated 30-12-2019 and then on 05-03-2020 for change of dosage form to capsule on fee challan. The firm had also submitted an undertaking on stamp paper that "Tramadol HCl 50mg is in capsule form as per form-5, but it is written mistakenly as tablet in fee challan No. **0844252** "
	Decision: Approved. Registration Board further decided that verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board, before issuance of Registration letter.	
74.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd, L-10-D, Block No. 21, Shaheed Rashid Minhas Road, Federal B Industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Nimex tablet 100mg
	Composition	Each tablet contains: Nimesulide 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 12988 dated 04-12-2024 and old intimation dated **19-06-2020** Dy. No. nil dated 28-08-2017 Rs. 20000/- dated 25-08-2017 (**photocopy**) to be verified
	Pharmacological Group	NSAID
	Finished product Specifications	Not mentioned
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	EMA approved
	Me-too status	Unix 100mg tablet of M/s Hilton Pharma (023397)
	GMP status	GMP certificate dated 15-02-2024 based on evaluation conducted on 15-02-2024
	Remarks of the Evaluator	
	Decision: Keeping in view the approval status of Nimesulide 100mg tablet in EMA, Registration Board approved the applied formulation of Nimesulide tablet 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • **Treatment of acute pain** • **Primary dysmenorrhea** **Registration Board further decided that Registration letter shall be issued after the following:**	

	• **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	
75.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd, L-10-D, Block No. 21, Shaheed Rashid Minhas Road, Federal B Industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Good Morning tablet
	Composition	Each film coated delayed release tablet contains: Doxylamine as Succinate.....10mg Pyridoxine as HCl.....10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 11113 dated 21-10-2024 and old intimation dated **19-06-2020** Dy. No. nil dated 08-06-2018 Rs. 20000/- dated 07-06-2018 (**photocopy**) to be verified
	Pharmacological Group	Antihistamine/ vitamin B-6 analogue
	Finished product Specifications	Not mentioned
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved
	Me-too status	Envepe tablet of M/s RG Pharma
	GMP status	GMP certificate dated 15-02-2024 based on evaluation conducted on 15-02-2024
	Remarks of the Evaluator	**Shortcomings:** Signed copy of complete form 5 along with master formula and method of manufacturing since all annexures are not attached.
	Decision: Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 20000/- within 6 months of publication of minutes of instant meeting on DRAP website.	
76.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd, L-10-D, Block No. 21, Shaheed Rashid Minhas Road, Federal B Industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Candy tablet 4mg
	Composition	Each tablet contains: Candesartan cilexetil.....4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. nil dated **19-06-2020** Dy. No. nil dated 28-09-2017 Rs. 20000/- dated 27-09-2017 (**photocopy**) to be verified
	Pharmacological Group	angiotensin II receptor blocker
	Finished product Specifications	Not mentioned
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	MHRA approved
	Me-too status	Cancardo Tablet 4mg of M/s Maxitech Pharma
	GMP status	GMP certificate dated 15-02-2024 based on evaluation conducted on 15-02-2024
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP specifications.**	

77.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Oblonec Injection
	Composition	Each 2ml contains: Diclofenac Sodium…….75mg Lignocain HCl……20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13933 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	NSAID/ anaesthetic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	2ml; As per SRO
	RRA status	Diclofenac-Mepha solution for injection IM, Switzerland
	Me-too status	Difam Plus of M/s Bosch
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** Form-5 is submitted by contract manufacturer instead of the applicant.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
78.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Cipcin 400mg/100ml Infusion
	Composition	Each 100ml contains: Ciprofloxacin as HCl……400mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13934 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Fluoroquinolone antibiotic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	100ml; As per SRO
	RRA status	USFDA approved (**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons)**
	Me-too status	Cipesta DS infusion of M/s Getz (contains Ciprofloxacin as lactate)

	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant. • In form 5 firm has mentioned Ciprofloxacin as HCl while in master formula Ciprofloxacin lactate is mentioned in addition to lactic acid
	Decision: Approved with following label claim: **Each 100ml contains:** **Ciprofloxacin as lactate……400mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **fee Rs. 37000/- for pre-approval variation in label claim in line with reference product and FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
79.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat , Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Cipcin 200mg/100ml Infusion
	Composition	Each 100ml contains: Ciprofloxacin as HCl……200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13932 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Fluoroquinolone antibiotic
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	100ml; As per SRO
	RRA status	USFDA approved (**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons)**
	Me-too status	Cipesta infusion of M/s Getz (contains Ciprofloxacin as lactate)
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant. • In form 5 firm has mentioned Ciprofloxacin as HCl while in master formula Ciprofloxacin lactate is mentioned in addition to lactic acid
	Decision: Approved with following label claim: **Each 100ml contains:** **Ciprofloxacin as lactate……200mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.**	

	• **fee Rs. 37000/- for pre-approval variation in label claim in line with reference product and FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
80.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Irofer 100mg/5ml Ampoule
	Composition	Each 5ml contains: Iron Sucrose ……100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13937 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Iron preparation
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	5ml, As per SRO
	RRA status	
	Me-too status	Ferobsv
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant. • Label claim correction also required as Iron Sucrose complex eq. to elemental iron 100mg/5ml.
	Decision: Approved with following label claim: **Each 5ml contains:** **Iron III hydroxide sucrose complex eq. to elemental iron……100mg** **Registration Board further decided that Registration letter shall be issued after the following:** • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **fee Rs. 37000/- for pre-approval variation in label claim in line with reference product and FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
81.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Ob-Flox 250mg/100ml
	Composition	Each 100ml contains: Levofloxacin as Hemihydrate ……. 250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13938 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Fluoroquinolone antibiotic
	Finished product Specifications	Inhouse specs

	Pack size & Demanded Price	100ml; As per SRO
	RRA status	**Not confirmed in applied pack size and strength**
	Me-too status	Bexus-250 Injection
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant.
	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.	
82.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Obmecomin 500mcg/ml Injection
	Composition	Each ml contains: Mecobalamin ……. 500mcg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13939 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Vitamin B12
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	PMDA
	Me-too status	Methicobal Hilton
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **latest GMP inspection report conducted within period of three years.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
83.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Medisave Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Vincam 20mg/ml Injection
	Composition	Each ml contains: Piroxicam …… 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13931 dated 26-12-2024 and **old intimation dated 10-03-2023**

		Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	NSAID
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	ANSM
	Me-too status	Piroxilite Elite Phrama
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant.
	Decision: Approved. Registration Board further decided that Registration letter shall be issued after the following: • **verification of duplicate fee challan will be done as per decision of 285th meeting of Registration Board.** • **fee Rs. 9000/- for pre-approval variation in FPP Specifications.** • **Submission of revised form 5 by the applicant.**	
84.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Friends Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Obzole 30mg Injection
	Composition	Each vial contains: Lansoprazole as Sodium (Lyophilized) ……. 30mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13936 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons
	Me-too status	Zolard 30mg Injection Davis
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant.
	Decision: Registration Board deferred the instant application for submission of following: • **clarification regarding method of manufacturing** • **Submission of revised form 5 by the applicant**	
85.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Friends Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Obrazole 40mg Injection

	Composition	Each vial contains: Pantoprazole as sodium (Lyophilized) ……. 40mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13935 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	MHRA
	Me-too status	P-Line 40mg Lyophilized Injection Medisave
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant. • MHRA approved formulation is Pantoprazole as sodium sesquihydrate.
	Decision: Registration Board deferred the instant application for submission of following: • **clarification regarding method of manufacturing** • **Submission of revised form 5 by the applicant**	
86.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceutical 209-S Quaid-e-Azam Industrial Estate, Lot Kakhpat, Lahore **Contract with** M/s Friends Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Acyver 250mg Injection
	Composition	Each vial contains: Acyclovir as Sodium (Lyophilized) …… 250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 13940 dated 26-12-2024 and **old intimation dated 10-03-2023** Dy No. Nil. Dated 23-02-2015 Rs.50000/- (photocopy) to be verified
	Pharmacological Group	Antiviral
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	As per SRO
	RRA status	USFDA Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons
	Me-too status	P-Line 40mg Lyophilized Injection Medisave
	GMP status	Medisave: GMP certificate dated 08-11-2023 based on evaluation conducted on 21-08-2023
	Remarks of the Evaluator	**Shortcomings:** • Form-5 is submitted by contract manufacturer instead of the applicant.
	Decision: Registration Board deferred the instant application for submission of following: • **clarification regarding method of manufacturing** • **Submission of revised form 5 by the applicant**	

b. Duplicate dossiers submitted after the deadline

87.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Aprazole 20 mg tablets
	Composition	Each enteric coated tablet contains: Pantoprazole (as Sodium Sesquihydrate) …… 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14041 dated 30-12-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	PPI
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	14's; As per SRO
	RRA status	USFDA approved
	Me-too status	Zopent of M/s Hilton
	GMP status	
	Remarks of the Evaluator	**Submitted after the deadline**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
88.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	CB sole-S Lotion
	Composition	Each gram contains: Betamethasone….0.05% w/w Salicylic acid …... 2% w/w
	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14053 dated 30-12-2024 Dy. No. nil dated 12-12-2019; Rs.12000/- dated 12-12-2019, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Corticosteroid/ antibacterial
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	20ml; As per SRO
	RRA status	**Could not be confirmed**
	Me-too status	Encore S Lotion of M/s Reko Pharmacal (PVT) Limited
	GMP status	
	Remarks of the Evaluator	**Submitted after the deadline** **Shortcoming:** • No evidence of fee Rs. 8000/- and initial application submission in DRAP is attached. • **RRA status could not be confirmed**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
89.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.
	Brand Name +Dosage Form + Strength	Isozole cream
	Composition	Each gram contains: Isoconazole nitrate ….10mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (**Duplicate dossier)** Dy. No. 14055 dated 30-12-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan **are not attached**
	Pharmacological Group	Antifungal
	Finished product Specifications	Inhouse specs
	Pack size & Demanded Price	10gm; As per SRO
	RRA status	Travogen 1% crema AIFA Italy approved
	Me-too status	Dermozole 1% Cream of M/s Vega Pharmaceuticals Pvt Ltd (069082)
	GMP status	
	Remarks of the Evaluator	**Submitted after the deadline**
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

c. **Intimation with only copies of R&I receiving and fee challans:**

Following firms have submitted only photocopies of covering letters of initial applications and photocopies/ original fee challans without attaching duplicate dossiers on form-5.

1. **Swan Pharmaceuticals (Pvt) Ltd., 11-E, Industrial Triangle, Kahuta Road, Islamabad** has submitted a request vide Diary No. 5465 dated 27-02-2023 in which they have attached only receipt as mentioned below against each.

Sr. No.	Brand Name and composition	Detail of Rs.8000/-	Detail of Rs.12000/-
90.	Wanfenac injection Diclofenac sodium 75mg	No receipt	Rs.204000/- (Rs.12000 x 17) diary no. Nil dated 01-06-2015 (photocopy)
91.	Sawntil injection Pochlorperazine 12.5mg	No receipt	
92.	Cyclowan injection Procycldine 10mg	No receipt	
93.	Tamowan Capsule Tramadol HCl 50mg	No receipt	
94.	Medazem injection (Midazolam 1mg)	Diary No. Nil. Dated 28-06-2010	
95.	Zithrowan-250 capsule Azithromycin 250mg	Diary No. Nil. Dated 06-06-2011	
96.	Esomeprin-20 tablet Esomeprazole 20mg	Diary No. Nil. Dated 06-06-2011	
97.	Esomeprin-40 tablet Esomeprazole 40mg	Diary No. Nil. Dated 06-06-2011	
98.	Polywan F Chewable tablet Iron polymaltose 100mg Folic acid 0.35mg	Diary No. Nil. Dated 06-06-2011	
99.	Ribazep -10 capsule (Rabeprazole 10mg	Diary No. Nil. Dated 06-06-2011	
100.	Ribazep -20 capsule (Rabeprazole 20mg	Diary No. Nil. Dated 06-06-2011	
101.	Rostin 10mg tablet Rosuvastain 10mg	Diary No. Nil. Dated 06-06-2011	
102.	Rostin 20mg tablet Rosuvastain 20mg	Diary No. Nil. Dated 06-06-2011	

103.	Zaprotin-20 capsule Paroxetine 20mg	Diary No. Nil. Dated 06-06-2011	
104.	Amikacin 100mg Injection Amikacin 100mg	Diary No. Nil. Dated 06-06-2011	
105.	Amikacin 250mg Injection Amikacin 250mg	Diary No. Nil. Dated 06-06-2011	
106.	Lincowan 600mg Injection Lincomycin 600mg	Diary No. Nil. Dated 06-06-2011	
107.	Calcid 0.5mg Tablet	Diary No. Nil. Dated 25-06-2010	No receipt
108.	Trinwan 500 Tranexamic Acid 500mg	Diary No. Nil. Dated 25-06-2010	No receipt
109.	Duloxet-30 Tablet	Diary No. Nil. Dated 25-06-2010	No receipt
110.	Oswin (Ossein Mineral Complex) 800mg Tablet	Diary No. Nil. Dated 25-06-2010	No receipt
111.	Ciprowan 250 Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
112.	Ciprowan 500 Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
113.	Estalwan 10 Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
114.	Estalwan D Tablet 10mg	Diary No. Nil. Dated 06-06-2011	No receipt
115.	Levowan 250 Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
116.	Levowan 500 Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
117.	Sapriwan D 50mg Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
118.	Sapriwan 25mg Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
119.	Sapriwan 50mg Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
120.	Omeprowan-20 Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
121.	Lumartin DS Chewable Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
122.	Lumartin Forte Dispersible Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
123.	Lumartin Forte Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
124.	Lumartin DS Dispersible Tablet	Diary No. Nil Dated 06-06-2011	No receipt
125.	Lumartin Forte Chewable Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
126.	Pirowan-C Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
127.	Pirowan-D Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
128.	Pirowan Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
129.	Fexowan-P Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
130.	Swancobal-C 500mg Tablet	Diary No. Nil. Dated 06-06-2011	No receipt
131.	Lincowan 500mg Capsule	Diary No. Nil. Dated 06-06-2011	No receipt
132.	Polywan 100mg Injection	Diary No. Nil. Dated 06-06-2011	No receipt

Registration Board decided as under:

i. **For the applications of products at Sr. No. 94-106 the submission of dossier has been verified from R&I section, hence Board advised PE&R Division to present the said applications in upcoming meetings of Registration Board with complete details of applied formulation.**

ii. **Deferred the applications of products at Sr. No. 90-93 for submission of original receipt for submission of fee of Rs. 8,000/- within 6 months of publication of minutes of instant meeting on DRAP website.**

iii. **Deferred the applications of products at Sr. No. 107-113, 115-123, 125, 127-129, 131-132 for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.**

iv. Deferred the applications of products at Sr. No. 114, 124, 126, 130 for submission of original receipt for submission of fee of Rs. 8,000/- and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website

2. **Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Ferozpur Road Lahore** has submitted only receipt of following products. Detail is as under:

Sr. No.	Brand Name and composition	Detail of Rs.8000/-	Detail of Rs.12000/-
133.	Fenticon-V 2% Cream Fenticonazole Nitrate	Diary No. Nil. Dated 27-10-2010	Only fee challan dated 05-12-2018
134.	Fenticon 2% Cream Fenticonazole Nitrate	Diary No. Nil. Dated 27-10-2010	Only fee challan dated 05-12-2018
135.	Titol Sachet Lactitol Monohydrate 10gm	Diary No. Nil. Dated 16-11-2010	Only fee challan dated 22-05-2013
136.	Ultra Tablet 120mg	Diary No. Nil. Dated 30-04-2008	Only fee challan dated 20-05-2013
137.	Daylite-Z ORS Sachet Sodium Chloride … 3.5gm Potassium Chloride … 1.50gm Sodium Citrate … 2.9gm Dextrose Anhydrous … 20gm	Diary No. Nil. Dated 14-09-2010	Only fee challan dated 20-05-2013
138.	Daylite ORS Sachet Sodium Chloride … 1.3gm Potassium Chloride … 0.75gm Sodium Citrate … 1.45gm Glucose Anhydrous … 6.75gm	Diary No. Nil. Dated 14-09-2010	Only fee challan dated 20-05-2013
139.	OMC Suspension Vitamin D3 … 400IU Ossein Mineral Complex … 250mg Eq. to Calcium … 53.5mg Phosphorus … 24.8mg Residual Mineral Salt … 7.5mg Collagen … 87.5mg Other Proteins … 20mg	Diary No. Nil. Dated 14-09-2010	Only fee challan dated 20-05-2013
140.	Cinpride Syrup 1mg/5ml Cinitapride as Tartrate	Diary No. Nil. Dated 29-11-2010	Only fee challan dated 05-12-2018
141.	Calcipo Ointment Calcipotriol as hydrate … 50mcg Betamethasone Dipropionate…0.5mg	Diary No. Nil. Dated 30-07-2010	Only fee challan dated 18-02-2019
142.	Rasa Tablet 1mg	Diary No. Nil. Dated 16-11-2010	Only fee challan dated 20-05-2013
143.	Rasa Tablet 0.5mg	Diary No. Nil. Dated 16-11-2010	Only fee challan dated 20-05-2013
144.	Betin Tablet 48mg Betahistine as Dihydrochloride	Diary No. Nil. Dated 29-12-2010	Only fee challan dated 22-05-2013
145.	Colmin Tablet Ossein Mineral Complex 830mg Eq. to Calcium … 177.6mg Phosphorus … 82.2mg Residual Mineral Salt … 24.8mg	Diary No. Nil. Dated 29-12-2010	Only fee challan dated 26-03-2015

	Collagen … 224mg Other Protein … 88.4mg		
146.	Mosefen Tablet 0.5mg Pizotifen Maleate	Diary No. Nil. Dated 18-10-2010	Only fee challan dated 20-05-2013
147.	Benz-C Lotion Clindamycin Phosphate … 10mg/ml Benzyl peroxide … 50mg/ml	Diary No. Nil. Dated 31-03-2010	Only fee challan dated 20-05-2013
148.	Noxicam Tablet 8mg Lornoxicam	Diary No. Nil. Dated 31-03-2012	Only fee challan dated 06-02-2018

Decision: Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.

3. **M/s. Fozan Pharmaceuticals Industries (Pvt) Ltd., Peshawar** has submitted a request vide diary No. 31678 dated 03-11-2022 stating that they have submitted application in 2010 as per following details. **They have not attached any receiving of applications** except for product at Sr. No. 05 for which receiving of Rs.12000/- was attached. They have submitted only copies of intimation vide dy. No. nil dated 09-10-2019. Submitted detail is as under:

Sr. No.	Brand Name and composition	Detail of Rs.8000/-	Detail of Rs.12000/-
149.	Nitrofoz SR 2.5mg Capsule	23-09-2010	28-12-2017
150.	Nitrofoz SR 6mg Capsule	23-09-2010	28-12-2017
151.	Pletoz Extra 150mg Tablet	23-09-2010	28-12-2017
152.	Pletoz Extra 75mg Tablet	23-09-2010	28-12-2017
153.	Amlozan 5mg Tablet	23-09-2010	Diary no. Nil 28-12-2017

Decision: Registration Board discussed that the submission of above cited dossiers have been verified from R&I section, hence Board advised PE&R Division to present the said applications in upcoming meeting of Registration Board with complete details of applied formulation. Registration Board further directed the firm to submit following:

- **Verification of duplicate fee challans as per decision of 285th meeting of Registration Board.**
- **Latest GMP inspection report conducted within period of three years.**
- **Fee of Rs. 9000/- for pre-approval variation in drug product Specifications.**

4. **Obsons Pharmaceuticals, Lahore** has submitted only receipt of following products. Detail is as under:

Sr. No.	Brand Name and composition	Remarks
154.	Clazine MR tablet 30mg Each modified release tablet contains: Gliclazide……30mg	Dy. No. 13930 dated 26-12-204 and old intimation dated 10-03-2023 (**No evidence regarding initial application and fee submission is attached**)
155.	Clazine MR tablet 60mg Each modified release tablet contains: Gliclazide……60mg	
156.	Obpizine syrup (120ml) Each 5ml contains: Levodropropizine……30mg	
157.	Obsilate tablet 500mg Each film coated tablet contains:	

	Calcium dobesilate……..500mg	
158.	Obispro tablet 2.5mg Each film coated tablet contains: Bisoprolol Fumarate……..2.5mg	
159.	Obispro tablet 5mg Each film coated tablet contains: Bisoprolol Fumarate……..5mg	
160.	Obfan syrup Each 5ml syrup contains: Dimemorfan phosphate…….12.5mg	
161.	Oboroxon capsule 250/300mg Each capsule contains: Chlorzoxazone……250mg Paracetamol……300mg	
162.	Obtor 90mg tablet Each film coated tablet contain: Etoricoxib……90mg	
163.	Obtor 120mg tablet Each film coated tablet contain: Etoricoxib……120mg	

Decision: Registration Board deferred the applications at Sr. No. 154-163 for submission of original receipt for submission of fee of Rs. 8,000/- and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.

5. M/s Shawan Pharmaceuticals, Rawat Rawalpindi has submitted request Dy. No. 13435 dated 17-12-2024 in which firm has attached letter dated 28-12-2016 in response to letter Dy. No. 924/PEC-DRAP-AD(PE&R) dated 10-11-2016 in which stability data was demanded. The firm has stated that please find attach stability data for **Hepa-C Kure 400mg tablet (Sofosbuvir)**. However, no evidence of initial application and fee Rs. 8000/- & Rs.12000/- submission attached.

Decision: Registration Board deferred the instant application for submission of original receipt for submission of fee of Rs. 8,000/- and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website.

6. Following receipts of **Masfa Industries (Pvt) Ltd.,** are available in PEC.

Sr. No.	Brand Name and composition	Detail of Submissions
164.	Natodine Suspension 200mg/5ml Each 5ml contains; Metronidazole benzoate … 200mg Di-Iodohydroxyquinoline … 200mg	Rs.8000/- Dy. No. nil dated 02-04-2011 **No evidence of Rs.12000/-**
165.	Mascon Gel Dicyclomine HCl … 2.5mg Aluminium Hydroxide … 200mg Magnesium Oxide … 100mg Simethicone 20mg	Rs.8000/- Dy. No. nil dated 02-04-2011 **No evidence of Rs.12000/-**
166.	Laxiron Liquid Sodium Picosulphate monohydrate … 5mg/5ml	Rs.8000/- Dy. No. nil dated 01-06-2011 **No evidence of Rs.12000/-**

Decision: Registration Board decided as follows:

i. **Deferred the product at Sr. No. 164 for evidence of approval of applied formulation in RRA**
ii. **Approved the products at Sr. No. 165-166. Registration Board further decided that Registration letter shall be issued after the following:**

- **Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.**
- **verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.**
- **fee Rs. 9000/- for pre-approval variation in FPP Specifications**

d. **Duplicate dossiers/intimation submitted after the deadline:**

Following firms have submitted duplicate dossiers after the lapse of deadline set by DRAP Authority for the submission of duplicate dossiers of Form 5/5D.

Sr. No.	Name of Firm	Name and composition of Drug Product	Detail of Diary No. Date of R& I & fee
167.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan	Clariper 125mg/5ml Dry Suspension Each 5ml contains: Clarithromycin…125mg	Dy. No. 8974 dated 28-08-2024 Rs. 20,000/- (**No STO endorsement**) Only photocopy of fee challan
168.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan **Contract with M/s Meditate pharmaceuticals Pvt. Ltd., Karachi**	Magnazon 500mg IM Injection Each Vial Contains: Ceftrixone as Sodium…500mg	Dy. No. 8974 dated 28-08-2024 Form-5 Copy of cover letter with fee endorsement Rs. 50,000/- dated 06-01-2019 (**No R&I receiving stamp)**
169.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan **Contract with M/s Meditate pharmaceuticals Pvt. Ltd., Karachi**	Magnazon 250mg IM Injection Each Vial Contains: Ceftrixone as Sodium…250mg	Dy. No. 8974 dated 28-08-2024 Form-5 Copy of cover letter with fee endorsement Rs. 50,000/- dated 06-01-2019 (**No R&I receiving stamp)**
170.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan	Uroperk CR 10mg tablets Each controlled release tablet contains: Potassium citrate…10mg	Dy. No. 8973 dated 28-08-2024 Dy. No. nil dated 04-03-2019 Rs. 20,000/- (photocopy) to be verified
171.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan	Hydroper Syrup 32mg/8mg/30mg/0.98mg Each 5ml contains: Aminophylline…32mg Diphenydramine HCl…8mg Ammonium Chloride…30mg Menthol…0.98mg	Dy. No. 8971 dated 28-08-2024 Rs. 20,000/- (**No STO endorsement**) **Only photocopy of fee challan** Submission of RRA and metoo reference vide letter dy. No. nil, dated 22-03-2021
172.	M/s Perk Pharma Pvt. Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan	Hydroper DM Syrup 6.25mg/5mg/ Each 5ml contains: Dextromethorphan HBr…6.25mg Diphenydramine HCl…5mg	Dy. No. 8970 dated 28-08-2024 **No evidence of application and fee submission in DRAP is attached**

173.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Benkomet tablet Glyburide …2.5mg Metformin HCl …500mg	Dy. No. 13434 dated 17-12-2024 Dy. No. nil dated 09-05-2009 Rs. 8000/- dated 09-05-2009 (photocopy to be verified) **No evidence of fee Rs. 12,000/- submission in DRAP is attached**
174.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	I-top 50mg tablet Itopride HCl	Dy. No. 13433 dated 17-12-2024 **No evidence of fee and initial application submission in DRAP is attached** Copy of deficiency letter No. F. 1-1/2018/PEC-DRAP (AD PEC-VI) dated 05-11-2018
175.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Velmin 50/1000mg tablet Vildagliptin 50mg / Metformin HCl 1000mg	Dy. No. 13433 dated 17-12-2024 **No evidence of fee and initial application submission in DRAP is attached** Copy of deficiency letter No. F. 1-1/2018/PEC-DRAP (AD PEC-VI) dated 05-11-2018
176.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Velmin 50/850mg tablet Vildagliptin 50mg / Metformin HCl 850mg	Dy. No. 13433 dated 17-12-2024 **No evidence of fee and initial application submission in DRAP is attached** Copy of deficiency letter No. F. 1-1/2018/PEC-DRAP (AD PEC-VI) dated 05-11-2018
177.	M/s Shawan Pharmaceuticals, Plot No. 37 road NS-1, National Industrial Zone, Rawat Rawalpindi	Tramol 100mg tablets Tramadol 100mg	Dy. No. 13433 dated 17-12-2024 **No evidence of fee and initial application submission in DRAP is attached** Copy of deficiency letter No. F. 1-1/2018/PEC-DRAP (AD PEC-VI) dated 05-11-2018
178.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Azilex 500mg capsule Each capsule 1383ontains: Azithromycin Dihydrate eq. tyo Azithromycin …500mg	Dy. No. 9728 dated 12-09-2024 Form 5 Dy No. nil dated 23-12-2013 Rs.20000/- dated 23-12-2013(photocopy) to be verified
179.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Laxit Syrup Each 5ml 1383ontains: Lactulose …..3.335g	Dy. No. 9728 dated 12-09-2024 Form 5 Dy No. nil dated 30-12-2014 Rs.20000/- dated 30-12-2014 (photocopy) to be verified

180.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	D'vela 50mg Tablet Desvenlafaxine Sucinate as Desvenlafaxine…50mg	Dy. No. 9728 dated 12-09-2024 Form 5 Dy No. nil dated 13-03-2014 Rs.20000/- dated 13-03-2014 (photocopy) to be verified
181.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Neuroline tablet Each tablet contains paracetamol ….650mg orphenadrine Citrate….50mg	Dy. No. 9728 dated 12-09-2024 Form 5 Dy No. nil dated 09-04-2014 Rs.20000/- dated 09-04-2014 (photocopy) to be verified
182.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Diclowim 50mg capsule Each capsule 1384ontains: Diclofenac Sodium as enteric coated pellets ….50mg	Dy. No. 9728 dated 12-09-2024 Form 5 Dy No. nil dated 20-06-2016 Rs.20000/- dated 20-06-2016 (photocopy) to be verified
183.	M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.	Meloximil 5/40mg Tablet Each tablet contains: Olmesartan Medoxomil…40mg Amlodipine (as besylate)…5mg	Dy. No. 13981 dated 27-12-2024 Form-5 Dy.No nil dated 06-03-2019 Rs.20,000/- dated 05-03-2019 (photocopy) to be verified
184.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Nalcid injection Nalbuphine HCl 10mg/1ml	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
185.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Ketone injection 2ml Ketoprofen 50mg/ml	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
186.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Tramin injection 2ml Tramadol HCl 100mg/2ml	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
187.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old	Succiride injection 2ml Suxamethonium Chloride 100mg/2ml	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in**

	industrial Area, Mirpur, Azad Kashmir		**covering letter and no fee challan submitted**
188.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Calcicure injection 10ml Calcium Gluobionate.....1.375gm Vitamin C.....500mg	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
189.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Spasmic injection 4ml Phloroglucinol 40mg	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 24-12-2004 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
190.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Tranamin tablet Tranexamine Acid 500mg	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 29-10-2005 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
191.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Buprine injection 1ml Buprenorphine as HCl 0.3mg/ml	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 20-03-2006; Fee. 8,000, (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
192.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Roudine tablet Roxithromycin.....150mg	Dy No.13991 dated 27-12-2024 Dy. No. nil dated 22-12-2006 (photocopy) **No STO stamp in covering letter and no fee challan submitted**
193.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Polyton syrup 60ml & 120ml Iron III Hydroxide polymaltose complex + Folic Acid	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 29-11-2008; Fee. 8,000 dated 23-11-2008 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
194.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area,	Dexofen suspension 120ml Dexibuprofen 100mg/5ml	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 29-11-2010; Fee. 8,000 dated 26-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**

	Mirpur, Azad Kashmir		
195.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Aksonol Syrup Ephedrine 5mg, Cholorpheniramine maleate 5mg, Tr. Ipecac 0.025mg, potassium Guaiacol sulphonate 5mg, potassium salt 0.1mg , Ammonium chloride 25mg , Tr. Senega 0.05ml, Menthol 1mg , Terpin hydrate 10mg, postassium Bicarbonate 0.1mg/5ml (120mlx 1's)	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 06-01-2011; Fee. 8,000 dated 06-01-2011 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
196.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Sulosin capsules Tamsulosin HCl.....0.4mg	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 22-10-2018; Fee. 20,000 dated 26-10-2018 (Photocopy) to be verified
197.	M/s Akson Pharmaceuticals Pvt. Ltd, Plot No 9-B/1 & 2 Sector D/1, Old industrial Area, Mirpur, Azad Kashmir	Esozole 60 capsules Dexlansoprazole 60mg capsule	Dy No.13991 dated 27-12-2024 Dy. No. nil, dated 07-12-2018; Fee. 20,000 dated 07-12-2018 (Photocopy) to be verified
198.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Airin EX Syrup Each 5ml contains: Salbutamol 1mg Guaifenesin 50mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 23-02-2011; Fee. 8,000 dated 22-02-2011 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
199.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Legaspar 100mg tablet Each film coated tablet contains: Sparfloxacin.....100mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 23-02-2011; Fee. 8,000 dated 22-02-2011 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
200.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Legocenic 100mg tablet Each film coated tablet contains: Acelofenec 100mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 23-02-2011; Fee. 8,000 dated 22-02-2011 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**

201.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Ribena F 0.55 tablet Each chewable tablet contains: Iron polymaltose 100mg Folic acid 0.55mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 23-02-2011; Fee. 8,000 dated 22-02-2011 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
202.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Lepride 50mg tablet Each film coated tablet contains: Itopride 50mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
203.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Levitor 10mg tablet Each film coated tablet contains: Atorvastatin as Calcium trihydrate 10mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
204.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Levitor 20mg tablet Each film coated tablet Atorvastatin as calcium trihydrate 20mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
205.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Levitor 40mg tablet Each film coated tablet Atorvastatin as calcium trihydrate 40mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
206.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Mylarin 200mg tablet Each tablet contains: Silymylarin 200mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
207.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Mylaring 100mg Syrup Each 5ml contains: Silymylarin 100mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
208.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Rocit syrup Each 5ml contains: Sodium Acid Citrate	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**

209.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Septra tablet Each tablet contains: Trimethoprim 80mg Sulphamethoxazole 400mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
210.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Septra Suspension Each 5ml contains: Trimethorprim 40mg Sulphamethoxazole 200mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
211.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Septra DS tablet Each tablet contains: Trimethorptim 160mg Sulphamethoxazole 800mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
212.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Zosar 25mg tablet Each film coated tablet contains; Losartan potassium 25mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
213.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Zosar 50mg tablet Each film coated tablet contains; Losartan potassium 50mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
214.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Zosar plus tablet Each film coated tablet contains; Losartan potassium 25mg Hydrochlorothiazide 12.5mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
215.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Rebina tablet Each tablet contains: Iron polymaltose 100mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
216.	M/s Legacy pharmaceuticals Pvt. Ltd., Peshawar	Lesolide 100mg Each tablet contains: Nimesulide 100mg	Dy.No.14190 dated 30-12-24 Dy. No. nil, dated 11-11-2010; Fee. 8,000 dated 11-11-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
217.	M/s Xenon Pharmaceuticals (Pvt) Ltd. Lahore	Volika BC tablet Pirocicam B Cyclodextrin 20mg	Dy.No.14161 dated 30-12-2024 Dy. No. nil, dated 20-12-2010; Fee. 8,000 dated 20-12-2010 (Photocopy) to be verified

			Dy. No. nil, dated 03-12-2019; Fee. 12,000 dated 02-12-2019 (Photocopy) to be verified
218.	M/s Xenon Pharmaceuticals (Pvt) Ltd. Lahore	Vosta tablet 5mg Rosuvastatin as calcium	Dy.No.14162 dated 30-12-2024 Dy. No. nil, dated 06-06-2012; Fee. 8,000 dated 06-06-2012 (Photocopy) to be verified Dy. No. nil, dated 03-01-2020; Fee. Rs. 108000/- (9x12,000?) (Photocopy) to be verified
219.	M/s Xenon Pharmaceuticals (Pvt) Ltd. Lahore	Zeflam tablet 75mg Diclofenac potassium	Dy.No.14163 dated 30-12-2024 Dy. No. nil, dated 30-01-2012; Fee. 8,000 dated 30-01-2012 (Photocopy) to be verified Dy. No. nil, dated 03-12-2019; Fee. 12,000 dated 02-12-2019 (Photocopy) to be verified
220.	M/s Xenon Pharmaceuticals (Pvt) Ltd. Lahore	Asefyl Syrup Acefylline piperazine & Diphenhydramine HCl	Dy.No.14160 dated 30-12-2024 Dy. No. nil, dated 23-05-2011; Fee. 8,000 dated 23-05-2011 (Photocopy) to be verified Dy. No. nil, dated 03-12-2019; Fee. 12,000 dated 02-12-2019 (Photocopy) to be verified
221.	M/s Semos Pharmaceuticals, Karachi **Contract manufacturing by** M/s Safe Pharmaceuticals (pvt) Ltd., Karachi	Moslve infusion 500mg/100ml Levofloxacin hemihydrate	Dy. No.14152 dated 30-12-2024 and intimation dated 01-08-2024 Dy. No. nil, dated 07-03-2019; Fee. 50,000 dated 07-03-2019 (Photocopy) to be verified The firm has mentioned on case management portal that they had sent reminders on 12-12-2023 and 13-05-2024, but no receiving is attached.
222.	M/s Semos Pharmaceuticals, Karachi **Contract manufacturing by** M/s Safe Pharmaceuticals (pvt) Ltd., Karachi	Semodazol infusion 500mg/100ml Metronidazole	Dy. No.14151 dated 30-12-2024 and intimation dated 01-08-2024 Dy. No. nil, dated 07-03-2019; Fee. 50,000 dated 07-03-2019 (Photocopy) to be verified The firm has mentioned on case management portal that they had sent reminders on 12-12-2023 and 13-05-2024, but no receiving is attached.
223.	M/s Semos Pharmaceuticals, Karachi **Contract manufacturing by** M/s Safe	Lizolid infusion 600mg /300ml Linezolid	Dy. No.14150 dated 30-12-2024 and intimation dated 01-08-2024 Dy. No. nil, dated 07-03-2019; Fee. 50,000 dated 07-03-2019 (Photocopy) to be verified The firm has mentioned on case management portal that they had

	Pharmaceuticals (pvt) Ltd., Karachi		sent reminders on 12-12-2023 and 13-05-2024, but no receiving is attached.
224.	M/s Semos Pharmaceuticals, Karachi **Contract manufacturing by** M/s Safe Pharmaceuticals (pvt) Ltd., Karachi	Volnac injection 75mg/3ml Diclofenac sodium	Dy. No.14149 dated 30-12-2024 and intimation dated 01-08-2024 Dy. No. nil, dated 07-03-2019; Fee. 50,000 dated 07-03-2019 (Photocopy) to be verified The firm has mentioned on case management portal that they had sent reminders on 12-12-2023 and 13-05-2024, but no receiving is attached.
225.	M/s Epoch pharmaceuticals, Karachi.	Unitears eye drops Hydroxypropylmethylcellulose	Dy. No.13354 dated 16-12-2024 Dy. No. nil, dated 02-03-2010; Fee. 8,000 dated 02-03-2010 (Photocopy) to be verified **No evidence of Rs.12000/- submission attached**
226.	M/s Epoch pharmaceuticals, Karachi.	Rosil tab 2mg Rosiglitazone	Dy. No.13354 dated 16-12-2024 **No evidence of initial application and fee Rs. 8000/- & Rs.12000/- submission attached**
227.	M/s Epoch pharmaceuticals, Karachi.	Rosil tab 4mg Rosiglitazone	Dy. No.13354 dated 16-12-2024 **No evidence of initial application and fee Rs. 8000/- & Rs.12000/- submission attached**
228.	M/s Epoch pharmaceuticals, Karachi.	Rosil tab 8mg Rosiglitazone	Dy. No.13354 dated 16-12-2024 **No evidence of initial application and fee Rs. 8000/- & Rs.12000/- submission attached**
229.	M/s Epoch pharmaceuticals, Karachi.	Emoglobin syrup Iron plus vitamins	Dy. No.13354 dated 16-12-2024 Dy No. nil dated 24-08-2004 **No evidence of fee Rs. 8000/- & Rs.12000/- submission attached**
230.	M/s Medisynth Pharmaceutical, Main G.T Road Banth stop Mouza jellyari Gujri Teshsil Fujar khan Rawalpindi **contract manufacturing by M/s Cure** Laboratories (pvt) Ltd, Plot No 11& 12 NS -2,RCCI Industrial estate , Rawawt	Medzone 500mg (IV) injection Each vial contains: Ceftriaxone as sodium ….250mg	Dy. No. 13494 R&I(DRAP) dated 18-12-2024. Dy. No. nil dated 21-11-2017 and claimed that **adjust 280000/- fee for renewal before SRO 1005(1)** which was not accepted, in these application Submitted the form 5 with new address

231.	M/s Medisynth Pharmaceutical, Main G.T Road Banth stop Mouza jellyari Gujri Teshsil Fujar khan Rawalpindi **contract manufacturing by M/s Cure** Laboratories (pvt) Ltd, Plot No 11& 12 NS -2,RCCI Industrial estate , Rawawt	Medzone 1Gm (IV) injection Each vial contains: Ceftriaxone as sodium ….1Gm	Dy. No. 13494 R&I(DRAP) dated 18-12-2024. Dy. No. nil dated 21-11-2017 and claimed that **adjust 280000/- fee for renewal before SRO 1005(1)** which was not accepted, in these application Submitted the form 5 with new address
232.	M/s Medisynth Pharmaceutical, Main G.T Road Banth stop Mouza jellyari Gujri Teshsil Fujar khan Rawalpindi **contract manufacturing by M/s Cure** Laboratories (pvt) Ltd, Plot No 11& 12 NS -2,RCCI Industrial estate , Rawawt	Medzone 250mg (IM) injection Each vial contains: Ceftriaxone as sodium ….250mg	Dy. No. 13493 R&I(DRAP) dated 18-12-2024. Dy. No. nil dated 21-11-2017 and claimed that **adjust 280000/- fee for renewal before SRO 1005(1)** which was not accepted, in these application Submitted the form 5 with new address

Decision: The Registration Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5907 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 25/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	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	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6411 dated 07-03-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 10/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…10mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	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	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F:

		Dy.No 7388 dated 14-03-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 12.5/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5908 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 5/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg

	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
Evaluation by PEC^{II}:		
Decision of 339th Meeting: Registration Board approved the applications of Voreta Plus XR Tablet 25/1000mg, Voreta Plus XR Tablet 10/1000mg, Voreta Plus XR Tablet 10/1000mg & Voreta Plus XR Tablet 12.5/1000mg.		

In above decision of 339th meeting Voreta Plus XR Tablet 10/1000mg was mentioned instead of Voreta Plus XR Tablet 5/1000mg. Hence, case is placed before Registration Bard for correction in minutes.

Decision: Registration Board noted the correction in minutes and approved the instant application of Voreta Plus XR Tablet 5/1000 mg.

b. RRR Section

Case No.01: Lucky Core Industries Limited (Formerly M/s. Pfizer Pakistan Limted B-2, S.I.T.E, Karachi

1.	Brand Name + Dosage Form and Strength	Ponstan Suspension
	Composition	Each 5ml contains: Mefenamic Acid…….50mg
	Dairy No. date of R &I fee	13721 dated 23.12.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	Not provided
	Pack size and Demand Price	As per SRO,60ml Amber glass bottle.
	GMP Status	GMP inspection report dated 03.07.2024
	RRA status	Applied formulation is approved in MHRA.
	Remark of the Renewal section	Registration of Ponstan Suspension (005539) was due on 29.05.2021. Firm has applied fresh due to non-submission of renewal. Approval for change of title from M/s Pfizer Pakistan limited to M/s lucky core industries dated 04.12.2024

		Applied formulation is not found available in any official monograph.
	Decision: Approved	

Case No. 02 M/s. Genome Pharma House No.593-B, Street no.10, Chaklala Scheme III, Rawalpindi

Sr. No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Decision /remarks
1.	057127	Gentogen 10 Injection Each ml Contains: Gentamycin Sulphate eq. to 100mg Gentamycin base	03/06/2009	Rs.80000/- Dated 02.09.2019	USFDA approved for the Treatment and Control of Internal and External Parasites of Cattle and Swine **Regularized renewal fee for the period of 03.06.2019 to 02.06.2024.** **However, renewal for the period of 03.06.2024 to 02.06.2029 yet to be applied.**
2.	057133	Ivect-1% Injection Each ml Contains: Ivermectin…10mg	03/06/2009	Rs.80000/- Dated 02.09.2019 Rs 30,000/- Dated 01.06.2024 Tracking ID UL1-28B-85LH	Renewal is granted w.e.f.03.06.2024 to 02.06.2029 USFDA approved. for the Treatment and Control of Internal and External Parasites of Cattle
3.	057140	Oxygen LA Injection Each ml Contains: Oxytetracycline HCl eq. to 200mg base	03/06/2009	Rs.80000/- Dated 02.09.2019	USFDA approved. For the treatment of disease in beef cattle; dairy cattle; calves, **Regularized renewal fee for the period of 03.06.2019 to 02.06.2024.** **However, renewal for the period of 03.06.2024 to**

					02.06.2029 yet to be applied.
4.	057141	Penstin 5gm Injection Each Vial Contains: Benzyl Penicillin…0.5MIU Procaine Penicillin…1.5MIU Dihydrostreptomycin Sulfate…5gm	03/06/2009	Rs.80000/- Dated 02.09.2019	**Regularized renewal fee for the period of 03.06.2019 to 02.06.2024.** **However, renewal for the period of 03.06.2024 to 02.06.2029 yet to be applied.**
5.	057144	Enronom 20 Injection Each ml Contains: Enrofloxacin…200mg	03/06/2009	Rs.80000/- Dated 02.09.2019	**Regularized renewal fee for the period of 03.06.2019 to 02.06.2024.** **However, renewal for the period of 03.06.2024 to 02.06.2029 yet to be applied.**
6.	057134	Ivect-2% Injection Each ml contains:- IVERMECTIN….20MG	03/06/2009	Rs.40000/- Dated 23.07.2019 Rs 30,000/- Dated 01.06.2024 Tracking ID GZA-SBH-WLSA	Renewal is granted w.e.f.03.06.2024 to 02.06.2029
7.	057138	Linkospel Injection Each ml contains:- Lincomycin…50mg Spectinomycin…100mg	03/06/2009	Rs.40000/- Dated 23.07.2019	EMA approved Linspec 50/100 mg/ml Solution for injection for dogs, cats, pre-ruminant calves **Regularized renewal fee for the period of 03.06.2019 to 02.06.2024.** **However, renewal for the period of 03.06.2024 to 02.06.2029 yet to be applied.**
8.	057143	Amoxygen LA Injection Each ml contains:- Amoxicillin trihydrate…150mg	03/06/2009	Rs.40000/- Dated 23.07.2019	EMA approved For Cattle, sheep, pigs, dogs, cats

					Regularized renewal fee for the period of 03.06.2019 to 02.06.2024. **However, renewal for the period of 03.06.2024 to 02.06.2029 yet to be applied.**
Manufactured By: M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd. China					

Remarks:

Firm has submitted differential fee as renewal applications of products at Sr No 6-8 submitted after prescribe time period but within 60 days while renewal application for products at Sr No 1-5 is received after 60 days but within a year. Now the firm has requested for regularization for above mentioned product.

c. Registration I&V

Case. No.01:- <u>Request of M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore for registration from import of local manufacturing of already registered veterinary drugs.</u>

M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore has requested registration from import to local manufacturing of already registered imported veterinary drugs. The details are as under:-

Sr. No.	Regn. No.	Name of Manufacturer	Name of Drug(s/Composition	Approved pack site(s)	Date of initial regn./ Renewal	Remarks
1.	022175	M/s. Farvet Laboratories, BV, office if at Handelsweg 25,5531 AE Bladel, The Netherlands.	Vitamin AD_3E Injection Each ml contains:- Retinyl Palmitate (Vitamin A).....…80,000IU Tocopherol Acetate (Vitamin E)……..….20mg Cholecalciferol (Vitamin D_3)……..…..40,000IU	50ml	04-12-1998 17-11-2023	Dy.No.7119-R&I Dated 12-07-2024
			Vitamin AD_3E Injection Each ml contains:- Retinyl Palmitate (Vitamin A)...…….80,000IU Tocopherol Acetate (Vitamin E)……...20mg Cholecalciferol (Vitamin D_3)……..40,000IU	100ml		
2.	026452		Oxyfar 10% Injectable Solution	50ml	06-02-2001	

			Each ml contains:- Oxytetracycline (as hydrochloride)…..100mg		11-03-2021	
			Oxyfar 10% Injectable Solution Each ml contains:- Oxytetracycline (as hydrochloride)…..100mg	100ml		
3.	015448		Gentafar 10% Injectable Solution Each ml contains:- Gentamicin Sulphate equivalent to 100mg Gentamicin base.	50ml	19-10-1994 07-10-2019	
			Gentafar 10% Injectable Solution Each ml contains:- Gentamicin Sulphate equivalent to 100mg Gentamicin base.	100ml		
4.	020761		Fartylo 200 Injection Each ml contains:- Tylosin……..200mg	50ml	04-12-1997 07-10-2019	
			Fartylo 200 Injection Each ml contains:- Tylosin……..200mg	100ml		

M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore has deposited the required fee of **Rs.30,000 x 8 = Rs. 240,000/-** and submitted following supporting documents:-

(i) Copies of registration letters/renewal.
(ii) Original NOC from manufacturer abroad M/s. Farvet Laboratories, BV, office if at Handelsweg 25,5531 AE Bladel, The Netherlands
(iii) Copy of latest GMP inspection report.
(iv) Registration dossiers for each product.

Decision:- Registration Board decided as follow;

(a) Approved cancellation of registration of above mentioned products from the name of M/s. Prix Pharmaceutica, 26-Abbot Road, Lahore manufactured by M/s. Farvet Laboratories, BV, office if at Handelsweg 25,5531 AE Bladel, The Netherlands.

(b) Approved the registration of above mentioned products in the name of M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore.

(c) Letter shall be issued after provision / verification of NOC form existing registration holder.

Recommendations of Sub-Committee on Veterinary Drugs Held on 27th December, 2024

Case. No.02:- INFORMATION FOR LISTING THIRD COUNTRIES-COMMISSION DELEGATED REGULATION (EU) 2023/905

Letter no. 2-5/2006-EPID-P-00004 dated 04th November 2024 received from Dr. Muhammad Shahjahan Zafar RO Epidemiology, ministry of National Food Security details of which is as under:

The undersigned is directed to refer to DRAP letter No.6-6/2023-QA dated 01-12-2023 above subject and to state that EU has inquired an update regarding the status of the deregistration process for amantadine used in veterinary medicine.

Amantadine has been classified by the EU among antibiotics reserved veterinary purposes may consequently lead to EU ban on the export of livestock products from Pakistan. Such de-registration in Pakistan holds particular significance, safeguarding the livestock trade interests and aligning with international standards.

DRAP, kindly requested to provide an update on the status of the deregistration of amantadine used in combination formulations and single amantadine formulations for veterinary use. If deregistration has not yet been completed, an anticipated timeline for the process's completion would be appreciated.

Above case was considered in 343rd meeting of Registration Board and Board decided to refer the case to Sub-committee on veterinary drugs.

European Commission Directorate General SANTE has requested and update on following two aspects:

a. *Pakistan's commitment to de-register amantadine for use in food producing animals. They have requested for an official reference de-registering the amantadine, and in case it has not been de-registered, the expected date of de-registration.*
b. *Update or modification to the regulatory framework of Pakistan, if any.*

International Practice:

Amantadine, originally developed as an antiviral medication, has been used off-label in veterinary medicine to manage chronic pain in animals, particularly dogs. However, concerns about antimicrobial resistance have led to regulatory changes regarding its use in animals.

In the European Union (EU), a ban on the use of certain antimicrobials in animals, including amantadine, came into effect on February 9, 2023. This measure aims to preserve the effectiveness of critical antimicrobials for human health by restricting their use in veterinary medicine.

The use of Amantadine in animals has been banned from February 9, 2023. Amantadine products are not authorised or marketed in Finland, but in individual cases special authorisations have been granted for the release of amantadine products for consumption for **dog and cat patients**.

In line with the objectives of the Veterinary Medicinal Products Regulation 2019/6, certain antimicrobials are reserved only for human treatment in order to maintain their efficacy. The Annex to Implementing

Regulation 2022/1255 lists the antimicrobials and categories of antimicrobials affected by the amendment. In practice, the use of the antimicrobials listed in the Annex in veterinary medicinal products is prohibited, as is the use of medicinal products for human use in animals containing them. The ban will apply from 9 February 2023.

According to information from Fimea and the Finnish Food Authority, the only antimicrobial medicine listed in the appendix that is used for animals in Finland is amantadine. All special authorisations for amantadine granted for animal use will be revoked during January 2023 so that the authorisations will expire when the ban enters into force. Fimea and the Finnish Food Authority will issue a joint letter informing veterinarians whose patients have a valid special authorisation for amantadine products.

Pharmaceutical wholesalers, pharmacies and veterinarians must take into account the upcoming ban when dispensing amantadine products. The quantity of amantadine donated prior to the start of the moratorium must correspond to actual need.

Ban on the use of Amantadine in animals enters into force 9.2.2023 - Fimea.fi - Fimea

Similarly, in the United States, the following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in **chickens, turkeys, and ducks**:

(1) Adamantanes. (Amantadine, Rimantadine)
(2) Neuraminidase inhibitors.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=530.41&utm_source=chatgpt.com

CFR - Code of Federal Regulations Title 21

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended that Amantadine be banned for use in food-producing animals due to concerns about drug resistance and food safety. However, Amantadine remains available for limited use in pet animals in some regions. Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only. Furthermore, the Sub-committee also recommended reviewing the pack sizes of Amantadine-containing formulations.

Decision:

Keeping in view the recommendations of the Sub-committee, the Registration Board decided as follows:

1. **Ban the use of Amantadine in food-producing animals** due to concerns about drug resistance and food safety. The use of Amantadine formulations is restricted to **non-food-producing pet animals only.**
2. Regarding pack sizes, the Board referred the case to the Sub-committee to **review the pack sizes of Amantadine-containing formulations and share recommendation for consideration of the Registration Board.**

The Board also advised the section to **issue an advisory regarding the restricted use of Amantadine formulations for non-food-producing pet animals only, without waiting for the approval of the minutes.**

d. Post Registration Variation-I

Case.No. 1 APPLICATION OF CHANGE OF MARKET AUTHORIZATION HOLDER AND CHANGE OF MANUFACTURING SITE OF XANAX TABLET 0.25MG, 0.5MG & 1MG

M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore having DML No. 000243 (Formulation) has submitted request for change of Importer/Market Authorization Holder in Pakistan along with Change of Manufacturing Site of Drug Product from M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi to M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore

NOC dated : 11th September, 2024 from M/s Pfizer Pakistan, Limited, Karachi regarding transfer of registration to M/s OBS Pakistan (Pvt) Ltd, Lahore is submitted.

Asset Purchase Agreement for trademark and marketing rights of Xanax is submitted.

As per PRV Guidelines 2nd Edition, following documents are required for change of manufacturing Site MaV-3:

Sr. No.	Documents required	Submission by the firm
1.	Application on Form 5F (CTD) for human drug products	The firm has submitted application on Form 5F
2.	Proof that the proposed site/ manufacturer is appropriately authorized for the pharmaceutical form concerned i.e., approval of manufacturing facility from Licensing Division and having valid GMP certificate.	The firm is authorized to manufacture psychotropic drug product vide Licensing Division letter No: F.1-43/85-Lic (Vol-IV) dated : 20th May 2024.
3.	In case of contract manufacturing, contract agreement with proposed manufacturer as per requirements laid down in SRO 1347(I)/2021 and contract termination letter with previously approved manufacturer by the MA holder.	Not applicable
4.	Comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms.	The firm has manufactured three lab scale batches of Xanax 0.25mg. 0.5mg and 1mg tablets. **Stability studies for both accelerated and real time are conducted for 01 month (02 points stability data is submitted i.e. initial and 1 month time point).**

		Batch details are as under: **For Xanax IMG** Batch No. OBSRD 01-001 Batch No. OBSRD 01-002 Batch No. OBSRD 01-003 **For Xanax 0.25 MG** Batch No. OBSRD 03-001 Batch No. OBSRD 03-002 Batch No. OBSRD 03-003 **For Xanax 0.5 MG** Batch No. OBSRD 02-001 Batch No. OBSRD 01-002 Batch No. OBSRD 01-003 Comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms is not provided
5.	Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the previous approved site.	The firm has submitted certificate of analysis in tabulated form of 03 lab scale batches manufactured at the proposed site and production batches of previously approved site.
6.	Revised drafts of the package insert and labeling incorporating the proposed variation (where applicable).	Revised drafts of the package insert and labeling incorporating the proposed variation are submitted

The cases submitted by the M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore pertains to change of registration holder and change of manufacturing site from M/s Pfizer Pakistan Limited, B-2, S.I.T.E. .Karachi to M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore .

As the change in registration holder for locally applied products does not cover under the ambit of post registration variation guidelines as matter also pertain to the registration of a psychotropic drug i.e Alprazolam hence the matter is placed before the registration Board for consideration please.

Decision of the Drug Registration Board in 343rd Meeting:

The Registration Board deliberated the matter in length and considered that as per PRV guidelines, document No. PE&R/GL/PV/001, Version II, for change of manufacturing site of registered Product, comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms is required. However, in the instant case, the firm is allocated limited Minutes of 343rd meeting of Registration Board (3rd-5th December, 2024) |858 quantity of API (Psychotropic) i.e. Alprazolam for the purpose of trial and stability study therefore, development of Production batch at new manufacturing is not possible. After thread bare deliberation, the Registration Board decided to defer the case for submission of stability data as per WHO TRS 981,2013 (47th report, Annex 3).

In the meanwhile, the firm has also submitted following documents on E-App for the aforementioned Products :

1. Comparison of release and shelf life specification of two batches of Xanax 0.25 mg, 0.5 mg & 1 mg., at the previously approved manufacturing site and at new proposed site i.e. M/s OBS Pharma, Lahore.
2. Analytical Method Verification and test reports.
3. BMR
4. Stability date for 1 month & 2 month stability studies test points (Date of Initiation of stability study i.e. 16/10/2024 & 2nd month stability test report is for 19/12/2024)

Moreover, M/s Lucky Core Industries Limited, B-2. S.I.T.E. Karachi has submitted an NOC dated 5th December,2024 issued by M/s Pfizer Pakistan Ltd, B-2, S.I.T.E. Karachi to their firm regarding transfer of market authorization of Xanax 0.25 mg Tablet, Xanax 0.5 mg Tablet and Xanax 1 mg tablet to M/s Lucky Core Industries Limited, B-2. S.I.T.E. Karachi, with the request of transfer of Market Authorization to the respective firm. The detail of application(s) received on e-app is as under :

Sr.No.	Tracing ID	Product Registration No.	Product Title/Name
01.	J8R-B2M-XM9Z	012303	Xanax 0.5 mg
02.	28V-A7X-E321	013349	Xanax 1mg
03.	GS7-XE1-RUR5	014417	Xanax 0.25 mg

The firms namely M/s Lucky Core Industries Limited, B-2. S.I.T.E. Karachi , M/s Pfizer Paksitan Ltd, B-2, S.I.T.E. Karachi & M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore are called for Personal hearing.

Decision of the Drug Registration Board in 344th Meeting:

Proceedings of the Board : Mr. Awais Naeem, Regulatory Manager M/s Lucky Core Industries Limited, B-2. S.I.T.E. Karachi, Mr. Zia Anwar, Regulatory Manager M/s Pfizer Pakistan Ltd, B-2, S.I.T.E. Karachi & Mr. Maaz Ahmed, Regulatory Manager, M/s OBS Pharma (Pvt) Ltd, Lahore appeared before the Board on behalf of their respective firms. Both, M/s Pfizer Pakistan Ltd, B-2, S.I.T.E. Karachi and M/s Lucky Core Industries Limited, B-2. S.I.T.E. Karachi gave consent before the board to grant the Market Authorization of the registered Products namely Xanax 0.25 mg Tablet, Xanax 0.5 mg Tablet and Xanax 1 mg tablet in the name of M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore.

Decision: Registration Board deliberated the matter in length as per WHO TRS 981,2013 (47th report, Annex 3) and decided to approve the change of Market Authorization Holder in Pakistan along with Change of Manufacturing Site of Drug Product from M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi to M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore. The Registration Board also deliberated that the letter for transfer of Market Authorization and change of manufacturing site may be issued to the firm before the finalization of minutes due to timely issuance of quota of alprazolam (Psychotropic substance) being innovator drug product.

Case No.2. M/s Getz Pharma (Pvt) Ltd, Karachi has submitted application for Grant of Additional Flavor (Orange Flavor) of Already Registered Product i.e. RISEK INSTA Sachet

Sr.#	Feature	Detail

1.	Applicant name	M/s Getz Pharma (Pvt.) Ltd. Plot No, 29-30, Sector-27, Korangi Industrial Area, Karachi.
2.	Already Registered Product	Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg **Registration No. 058547**
3.	Applied Product name	Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg **with Orange Flavor**
4.	Dosage Form	Powder for Oral Suspension
5.	Composition	Each Sachet Contains: Omperaole USP…20mg Sodium Bicarbonate…1680mg
6.	Pack Size	10's, 14's, 50's
7.	API Source	Omeprazole: 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.), 500055, Telangana, India Sodium Bicarbonate: M/s TATA Chemicals Europe Limited Mond House Winnington Northwich CW48 4DT, UK
8.	Reference product for PE/CDP	Firm has submitted **pharmaceutical equivalence** of their product against 'Risek Insta Powder for Oral Suspension 20mg + 1680mg by performing quality tests (Appearance, Average weight, pH, Assay of Omeprazole and Sodium Bicarbonate, Dissolution of Omeprazole & Related Substances). Firm has also submitted **comparative dissolution** in release medium of their product against 'Risek Insta Powder for Oral Suspension 20mg + 1680mg ' in pH 6.8 Phosphate Buffer.
9.	Procurement documents approval office/Loan Detail	Omeprazole: Firm has submitted copies of Import License on Form 6 (Computerized no. E-785852634538 dated 28-04-2022 & Computerized no. E-876752634875 dated 18-04-2022, specifying 300 Kg & 600Kg of Omeprazole Powder respectively. Both Form 6 have been approved by Assistant Director DRAP, Karachi. Sodium Bicarbonate: Firm has submitted copies of Invoices of Sodium Bicarbonate used in stability batches as the material was purchased from local vendor.
10.	Drug product container	Aluminum sachet packed in printed unit carton
11.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following two batches :

		Batch No. 628DS01 & Batch No. 628DS04 Batch Size 2000 Sachet, Date of Initiation 3-12-2022
12.	HPLC Documents	Submitted

Decision: Approved

The Registration Board deliberated the matter in length and decided to approve the additional flavor i.e. Orange flavor of registered product Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg having Registration No. 058547

Case No.3. M/s Getz Pharma (Pvt) Ltd, Karachi has submitted application for Grant of Additional Flavor (Lemon Flavor) of Already Registered Product i.e. RISEK INSTA Sachet

Sr.#	Feature	Detail
1.	Applicant name	M/s Getz Pharma (Pvt.) Ltd. Plot No, 29-30, Sector-27, Korangi Industrial Area, Karachi.
2.	Already Registered Product	Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg **Registration No. 058547**
3.	Applied Product name	Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg (**Lemon Flavor)**
4.	Dosage Form	Powder for Oral Suspension
5.	Composition	Each Sachet Contains: Omperaole USP…20mg Sodium Bicarbonate…1680mg
6.	Pack Size	10's, 14's, 50's
7.	API Source	Omeprazole: 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.), 500055, Telangana, India Sodium Bicarbonate: M/s TATA Chemicals Europe Limited Mond House Winnington Northwich CW48 4DT, UK
8.	Reference product for PE/CDP	Firm has submitted **pharmaceutical equivalence** of their product against 'Risek Insta Powder for Oral Suspension 20mg + 1680mg by performing quality tests (Appearance, Average weight, pH, Assay of Omeprazole and Sodium Bicarbonate, Dissolution of Omeprazole & Related Substances). Firm has also submitted **comparative dissolution** in release medium of their product against 'Risek Insta Powder for Oral Suspension 20mg + 1680mg' in pH 6.8 Phosphate Buffer.
9.	Procurement documents approval office/Loan Detail	Omeprazole: Firm has submitted copies of Import License on Form 6 (Computerized no. E-785852634538 dated 28-04-2022 & Computerized no. E-876752634875 dated 18-04-2022,

		specifying 300 Kg & 600Kg of Omeprazole Powder respectively. Both Form 6 have been approved by Assistant Director DRAP, Karachi. Sodium Bicarbonate: Firm has submitted copies of Invoices of Sodium Bicarbonate used in stability batches as the material was purchased from local vendor.
10.	Drug product container	Aluminum sachet packed in printed unit carton
11.	Stability Studies	Accelerated Stability studies (06 Months) & Real time Stability studies (06 months) are conducted on following two batches : **Batch No. 629DS02 & Batch No. 629DS05** **Batch Size 2000 Sachet, Date of Initiation 3-12-2022**
12.	HPLC Documents (Chromatograms & Raw data sheet)	Submitted

Decision:

The Registration Board deliberated the matter in length and decided to approve the additional flavor i.e Lemon Flavor of registered product Risek Insta (Omeprazole + Sodium Bicarbonate) Powder for Oral Suspension 20mg + 1680mg having Registration No. 058547.

e. Post Registration Variation-II

Case No. 01: PQCB order dated 19-09-2024 regarding Pivacaine-SP Injection of M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Sheikhupura.

PQCB in its order dated 19-09-2024 directed to seek rectification from NIH regarding the NIH report of subject sample and further directed the Committee to submit their registration certificate of subject sample and take corrective measures by applying to DRAP either for Manufacturer's Specifications or for changing dextrose anhydrous with glucose monohydrate in label and then perform test according to BP specifications.

The above document further states that the subject Sample Injecton Pivacaine-SP (Each 2ml contains: Bupivacaine Hydrochloride BP……..15mg, Dextrose Anhydrous BP…….165mg) batch no. PV-0523has been declared substandard with regards to Assay Test of Glucose Monohydrate. The sample injection Pivacaine-SP was sent to NIH vide letter No. PQCB/MSS-182677/2024 dated 31-05-2024. The appellate laboratory has communicated vide test report No. 0125-P/2024 dated 07-08-2024, the subject sample as standard, on the basis of Assay Test. The manufacturing specifications for Injection Pivacaine-SP is BP specifications and in BP monograph of Injection Pivacaine-SP Glucose is mentioned as Glucose monohydrate. While NIH declared the report of said sample Standard on the basis of Assay Test of Dextrose Anhydrous while applying BP specifications. The firm also applied BP specifications and performed assay test for dextrose anhydrous instead of of Glucose monohydrate.

It is further informed that M/s Bajwa Pharmaceuticals has applied for change in specifications from BP to USP through E-App vide tracking ID: XU2-TBV-974Y as per following details:

Reg. No.	**Name of Product**	**Existing Formulation and Specifications**	**Proposed Formulation and Specifications**

078951	Pivacaine-SP Injection	Each ml contains: Bupivacaine HCl BP……..7.5mg Dextrose Anhydrous BP……165mg BP Specifications	Each ml contains: Bupivacaine HCl BP……..7.5mg Dextrose Anhydrous BP……165mg USP Specifications

It is pertinent to mention that the product was declared substandard by PQCB because the firm is claiming BP specifications and using Dextrose Anhydrous while BP monograph of this product is with Glucose Monohydrate.

In this context, it is submitted that there is no anomaly in the label claim of the product as BP monograph of the product states the following:

"Bupivacaine Heavy Injection is a sterile solution of Bupivacaine Hydrochloride and either Glucose or Glucose Monohydrate in Water for Injections."

upivacaine Heavy Injection

eneral Notices

pivacaine and Dextrose Injection; Bupivacaine and Glucose Injection

tion and use

cal anaesthetic.

EFINITION

pivacaine Heavy Injection is a sterile solution of Bupivacaine Hydrochloride and either Glucose or Glucose onohydrate in Water for Injections. No preservative is added. The inclusion of glucose in the formulation sists the gravitational flow of the injection when administered.

e injection complies with the requirements stated under Parenteral Preparations and with the following quirements.

ntent of bupivacaine hydrochloride, $C_{18}H_{28}N_2O,HCl,H_2O$

.0 to 105.0% of the stated amount.

ntent of glucose monohydrate, $C_6H_{12}O_6,H_2O$

.0 to 88.0 mg per mL.

HARACTERISTICS

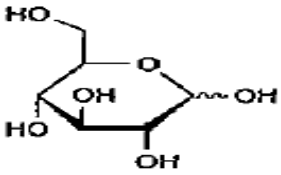
clear, colourless solution.

Moreover, the monograph of Glucose available in BP clearly states that it is "Anhydrous Glucose:

I-1182 Glucose

Glucose[1]

Anhydrous Glucose
(Ph. Eur. monograph 0177)



$C_6H_{12}O_6$ 180.2 *50-99-7*

Preparations
Glucose Infusion
Compound Glucose, Sodium Chloride and Sodium Citrate Oral Solution
Oral Rehydration Salts
Potassium Chloride and Glucose Intravenous Infusion
Potassium Chloride, Sodium Chloride and Glucose Intravenous Infusion
Sodium Chloride and Glucose Intravenous Infusion

Hence, as per BP monograph of the product, the Bupivacaine Injection can be manufactured either by using Glucose Anhydrous or Glucose Monohydrate and in instant case the firm is using Dextrose Anhydrous which is synonym to Glucose Anhydrous. Moreover, the label claim of innovator product in USFDA is as follows:
"Each mL of MARCAINE SPINAL contains 7.5 mg bupivacaine hydrochloride (anhydrous) (equivalent to 7.9 mg of bupivacaine hydrochloride monohydrate), 82.5 mg dextrose (anhydrous) as baricity agent." accessed on 30-12-2024 @ https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/018692s024lbl.pdf

Decision:

Registration Board deferred the case for further deliberation in next meeting.

Case No. 02: <u>Application for change in registration status from finished import to local contract manufacturing of already registered products applied by M/s Biocare Pharmaceutical, 807, Shadman-I, Lahore.</u>

M/s Biocare Pharmaceutica, 807, Shadman-I, Lahore applied for change in registration status from finished import to local contract manufacturing of following registered products as under:

i		M/s Biocare Pharmaceutica, 807, Shadman-I, Lahore			
S. #	**Details of Product**	**Existing**	**Proposed**	**Details of Application & fee received**	**Products already Approved on**

					CTD format for the proposed manufacturing site
1.	**Penitrax for Injection 2.25g** Each vial contains: Piperacillin Sodium equivalent to Piperacillin……2gm Tazobactam Sodium equivalent to Tazobactam……0.25gm **(Reg. No. 079235)** **Initial reg.** 26-11-2015 **Last Renewal:** 20-11-2020	M/s Xiangbei Welman Pharmaceutical Co. Ltd., Liuyang Bio-Pharmaceutical Industrial Park, Hunan Province, China.	M/s. English Pharmaceutical Industries, (**DML # 000339)** Link Katar Band Road, Thokar Niaz Baig, Multan Road, Lahore.	**Fee:** PKR 75000/- *Vide slip #* 9043550429 **Dated** 08-03-2023 **Ref. No.** BCPL/QUOTE/50-23 & Dy. No. 13465 **Dated:** 08-03-2023 & 18-12-2024	ARDCIL Injection 2.25g Injection Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium …….0.25g **Case No. 237** **Meeting of RB:** 321 **Page no.** 1581-1584
2.	**Penitrax for Injection** Each vial contains: Piperacillin Sodium equivalent to Piperacillin……4.0gm Tazobactam Sodium equivalent to Tazobactam……0.5gm **(Reg. No. 079236)** **Initial reg.** 26-11-2015 **Last Renewal:** 20-11-2020	M/s Xiangbei Welman Pharmaceutical Co. Ltd., Liuyang Bio-Pharmaceutical Industrial Park, Hunan Province, China.	M/s. English Pharmaceutical Industries, (**DML # 000339)** Link Katar Band Road, Thokar Niaz Baig, Multan Road, Lahore.	**Fee:** PKR 75000/- *Vide slip #* 86901527624 **Dated** 08-03-2023 **Ref. No.** BCPL/QUOTE/49-23 & Dy. No. 13465 **Dated:** 08-03-2023 & 18-12-2024	ARDCIL Injection 4.5g Injection Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium …….0.5g **Case No. 238** **Meeting of RB:** 321 **Page no.** 1584-1586
3.	**Secomep (Lyphilized) Powder for Injection 40mg** Each vial contains: Omeprazole Sodium…….40mg **(Reg. No. 053893)** **Initial reg.** 10-07-2009 **Last Renewal:** 29-05-2024	M/s Chengdu Tiantaishan Pharmaceutical Co. Ltd., Sichuan, China.	M/s. English Pharmaceutical Industries, (**DML # 000339)** Link Katar Band Road, Thokar Niaz Baig, Multan Road, Lahore.	**Fee:** PKR 75000/- *Vide slip #* 339025599925 **Dated** 08-03-2023 **Dy. No.** 13465 **Dated:** 18-12-2024	NILCID 40mg Injection Each vial contains: Omeprazole as sodium (lyophilized)…….40mg **Case No. 131** **Meeting of RB:** 313 **Page no.** 400 - 403

The firm has not submitted the No Objection Certificate from previously approved manufacturer/ exporter for local manufacturing of above product. The instead submitted the following:

"Demanding (NOC) from foreign principal to manufacturer our brand locally in Pakistan, is against the spirit of law. However, we were recently informed that our application was deferred due to the reason aforementioned.

As you are well aware, there has been a significant shortage of medicines in the country, primarily due to delays in import mainly because of shortage of foreign exchange. This situation has created considerable difficulties in meeting the demand for essential medicines. In this context, we kindly request that DRAP consider the benefits of local manufacturing in alleviating this shortage rather than discouraging the efforts of local manufacturers.

In addition, I would like to bring to your kind attention that the trademarks for all the aforementioned products belong to Biocare Pharmaceutica, and the brand names used by the foreign principals differ from those of our products. For your reference, we have enclosed copies of all the trademark certificates issued by the Trade Mark Registry, Government of Pakistan".

Decision: Registration Board deliberated that requirement of NOC has not been mentioned either in Rule 20A or relevant guidelines, so the Board acceded to the request of firm for change in registration status from finished import to local manufacturing on contract manufacturing basis from M/s. English Pharmaceutical Industries, (DML # 000339), Link Katar Band Road, Thokar Niaz Baig, Multan Road, Lahore for already registered products Penitrax for Injection 2.25g (Reg. No. 079235), Penitrax for Injection 4.5g (Reg. No. 079236) & Secomep (Lyphilized) Powder for Injection 40mg (Reg. No. 053893)

Item No. VII Miscellaneous Cases

A. Borrowing of APIs for performing product development, R&D & Stability testing.

Registration Board referred to its following decision of 322nd meeting regarding the subject matter which was also notified vide Notification no. 14-1/2022-PEC dated 16-01-2023:

"Firm shall submit the documents of loan of API to PE&R division within 15 days of such acquisition along with requisite documents and shall secure its receiving from R&I section, DRAP. This receiving shall be presented along with Form 5F at the time of dossier submission. Those firms who have already obtained such materials on loan and their product development studies are in process, are also advised to inform PE&R Division as per aforementioned procedure."

With reference to above cited decision, the Board noted the fact several firms are not complying with the said decision and the intimation for the borrowed drug substance is not being done as per defined procedure in Notification no. 14-1/2022-PEC dated 16-01-2023. Hence Board decided to verify the loan letters for all such cases where product development has been done by the borrowed drug substances and directed the applicants to comply the above cited decision of 322nd meeting notified vide Notification no. 14-1/2022-PEC dated 16-01-2023 in true letter and spirit.

B. Establishment of Pharmacovigilance System By Registration Holders.

The Drug Regulatory Authority of Pakistan (DRAP) has the mandate to ensure access to safe, efficacious, and quality drugs/ medicines/ therapeutic goods at affordable prices to the people of the country. To uphold this mandate, the National Pharmacovigilance Centre (NPC), Division of Pharmacy Services was established in 2017 under the DRAP to monitor the safety of therapeutic goods across the country to prevent harm to patients. Subsequently, the DRAP notified Pharmacovigilance Rules, 2022 vide S.R.O 540 (I)/2022, dated 22nd of October, 2022, which outline the roles and responsibilities of pharmacovigilance stakeholders, including registration holders of therapeutic goods. The NPC-DRAP has also developed guidelines on "*Good Pharmacovigilance Practices*" for registration holders (manufacturers or importers of therapeutic goods) that outline step-by-step guidelines on the establishment of pharmacovigilance systems in pharmaceutical companies.

2. Furthermore, the NPC has dedicated tools in place for the collection of adverse drug reactions (ADRs)/Adverse Events (AEs) reports from all stakeholders through the VigiMobile Application, Med Vigilance e-reporting system, E2Bxml submission, and hard copy submissions via mailing address. To ease the submission of ADRs/AEs by registration holders within the defined timelines, the DRAP has recently launched an Industry e-reporting system, where the pharmaceutical companies can directly submit the reports to the NPC-DRAP through two modules namely: E2B XML submission; and manual data entry for non-E2B pharmaceutical companies. Access to this system is through secure logins and NPC-DRAP is managing the provision of logins to registration holders. This system has been effective since the 1st of September 2024 and many registration holders are reporting through this platform.

3. However, despite the above efforts of DRAP, very few registration holders (manufacturers and importers) have established their pharmacovigilance system and nominated their qualified persons for pharmacovigilance (QPPV) and/or Local Safety Officer (LSO). Implementing Pharmacovigilance Rules, 2022 and establishing effective pharmacovigilance systems by all stakeholders, including registration holders is a prerequisite for ensuring the safety of medicines in Pakistan. Since the promulgation of these rules, very few registration holders have started submission of reports which are mostly "Nil" reports. As per Rule.11 of Pharmacovigilance Rules, 2022, the following are the responsibilities of registration holders, which are further explained in the guidelines on GVP:

- Establishment of Pharmacovigilance system by registration holders as per Pharmacovigilance Rules, 2022.
- Nomination of a Qualified Person for Pharmacovigilance (QPPV) or Local Safety Officer (LSO) as the case may be and submission of these nominations to NPC-DRAP.
- Development or maintenance of the Pharmacovigilance System Master File (PSMF) or National Pharmacovigilance System File (NPVSF) as applicable on the approved format and its submission to the NPC-DRAP.
- Collection and assessment of ADRs/AEs reports in the context of spontaneous reporting or post-authorization studies and accordingly submit to NPC-DRAP within defined timelines as per Pharmacovigilance Rules, 2022 through approved reporting channel i.e. Industry-e reporting system.
- Conduction or initiation of voluntarily non-interventional post-authorization efficacy studies (PASS) or safety studies (PAES) or if imposed by the Registration Board on the recommendation of Pharmacovigilance Risk Assessment Expert Committee (PRAEC) on the format approved by DRAP.
- Submission of Periodic Benefit-Risk Evaluation Report (PBRER) through the approved format and as per defined timelines and frequency to NPC-DRAP.
- Development and submission of a Risk Management Plan (RMP) on the approved format for all new drugs along with a registration dossier to the Registration Board, followed by post-registration submission to NPC-DRAP.
- Submission of reports associated with adverse outcomes as a result of overdose, abuse, misuse, off-label use, occupational exposure and medication error on approved format and within defined timelines to NPC-DRAP.
- Submission of reports of lack of therapeutic efficacy in case of vaccines, contraceptives, antimicrobials and drugs used in critical conditions or life-threatening situations to the NPC-DRAP with defined timelines.
- Submission of significant safety issues within defined timelines to the concerned Board and NPC-DRAP.
- Signal detection and management followed by regular communication of risk to stakeholders through approved means.

4. The team from the National Pharmacovigilance Centre, DRAP presented the updated status of the Pharmacovigilance activities of registration holders in the meeting of the Registration Board and apprised the members about low reporting from registration holders including very few nominations of QPPV/LSO.

Decision: **The Board advised the National Pharmacovigilance Centre (NPC) to come up with a proposal in the next meeting of the Registration Board for quick implementation of Pharmacovigilance Rules, 2022.**

C. Change of specifications to officially recognized pharmacopeia standards.

Registration Board was apprised regarding the following data requirements for the subject matter as defined in the "Post-Registration Variation Guidelines For Pharmaceutical And Biological Products" (2nd edition.)

"*1. Copy of the proposed drug product specifications dated and signed by authorized personnel and a comparative table of approved and proposed specifications.*

2. Certificate of analysis of at least one batch and comparative summary of results, in tabular format, for one batch using current and proposed procedures.

3. Validation studies

4. Demonstration of suitability of the monograph to control the drug product.

5. Time line for change

6. Undertaking that:

i. The change is made exclusively to comply with the pharmacopeia of reference regulatory authorities. ii. No case is pending at any forum / court of law regarding this product.

iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same will be reported to Registration Board and all the stock will be recalled from the market immediately."

While referring to above cited data requirements the Board deliberated that the change of specifications form in-house standards to the pharmacopoeia standards is related to adoption of a more stringent & robust standard for the drug product specifications hence Board decided that the subject change shall be processed from now onwards with the following data requirements only:

1. Copy of the proposed drug product specifications dated and signed by authorized personnel.
2. Undertaking that:
    i. The change is made exclusively to comply with the pharmacopeia of reference regulatory authorities.
    ii. No case is pending at any forum / court of law regarding this product.
    iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same will be reported to Registration Board and all the stock will be recalled from the market immediately."

Registration Board further advised the PE&R Division to revise the "Post-Registration Variation Guidelines For Pharmaceutical And Biological Products" as per above cited data requirements for the subject change.

Item No. VIII Post Registration Variation And Export Registrations submitted on e-app

POST REGISTRATION-II

Sr. No	Title	Description
1	Name, address of Manufacturing site.	**Lahore Chemical and Pharmaceutical Works Pvt. Ltd.** 137- Shahrah Maulana Jalaluddin Roomi, Lahore**(000064)**
	Case Category	PRV-II (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(1NT-SBR-E65L, 2024-10-08)
	Detail of Fee Submitted	12000.0, 2024-10-08,
	The proposed proprietary name / brand name	Cyclonorm 2mg Tablet
	Label Claim	Each tablet contains: Estradiol Valerate 2mg
	Reg. No.	065986
	Evaluation	The initial registration was granted in 2010 and for last 14 years firm has not applied for correction. More over, Estradiol Valerate 2mg Tablet is also registered as separate product i.e. Zumenon 2mg Film- Coated Tablet @ https://mhraproducts4853.blob.core.windows.net/docs/4ebf29c2a544fb5af648697bb5ab363da7256792 Now, the firm is applying for correction. It is proposed that the application of the firm may be disposed with the advice to the firm to apply afresh on CTD.
	Shortcoming	
	Decision	Deferred Registration Board deferred the case for submission of clarification by the firm that which formulation they have been manufacturing & marketing since registration.

Sr. No	Title	Description
1	Name, address of Manufacturing site.	**Maxitech Pharma (Pvt) Ltd.** E-178, S.I.T.E., Super Highway Phase-II, Karachi**(000851)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(44J-XNA-M3PZ, 2024-12-27)
	Detail of Fee Submitted	30000.0, 2024-02-20,
	The proposed proprietary name / brand name	**Erbifine 1% Cream**
	Label Claim	Each 1 gm contains: 10mg terbinafine HCL equivalent to TERBINAFINE..... 8.89mg
	Reference to Finished product specifications	As per Importing Country
	The status in reference regulatory authorities	terbinafine 1% cream UK
	For generic drugs (me-too Status)	(013210) Lamisil cream 1% By GSK
	Evaluation	The proposed brand name resembles with already registered brand name "Erbifin" of M/s Webros Pharma. The firm has been asked multiple times to propose alternate names but they insist on same brand name.
	Shortcoming	
	Decision	Approved. Registration Board advised the firm to provide more brand names and if the firm provides alternate names, then there will be no need to again present the case before Registration Board and Chairman Registration Board is authorized for deciding the case.

Sr. No	Title	Description
2	Name, address of Manufacturing site.	**Wilshire Laboratories (Private) Limited** 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**(000232)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(JGH-77Q-1G5S, 2024-12-27)
	Detail of Fee Submitted	30000.0, 45000 2024-08-08, 2024-11-15
	The proposed proprietary name / brand name	**Qink 200mg Capsule**
	Label Claim	Each Capsule Contains: Cefpodoxime as Proxetil.....200mg
	The status in reference regulatory authorities	Vantin

	For generic drugs (me-too Status)	Cefprox
	Name & address of API manufacturer	Nectar Lifesciences Ltd.
	Evaluation	The proposed formulation is not available in Capsule dosage form instead it is available in Tablet dosage form both as me-too and in RRAs. The firm has submitted purchase order from Afghanistan.
	Shortcoming	
	Decision	Approved Registration Board approved the product for Export Purpose only.

Sr. No	Title	Description
3	Name, address of Manufacturing site.	**Reign Pharmaceuticals PCSIR - KLC (Pvt.) Ltd.** TBIC Building - I, PCSIR Laboratories Complex, Shahrah e Dr. Salim - uz - Zaman Siddiqui Off University Road.**(000757)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(VTH-JLV-WNDN, 2024-12-27)
	Detail of Fee Submitted	30000.0, 45000 2024-07-26, 2024-07-26
	The proposed proprietary name / brand name	**Non-Asidoz 1000 mg gastro resistant Tablet**
	Label Claim	Each gastro resistant Tablet contains: Sodium Bicarbonate ……1000 mg
	Reference to Finished product specifications	As per Importing Country
	The status in reference regulatory authorities	Turkey
	For generic drugs (me-too Status)	Not available in Pakistan
	Name & address of API manufacturer	API
	Evaluation	The proposed formulation is neither available in RRAs nor in Pakistan. The firm has submitted Export Order from Azerbaijan.
	Shortcoming	
	Decision	Approved Keeping in view the availability of formulation in India; Registration Board approved the product for Export Purpose only.

Sr. No	Title	Description
4	Name, address of Manufacturing site.	**Wilshire Laboratories (Private) Limited** 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**(000232)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(5SX-X85-PAGW, 2024-12-27)

	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	**FluGone Tablet**
	Label Claim	Each tablet contains: Paracetamol.....400mg Pseudoephedrine HCl.....30mg Caffeine.....32mg Chlorpheniramine maleate.....3mg
	The status in reference regulatory authorities	Fludrex Tablet
	For generic drugs (me-too Status)	NA
	Name & address of API manufacturer	Aarti Pharma Labs Limited,Alpha Chemicals (Pvt) Limited,Pharmagen Ltd,Supriya Lifescience Ltd
	Evaluation	The applied formulation is neither available in RRAs not in Pakistan. The firm has submitted Export Order from Qatar.
	Shortcoming	
	Decision	Approved Registration Board approved the product for Export Purpose to Qatar only. Registration letter shall be issued with the condition that *Before issuance of NOC, QA&LT Division, DRAP will assure that following additional pre-requisites are also verified; a. Registration of Pseudoephedrine containing product(s) of exporter in importing country. b. Legal status of Pseudoephedrine in importing country whether controlled under INCB convention or otherwise. c. Evidence of quota allocation from Controlled Drug Division of DRAP. c. In case of any already exported consignment, clearance document of Customs and regulatory authority of the importing country.
Sr. No	**Title**	**Description**
5	Name, address of Manufacturing site.	**Medisure Laboratories Pakistan Pvt Ltd** A-115 S.I.T.E-II Super Highway Karachi**(000503)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(7QH-A3J-QS3M, 2024-12-27)
	Detail of Fee Submitted	75000.0, 2024-11-06,
	The proposed proprietary name / brand name	**Monteccet 10mg/5mg Tablet**
	Label Claim	Each film coated tablet contains: Montelukast Sodium equivalent to Montelukast..... 10mg Levocetirizine Dihydrochloride. 5mg
	Reference to Finished product specifications	As per Importing Country
	The status in reference regulatory authorities	Reference available in MIMS-Philippines. Weblink: https://www.mims.com/philippines/drug/info/monti%20plus?type=full
	For generic drugs (me-too Status)	N/A
	Evaluation	The product is neither available in RRAs nor in Pakistan. The firm has submitted Export Order from Philippines.
	Shortcoming	
	Decision	Approved Registration Board approved the product for Export Purpose only.
Sr. No	**Title**	**Description**

6	Name, address of Manufacturing site.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE**(000130)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(SUT-UWL-5GBM, 2024-12-23)
	Detail of Fee Submitted	75000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Brochick Booster powder**
	Label Claim	Each 1000gm contains:- Vitamin A……1525000 IU Vitamin D3…450000 IU Vitamin E……..136 IU Vitamin K…….. 450 mg Vitamin B2……..450 mg Vitamin B6……..235 mg Vitamin B12 …..1150 mcg Vitamin C……..100 mg Niacin …… 1675 mg Dextrose Monohydrate (Glucose)….17KJ/g Methionine……..1020 mg Lysine……..1525mg Copper sulphate……750 mg Zinc Sulphate ……..1225 mg Manganese Sulphate…..1225mg Magnesium sulphate…..1225 mg Sodium chloride… 5000 mg Sodium sulphate ….21000 mg Potassium chloride….8800mg
	Reference to Finished product specifications	As per Importing Country
	The status in reference regulatory authorities	chick start(vetcare africa nairobi)
	For generic drugs (me-too Status)	not available
	Evaluation	The proposed formulation is neither available in RRAs nor in Pakistan. The firm has submitted Export Order from Kenya.
	Shortcoming	
	Decision	Approved Registration Board approved the product for Export Purpose only.
Sr. No	**Title**	**Description**
7	Name, address of Manufacturing site.	**Maxitech Pharma (Pvt) Ltd.** E-178, S.I.T.E., Super Highway Phase-II, Karachi**(000851)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(UL7-2GY-2SG3, 2024-12-27)
	Detail of Fee Submitted	30000.0, 2024-02-20,
	The proposed proprietary name / brand name	**Devit 5mg/ml Injection**
	Label Claim	Each 1ml ampoule contains: Cholecalciferol 5mg
	The status in reference regulatory authorities	ergocalciferol 300,000IU Sweden
	For generic drugs (me-too Status)	D-tress by Sami
	Evaluation	The proposed brand name resembles with already registered brand name "Erbifin" of M/s Webros Pharma. The firm has been asked multiple times to propose alternate names but they insist on same brand name.
	Shortcoming	

	Decision	Approved. Registration Board advised the firm to provide more brand names and if the firm provides alternate names, then there will be no need to again present the case before Registration Board and Chairman Registration Board is authorized for deciding the case.
Sr. No	**Title**	**Description**
8	Name, address of Manufacturing site.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE**(000130)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(ULZ-V39-7QJR, 2024-12-23)
	Detail of Fee Submitted	75000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Starmix Antistress Powder**
	Label Claim	Each 100 gm contains:- Vitamin A…….2000000 IU Vitamin D3…….360000 IU Vitamin E……. 100 mg Vitamin K3…… 200 mg Vitamin C……..100 mg Vitamin B1…….200 mg Vitamin B2……200 mg Vitamin B6 ……..235 mg Vitamin B12 ……. 1150 mcg D-Calcium ……..1000 mg Nicotinamide……. 1500 mg DL-Methionine……..1000 mg Lysine hydrochloride….1500 mg Manganese sulphate… 1200 mg Zinc sulphate……..1200 mg Copper sulphate……1200 mg Potassium chloride….8800mg Sodium Sulphate….20000mg Sodium chloride…..5000mg Magnesium sulphate….1200 mg Glycine ……. 4000 mg Biotin ……..1000 mcg Iron sulphate ……. 100 mg Folic acid ……. 5000 mg (Innovator's Specifications
	Reference to Finished product specifications	As per Importing Country
	The status in reference regulatory authorities	BIOMIX ANTISTRESS(Veterinary Medicine Directorate. The Pest Control Plaza, Westlands)
	For generic drugs (me-too Status)	not available
	Evaluation	The proposed formulation is neither available in RRAs nor in Pakistan. The firm has submitted Export Order from Kenya.
	Shortcoming	
	Decision	Approved Registration Board approved the product for Export Purpose only.
Sr. No	**Title**	**Description**
9	Name, address of Manufacturing site.	**Maxitech Pharma (Pvt) Ltd.** E-178, S.I.T.E., Super Highway Phase-II, Karachi**(000851)**
	Case Category	Export Registration (Muhammad Zubair)
	Application Form Dy. No / Tracking ID & date of submission	(ZMM-WDS-2TE5, 2024-12-27)
	Detail of Fee Submitted	30000.0, 2024-02-20,
	The proposed proprietary name / brand name	**Erbifine 250mg Tablet**
	Label Claim	Each Tablet Contains: terbinafine 250mg (as 281.250mg terbinafine Hydrochloride)

Reference to Finished product specifications	As per Importing Country
The status in reference regulatory authorities	Terbinafin 250 mg UK
For generic drugs (me-too Status)	Lamisil 250 mg tablet by Novartis (013208)
Evaluation	The proposed brand name resembles with already registered brand name "Erbifin" of M/s Webros Pharma. The firm has been asked multiple times to propose alternate names but they insist on same brand name.
Shortcoming	
Decision	Approved. Registration Board advised the firm to provide more brand names and if the firm provides alternate names, then there will be no need to again present the case before Registration Board and Chairman Registration Board is authorized for deciding the case.

Registration Board 344 Meeting Additional/Supplementary Agenda: (PRV-I)

Sr. No	Title	Description
1	Name, address of Manufacturing site.	**Lucky Core Industries Limited** B-2, SITE**(000025)**
	Case Category	PRV-I (Muhammad Usman)
	Application Form Dy. No / Tracking ID & date of submission	(BSJ-5TE-1MV1, 2024-12-16)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Dilantin 100mg Capsule**
	Label Claim	**Each capsule contains:** **Phenytoin…….100mg**
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	The status in reference regulatory authorities	
	For generic drugs (me-too Status)	
	Proposed Pack Size	
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	**Lucky Core Industries Limited** B-2, SITE**(000025)**
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Change of Title of Market Authorization Holder of Registered Product Renewal of Registration needs to be regularized
	Shortcoming	Renewal was due on 30th May 2016 and submitted on 4th December 2017. Please review and place before Registration Board for regularization if not done yet.
	Decision: Registration Board regularized the renewal of registration of year 2016 of above product.	

Sr. No	Title	Description
2	Name, address of Manufacturing site.	**Lucky Core Industries Limited** B-2, SITE**(000025)**
	Case Category	PRV-I (Muhammad Usman)
	Application Form Dy. No / Tracking ID & date of submission	(L75-2AP-LPRS, 2024-12-16)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Ponstan Flash Tablet**
	Label Claim	**Each Tablet contains: Mefenamic acid…… 250mg**
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	The status in reference regulatory authorities	
	For generic drugs (me-too Status)	
	Proposed Pack Size	
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Change of Title of Market Authorization Holder of Registered Product. Renewal of Registration needs to be regularized Case is resubmitted as discussed
	Shortcoming	Renewal of registered drug needs to be regularized.
	Decision: Registration Board regularized the renewal of registration of above product.	

Sr. No	Title	Description
3	Name, address of Manufacturing site.	**Lucky Core Industries Limited** B-2, SITE**(000025)**
	Case Category	PRV-I (Muhammad Usman)
	Application Form Dy. No / Tracking ID & date of submission	(RR1-YWE-6D7W, 2024-12-16)
	Detail of Fee Submitted	37000.0, 2024-12-10,
	The proposed proprietary name / brand name	**Dilantin Suspension**
	Label Claim	**Each 5ml contains: Phenytoin…….30mg**
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	The status in reference regulatory authorities	
	For generic drugs (me-too Status)	
	Proposed Pack Size	
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Name & address of API manufacturer	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Improt)	
	Evaluation	Change of Title of Market Authorization Holder of Registered Product
	Shortcoming	Renewal was due on 30th May 2016 and submitted on 4th December 2017. Please review and place before Registration Board for regularization if not done yet.
	Decision: Registration Board regularized the renewal of registration of year 2016 of above product.	

Meeting ended with a vote of thanks to and from the Chair

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