MINUTES OF 354TH MEETING OF REGISTRATION BOARD HELD ON 04TH – 05TH MARCH, 2026

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

354th meeting of Registration Board was held on 04th – 05th March, 2026 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 Mr. Sayyad Hussain Khan, 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.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
2.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
3.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member
4.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
5.	Mr. Asad Abrar, Director Drugs Testing Laboratory, Govt. of Punjab, Bahawalpur.	Member
6.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
7.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member (Virtual)
8.	Mrs. Tehreem Sara, Representative of Quality Assurance & Lab Testing Division, DRAP.	Member
9.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
10.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
11.	Dr. M. Shahjahan Zafar, Representative of Animal Husbandry Commissioner Ministry of National Food Security and Research.	Co-Opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Dr. Riaz Ahmed and Mr. Maaz Ahmaed (PPMA) and Dr. Shahnawaz (PCDA) attended the meeting as observers.

Item No. I Confirmation of Minutes of 353rd meeting of Registration Board.

353rd meetings of Registration Board were held on 14th – 15th January, 2026. Accordingly, draft minutes of the 353rd meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes of 353rd meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 353rd meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 353rd meeting.

Item No. II Division of Pharmaceutical Evaluation & Registration

Miscellaneous

CASE NO. 01: PROPOSAL FOR MANDATORY INDICATION OF MAXIMUM STACKING CAPACITY ON PACKAGING OF LARGE VOLUME PARENTERALS (LVPS) AND LARGE VOLUME SOLUTIONS:

Director Pharmacy & Pharmacovigilance, Directorate of Drugs Control Punjab has forwarded a letter communicating that the Provincial Pharmacovigilance Committee (PPVC), in its 17th meeting held on 22.12.2025, deliberated upon a Therapeutic Goods Related Problem (TGRP) reported from DHQ Hospital Muzaffargarh. Leakage was detected in Life Med Bicarb Concentrate (3NLPSV) Part A 4.0L solution bottles, Batch Nos. 00695 & 00694, manufactured by M/s 3N-Life Med Pharmaceuticals. Despite reducing stacking height from 8 feet to 4 feet, leakage persisted, raising concerns about efficacy, sterility, and patient safety.

The PPVC decided / recommended to propose that the Drug Regulatory Authority of Pakistan (DRAP) ensure all manufacturers of LVPs, large-volume solutions, and other medicinal products clearly indicate maximum stacking capacity (height in feet or permissible number of cartons) on secondary/tertiary packaging to prevent rupturing, tearing, leakage, and subsequent therapeutic-related problems during storage and administration.

Decision:

The Board in light of recommendations of Provincial Pharmacovigilance Committee (PPVC) decided to issue a circular to pharmaceutical industry for ensuring that all manufacturers of LVPs, large-volume solutions, and other medicinal products should clearly indicate maximum stacking capacity (height in feet or permissible number of cartons) on secondary/tertiary packaging to prevent rupturing, tearing, leakage, and subsequent therapeutic-related problems during distribution, storage and administration.

Case No. 02: Inspection of Veterinary Manufacturers with Highest Incidence of Substandard Products

It has been observed that certain veterinary pharmaceutical manufacturing companies have reported a comparatively higher number of **substandard products**. In order to ensure the quality, safety, and efficacy of veterinary medicines available in the market, it is proposed that the **five veterinary manufacturing companies** with the highest incidence of substandard samples during the last six months may be identified.

The **Quality Assurance & Laboratory Testing (QA&LT) Division** may conduct **Good Manufacturing Practice (GMP) inspections** of these identified manufacturers to evaluate their manufacturing practices, quality control systems, and compliance with the applicable regulatory requirements.

The inspection findings along with recommendations may subsequently be **submitted to the PE&R Division** for further regulatory action and review by the Registration Board.

The matter is placed before the **Registration Board for deliberation.**

Decision:

The Board expressed its concern over the numerous veterinary products declared substandard as identified by the Director, DTL, Bahawalpur.

After deliberation, the Board decided that:

1. The top **five veterinary pharmaceutical manufacturing companies** with the **highest number of substandard samples** reported during the last six months shall be identified based on available quality surveillance data.
2. The **QA&LT Division** shall conduct **comprehensive GMP inspections** of the identified five manufacturers to assess their compliance with the **Good Manufacturing Practice (GMP) requirements**, including manufacturing processes, quality control systems, documentation practices, and overall quality management systems.
3. Recommendations of the inspection teams/panel be **placed before the Registration Board**, for its consideration.

Registration-I Section

Case No.01. Cancellation of Drug Manufacturing License of M/s. Ciba Pharmaceuticals (Pvt) Ltd, Jamshoro.

Deputy Director, QA&LT Division, DRAP has communicated vide letter No.F.04-18/2025-QALT(313-CLB) dated 20-01-2026 that CLB in its 313th meeting held on 31st December 2025 cancelled the Drug Manufacturing License of M/s Ciba Pharmaceuticals (Pvt) Ltd, Plot No.A-371, S.I.T.E, Nooriabad, District, Jamshoro (No.000825-By Way of Formulation) with immediate effect under section 41 of the Drugs Act 1976.

Reason of Cancellation:

Manufacturing of unregistered Tramadol Tablets.

Keeping in view the above mentioned detail, the case has been placed before the Board for deciding the fate of all under process applications and products already registered/ approved in favor of M/s Ciba Pharmaceuticals (Pvt) Ltd, Plot No.A-371, S.I.T.E, Nooriabad, District, Jamshoro (No.000825-By Way of Formulation)

Decision: Keeping in view the decision taken by the Central Licensing Board, in its 313th meeting, regarding cancellation of DML of M/s Ciba Pharmaceuticals (Pvt) Ltd, Plot No. A-371, S.I.T.E, Nooriabad, District, Jamshoro (DML No.000825), Registration Board cancelled all registered products of the firm w.e.f. 20.01.2026. Furthermore, all under process and approved applications of the firm shall also stand disposed of.

Case No. 02: Cancellation of Drug Manufacturing License of M/s Healer Laboratories., Plot No.78, Industrial Estate., Peshawar.

Deputy Director QA&LT Division, DRAP has communicated vide letter No.F.04-18/2025-QALT(313-CLB) dated 22-01-2026 that the Drug Manufacturing License of M/s Healer Laboratories, Plot No.96/102 C, Small Industrial Estate, Kohat Road, Peshawar (DML No.000303) was cancelled with immediate effect under section 41 of the Drugs Act, 1976 with immediate effect.

Reason of Cancellation:

The firm has stopped further development at new premises (located at Plot No. 78, Industrial Estate, Hayatabad, Peshawar) and is willing to surrender DML No.000303 of Healer Lab at existing site i.e., Plot No.96/102 C, S.I.E., Kohat Road, Peshawar.

Keeping in view the above mentioned detail, the case has been placed before the Board for deciding the fate of all under process applications and products already registered/ approved in favor of M/s Healer Laboratories, Plot No.96/102 C, Small Industrial Estate., Kohat Road, Peshawar (DML No.000303)

Decision: **Keeping in view the decision taken by the Central Licensing Board, in its 313th meeting, regarding cancellation of DML of M/s Healer Laboratories, Plot No.96/102 C, Small Industrial Estate, Kohat Road, Peshawar (DML No.000303), Registration Board cancelled all registered products of the firm w.e.f. 22.01.2026. Furthermore, all under process and approved applications of the firm shall also stand disposed of.**

Case No. 03: Suspension of Drug Manufacturing License of M/s Hassan Pharmaceuticals Industry, 99-A Industrial Estate, Jamrud Road Hayatabad, Peshawar.

Deputy Director QA&LT Division, DRAP vide letter No.F.04-18/2025-QALT(313-CLB) dated 22-01-2026 has informed that the Drug Manufacturing License of M/s Hassan Pharmaceuticals Industry, 99-A Industrial Estate, Jamrud Road Hayatabad, Peshawar (DML No.000357) has been suspended for a period of four (04) months under section 41 of the Drugs Act, 1976.

The case has been placed before the Board for information/ record and further necessary action (if required) to be taken by PE&R Division.

Decision: **Registration Board noted the information.**

Case No. 04: Suspension of Drug Manufacturing License of M/s Alson Pharmaceutical Pvt Ltd, Peshawar

Deputy Director QA&LT Division, DRAP vide letter No.F.04-18/2025-QALT(313-CLB) dated 22-01-2026 has informed that that the Drug Manufacturing License of M/s Alson Pharmaceutical Pvt Ltd., Plot No.169,7-B Road, Industrial Estate, Hayatabad, Peshawar (DML No.000522) has been suspended for a period of three (03) months.

The case has been placed before the Board for information/ record and further necessary action (if required) to be taken by PE&R Division.

Decision: **Registration Board noted the information.**

Case No. 05: RRA Status of Citicoline Injection 250mg/2ml Approved in 352nd Meeting of Registration Board

Registration Board in its 352nd meeting approved the following product of M/s High-Q Pharmaceuticals, Karachi subject to the condition that **"RRA status of Citicoline Sodium 250mg/2ml be checked and placed in the Board for harmonized decision".**

Details of the case are reproduced below:

Case Category	Routine (Haleema Sharif)
Name, address of Applicant.	**High-Q Pharmaceuticals** Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi **(000597)**
Application Form Dy. No / Tracking ID & date of submission	**(XEL-1X3-NU1B, 2024-06-24)**
Detail of Fee Submitted	**75000.0,** **2024-02-14,**

The proposed proprietary name / brand name	**Alphacoline**
Claim	**Each ampoule (2ml) contains:** **Citicoline as Citicoline Sodium.....250mg** **(Manufacturer Specifications)**
Reference to Finished product specifications	**Manufacturer Specification**
Proposed Pack Size	**10's-As per SRO,5's-As per SRO**
Shelf Life (Unit)	**24 Year(s)Store at room temperature (1-30°C)**
For generic drugs (me-too Status)	**Citolin 250mg/2ml Injection by Global Pharmaceuticals**
Pharmacotherapeutic Group of (API)	**Nootropic**
Name, address of Manufacturing site:	**NovaMed Pharmaceuticals-28-KM, Ferozepur Road, Lahore-**
Name & address of API manufacturer	**Xinxiang Pharmaceuticals Co., Ltd.**
Detail of stability batches of drug product	**Provided**
Documents for the procurement of API with approvalfrom DRAP(in case of Import)	**DRAP attested invoice is uploaded in dossier**
Pharmaceutical Equivalence and ComparativeDissolution Profile	**PE has been carried out with Alphacoline injection Manufactured by Korea United Pharma. NC(informed byfirm).**
Stability Studies of Drug Substance/Product(Conditions & duration of Stability studies)	**Provided**
The status in reference regulatory authorities	**Citicoline 250mg/2ml Injection by Panpharma S.A. Approved in France**
GMP status of the firm	**GMP certificate issued to the firm based on inspection conducted on 07.11.2023.**
Evidence of approval of manufacturing facility	**CLB letter No. 1-9/2003-Lic-V-II dated 14th September 2021 indicated liquid injectable ampoule section of firm.**
Evaluation Remarks	
The observations and response of firm is summarized in table below:	
Observations	**Response of Firm**
Valid GMP certificate of drug substance manufacturer.	Valid DML is enclosed
Acceptance criteria of drug substance in Assay is NLT 98%. What is upper limit of it?	Limits are categorically mentioned in Specification, FP Testing Method and stability COAS. (Assay limit 98% - 102.0%) (Enclosed in Module 3, Page# 52-53) (Copy of specs enclosed)
Pharmaceutical Equivalence studies along with name of product against which pharmaceutical equivalence studies are carried out.	PE has been carried out with Alphacoline injection Manufactured by Korea United Pharma. Inc
Evidence that excipients of applied products are similar to innovator products otherwise submit drug excipient compatibility studies.	No excipient used in formulation as it's an injectable dosage form. Just PH is adjusted with the NaOH.
Evidence of approval applied formulation in RRA as adopted by the Registration Board in its 275th Meeting	Enclosed, please find documentation verifying this approval in ANSM, with the status noted as "archived." It's noteworthy that the archived status of the authorization from ANSM does not suggest any withdrawal of the product due

stated the reference product is discontinued in France.	to safety or efficacy concerns, affirming its continued validity. Additionally, the same formulation of Saydon Pharmaceuticals is also approved by DRAP in 317th DRB meeting. (Copy of meeting minute attached) Additionally its me too's are also available in the market like:1. Neurocoline ampoule by Medisure chemicals is available in the market since 1994 2. Citolin ampoule by Global Pharma is available in the market since 2002 3. Cercolin ampoule by Schazoo Pharma is available in the market since 2009
API import documents like clearance certificate from DRAP I&E.	Enclosed
Analytical method validation studies of drug product by drug product manufacturer on all parameters as recommended by guidelines.	Enclosed
Decision	
Approved **Approved with innovator's Specifications.** **Firm shall submit 9,000/- fee for revision of specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of Registration letter.** **The Board directed that RRA status of Citicoline Sodium 250mg/2ml be checked and placed in the Board for harmonized decision.**	

Regarding the RRA status, the applicant (vide e-App TID: WHZ-BEM-VPG7) has submitted evidence confirming approval of "Cidilin (Citicoline as Sodium) Solution for Injection 250mg/2ml (IV/IM)" by AIFA Italy [https://medicinali.aifa.gov.it/it/#/it/dettaglio/0000012133 accessed on 09.02.2026]

Decision: **Registration Board noted the information. Furthermore, the Board advised to process any other registration application of "Citicoline Sodium Injection 250mg/2ml" i.e., deferred for confirmation of approval status in reference regulatory authorities.**

Case No. 06: Approvals of Sildenafil Tablets 50mg & 100mg Granted to M/s Welwrd Pharmaceuticals, Hattar (000574) in 351st Meeting

Registration Board in its 351st meeting held on 23rd-24th Sep, 2025 approved following applications of M/s Welwrd Pharmaceuticals Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) for registration of Sildenafil Tablet 50mg & 100mg.

S/N	Name of Applicant/ Manufacturer	Product Detail	e-App TID/ Date	Decision	Remarks (if any)
1.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)**	**Welfil 100mg Tablet** Each Film Coated Tablet Contains: Sildenafil Citrate eq.to Sildenafil.....100mg United States Pharmacopeia	GM2-BSG-TT1U 2025-06-25	**Approved**	-
2.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial	**Silafold 50mg Tablet** Each Film Coated Tablet Contains: Sildenafil as	QH3-JNV-WWPM 2025-07-22	**Approved**	-

	Estate, Hattar **(000574)**	Citrate(USP)...50mg (Product complies USP Specs) United States Pharmacopeia			
3.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)** **Contract Manufactured by:** M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar	**SILTRATE 100MG TABLET** Each Film Coated Tablet contains: Sildenafil as Citrate.....100mg United States Pharmacopeia	BNA-479-WGV6 2025-07-29	**Approved**	Applicant has telephonically informed that instant case will be withdrawn as they have applied same product on self-manufacturing basis (i.e., approved in M-351).
4.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)** **Contract Manufactured by:** M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar	**SILTRATE 50MG TABLET** Each Film Coated Tablet contains: Sildenafil as Citrate.....50mg United States Pharmacopeia	E3X-MND-QGE5 2025-07-29	**Approved**	Applicant has telephonically informed that instant case will be withdrawn as they have applied same product on self-manufacturing basis (i.e., approved in M-351).

Registration letters have been issued for products at S.No. 01-02. However, instant case has been placed before the Board to decide the fate of products at S.No. 03-04 of above table.

Decision: **Registration Board rejected the registration applications mentioned at S.No. 03-04 of above table as the applicant already holds registration of same products. Accordingly, the relevant approvals granted by the Board in its 351st meeting shall stand redundant/ disposed of.**

Registration-II Section

CASE NO. 01: CANCELLATION OF APPROVED PRODUCT OF M/S NEUTRO PHARMA (PVT) Ltd. 9.5 KM, SHEIKHUPURA ROAD, LAHORE:

The Registration Board in its 329th meeting approved following product in the name of M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore.

Name of the firm	**Composition**	**Decision of the RB taken in its 329th meeting**
M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore	Ciprine 5mg Tablet Each Film coated Contains: Cyclobenzaprine as Hcl …5mg	**Approved with USP specification and with the following label claim:** **Each Capsule contains:** **Cyclobenzaprine HCl (extended release pellets 22%)……5mg** **The firm shall submit fee of Rs. 30,000/-**

		for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before i of registration letter. Firm has submitted fee of Rs. 38700/- on 02-01-2026 vide challan No. 26456801. (verified from website)

However, the Firm already holds the registration of **Clobizin 5mg Tablet Reg. No. 108285** containing Cyclobenzaprine. And also registration letter for Clobizin 15mg and 30mg capsules were already issued.

Decision: Registration Board rejected the application of above product as firm already holds registration of same formulation Clobizin 5mg Tablet Reg. No. 108285

Case No. 02: <u>Cancellation of Approved Product</u>

Registration Board in its 343rd meeting also approved following registration applications. While issuing registration letters it is transpired that registration letters of these products has already been issued in different meetings as per details mentioned against each in last column. Detail is as under:

I	II	III	IV	V
Sr. No.	**Name of firm**	**Product Name and Composition**	**Diary No. and dated**	**Decision / Remarks**
1.	M/s. Wezen Pharmaceutical. Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat	Odenzz 8mg Tablet Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate …. 8mg USP Specifications	Dy. No 22448 dated 12-09-2023.	**Approved** Firm already holds registration of instant product **Onsowit 8mg Tablet Reg. No. 131831** by way of contract manufacturing from M/s. Weather Folds Pharmaceuticals, Hattar.
2.	Daneen Pharma Pvt Limited plot no: 27 sunder industrial estate, sunder raiwind road, Lahore **Contract Manufactured By: M/s.** Genix Pharma (Pvt) Ltd.Pakistan-44, 45B, Korangi Creek Road, Karachi.	TRAMDER Each film coated tablet contains: Paracetamol ....325mg Tramadol HCl ...37.5mg United States Pharmacopeia **7RT-48B-WRGP**	7RT-48B-WRGP 13-12-2023	**Approved** Firm already holds registration of instant product **Tramder 37.5/325 mg Tablet Reg. No. 109423** on self-manufacturing.
3.	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad	Ceftione 1g IV Injection Each Vial Contains: Ceftriaxone Sodium……1g USP	Dy. No. 1846 Dated 14-01-2021	**Approved** Firm already holds registration of instant formulation **Traxocef 1g Injection IV Reg. No. 111604.**

	Contract Manufactured By: M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad			

Decision: **Registration Board rejected the applications of above said products as firms already holds registrations of these formulations as mentioned against each in Column-V.**

Case No. 03: Registration of M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District Kasur.

Registration Board in its 326th meeting deferred following registration application of M/s. Liven Pharmaceuticals. Detail is as under:

1.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Liquid Ampoule (general) Section
	Brand Name + Dosage Form + Strength	Texa 250mg injection
	Composition	Each injection contains; Tranexamic acid……..250mg
	Diary No. Date of R & I & fee	Dy. No. 16273 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782571 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP, BP, JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for strength of 250mg
	Me-too status	Transamin Injection 250mg Reg. No. 007534
	GMP status	Not provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. Evidence of product approval in RRA is required. iv. Volume of injection needs to be defined and also whether it will be an ampoule or vial.
	Decision: Deferred for following; • **Submission of details whether product is ampoule or vial along with its volume.** • **Reference of finished product specifications.** • **Latest GMP inspection report conducted within last three years.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	

Later on, firm vide tracking ID: G8Q-256-A8UH has submitted that their applied strength was 500mg/5ml instead of 250mg. Firm has also submitted fee of Rs.9400/- vid challan No. 169460641407 for such correction along with Form-5.

Hence, correct formulation is as;

Each 5ml contains;

Tranexamic acid ……. 500mg

Decision: Registration Board approved the registration of above product in the name of M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District Kasur as per following details:

Texa 500mg injection
Each 5ml contains:
Tranexamic acid ……. 500mg

Case No. 04 Registration of M/s. Medipak Ltd. Plot No 132 Industrial Estate Kot Lakhpat, Lahore.

Registration Board in its 297th meeting deferred following product of M/s Medipak, Lahore in 286th meetings for confirmation of formulation of Innovator Product. Detail is as under;

Sr. No.	Product Name and Composition	Demanded MRP/Pack size	Remarks	Decision of 297th Meeting of Registration Board
1.	Voluven Infusion Solution. Each 1000ml Contains: Poly(O-2-Hydroxyethyl) starch (Hydroxyethyl starch 130/0.4) …… 60.0gm Sodium Chloride … 9.0gm	Rs.521.70 / 500ml	Approved in TGA Australia as under; Poly(O-2-Hydroxyethyl) starch (Hydroxyethyl starch 130/0.4)……60.0gm/L **Excipient;** Sodium Chloride…9.0gm	**Deferred the product at Sr. No. 1 for confirmation of formulation of Innovator Product**

Firm has also submitted fee of Rs.37000/- dated for correction of formulation as per innovator product Voluven® 6% (Hydroxyethyl Starch 130/0.4 In A Balanced Electrolyte Solution) Approved in TGA.

Decision: Registration Board approved the registration of above product in the name of M/s. Medipak Ltd. Plot No 132 Industrial Estate Kot Lakhpat, Lahore as per following details:

Voluven 6% Infusion Solution.
Each 1000ml Contains:
Poly(O-2-Hydroxyethyl) starch
(Hydroxyethyl starch130/0.4) …… 60.0gm

Case No.01. REQUEST OF M/S CREED PHARMACEUTICAL RAWALPINDI FOR CHANGE OF LOCAL MAH OF "PENSTIN 20/20 INJECTION" TO THEIR NAME FROM M/S ETERNA INTERNATIONAL, ISLSMABAD.

M/s Creed Pharmaceutical, House No.29-C, Lane 2, Shalley Valley Range Road, Rawalpindi, has submitted an application for change of local MAH of following Veterinary Registration from M/s Eterna International, House No.47, School road, F-6/2, Islamabad to their name.Detail of proposed product is as under: -

Product: Penstin 20/20 Injection (Reg. No. 057125)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. No.** Penstin 20/20 Injection Each 100ml contains: Penicillin G Procaine 20gm. Dihydrostreptomycin Sulfate 20gm.	**As per CoPP (No.21100BO/055175)** Penicillin G Procaine…200mg. Dihydrostreptomycin Sulfate …….. 200mg.
	Reg. date / renewal status	Reg. Date 03-06-2009 Renewal due date 02-06-2024 Renewal submission date 22-07-2019	
	Name and address of Applicant (Transferee)	M/s Creed Pharmaceutical, House No.29-C, Lane 2, Shalley Valley Range Road, Rawalpindi	
	Name of Transferor	M/s Eterna International, House No.47, School road, F-6/2, Islamabad	
	Detail of Drug Sale License	**DSL No. 01-374-0176-114995D (valid upto 30-03-2029)** **Address:** M/s Creed Pharmaceutical, House No.29-C, Lane 2, Shalley Valley Range Road, Rawalpindi	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder & Manufacturer:** M/s Hebei Yuanzheng Pharmaceutical Co. Ltd, China	**As per CoPP (No.2024-A1-478).** **Product License Holder & Manufacturer:** M/s Hebei Yuanzheng Pharmaceutical Co. Ltd, No.16, Liuyuan Road, Chang'an District, Shijiazhuang City, Hebei Province, China
	Name of exporting Country	China	
	Diary No. & Date of R& I	Dy. No. ID; 6AX-RAH-49X3 Dated 31/05/2024.	
	Finished Product Specification	Not mentioned on Registration Letter	
	Shelf life	02 Years	
	MRP/Pack Size	50ml & 100ml	

The firm has submitted the following supporting documents / information for approval of abovetransfer of registrations: -

a) Application with a fee of Rs.300,000/-.
b) Copy of Reg. letter.
c) Original & Legalized CoPP issued by China.
d) Original Legalized of Letter of authorization in the name of new importer.
e) Original Legalized Termination / Cancellation letter from Product License Holder in the name of M/s Eterna International, House No.47, School road, F-6/2, Islamabad.
f) Original NOC for transfer of registration from M/s Eterna International, House No.47, School road, F-6/2, Islamabad **(issued on 15-03-2024).**
g) An Undertaking.

Remarks:

Firm has submitted application before renewal expiry.

Decision: Registration Board decided to consider out of queue application of M/s. Creed Pharmaceutical as the transfer of registration was applied within the validity period with previous registration holder i.e M/s. Eterna International and approved the Veterinary registration "Penstin 20/20 Injection" in the name of M/s Creed Pharmaceutical, House No.29-C, Lane 2, Shalley Valley Range Road, Rawalpindi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).

Case.No.02: <u>REQUEST OF M/S MARTIN DOW LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCT.</u>

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternate Brands
1.	Sugammadex Sodium eq. to Sugammadex……..100mg	125493	In view of the availability of suitable therapeutic alternatives in the local pharmaceutical market, the continued presence of this product has become commercially and strategically unfeasible. Considering internal business realignment and product portfolio rationalization, the company does not have any future plans to continue marketing, promotion, or distribution of this product in Pakistan. Additionally, this decision will not have any negative impact on patient care, as multiple alternate brands of the same molecule with comparable quality, safety, and	Sugammadex Injection IV by M/s Bajwa Pharma, Sugamatic Injection by M/s Seatle Private Limited. Sumexa Injection by M/s Surge Laboratories. Suga Injection IV by M/s Brookes Pharma Private Limited.

			efficacy are readily available in the market. Therefore, in light of the above reasons, Martin Dow Limited has decided to request voluntary deregistration of the product	

Firm has submitted following supporting documents:

a. Copy of Registration letter issued on 17-12-2024.
b. Fee of Rs.7500/- for above product.
c. List of alternative brands as mentioned above.
d. Justification as mentioned above.
e. An Undertaking.

Decision: Registration Board acceded the firm's request for de-registration of following imported product:

S. No	Product(s) Name	Reg. No.
1.	**Sugammadex Sodium eq. to Sugammadex……100mg**	**125493**

Case.No.03: **REGISTRATION OF DRUGS UNDER DRUGS ACT, 1976.**

Registration Board in its 352nd meeting considered and approved the following product of M/s Brand Station, 69 Wocland Villas Near Raiwind Road, Opposite Alfatah Store Near Valencia Town, Lahore.

Name of Importer/Manufacturer	Name of Product and Composition
M/s Brand Station 69 Wocland Villas Lahore Near Raiwind Road, Lahore. **Product License Holder & Manufacturer:** M/s Inner Mangolia Huatian Pharmaceutical Co. Ltd - Economic Development & Experiment Zone Economical Transformation of Resource Dependent City, ChiFeng, Inner Mongolia, P.R. China.	Lincospecto BS (Water Soluble Powder) Each gram contains: Amoxicillin trihydrate ……..200mg Lincomycin hydrochloride…..88mg Spectinomycin hydrochloride..... 88mg Vitamin E Acetate 30mg

Decision: Approved as per current import policy and firm shall submit original legalized FSC, GMP and Letter of Authorization before issuance of registration letter

Virtual inspection of manufacturer abroad was conducted on 30th December, 2025 and not recommended on by nominate panel Madam Sara Mehreen, Assistant Director PE&R Division DRAP, Islamabad and Mr. Muhammad Sarfraz Nawaz, Deputy Director PE&R Division DRAP, Islamabad Conclusion of the panel of experts is as under:

Conclusion

A virtual inspection was conducted covering the activities mentioned in the preceding paragraphs. There is a clear distinction between physical and virtual inspections, as the depth of a virtual inspection is inherently limited. Since dedication of a penicillin production area was not indicated on the GMP certificate, the firm was requested to submit the facility layout. Assessment of the initially provided layout did not show any dedicated penicillin section. Later a revised layout was submitted, wherein the previously identified (on initially submitted layout) Powder & Pulvis Workshop of TCM & Western Medicine was shown (on later submitted layout) as a penicillin-producing workshop. However, based on the documents provided including the Veterinary Medicine Production License, GMP certificate, and facility layout it appears that the manufacturer does not maintain a dedicated penicillin production section. Consequently, the inspection panel rejected the site for GMP non-compliance.

In view of above, a personal hearing notice issued to the firm dated 20th February, 2026. The firm has submitted **Reply received from their Manufacturer and re-produced as under:**

We, Inner Mongolia Huatian Pharmaceutical Co., Ltd here Sincerely Clarify that Our Penicillin Powder producing workshop area is definitely different from other General Antibiotics powder producing workshop areas.

Regarding the GMP certificate not clearly point out a isolated Penicillin workshop, Which is our Agricultural Ministry permitted statement, As in China the GMP regulation not required the words of “isolated penicillin workshop “ on the certificate, According to the factory inspecting on 19-20th, November 2025with DRAP, We are cleared that in Pakistan it needs certificate also put isolated penicillin workshop or some relevant letters on, After consulted from our country agricultural ministry, they said it cannot be added, Because In China, Near all Medicine Manufacturers knew that the penicillin powder producing area should be isolated from others. They said we can give you a good explanation paper and say some promised words with the company seal stamped if it is necessary.

We promise again that the penicillin powder-producing workshop area will be isolated from others at all times. This one penicillin-producing workshop (see the attached Layout below) is now only used for

Penicillin powder products, which will not be used for other antibiotic powder production. Hope you could give a kind understanding.

Decision:

The Board deferred the case for evidence of approval of penicillin containing products in the country of origin and supporting documents for relevant regulatory authority showing availability of claimed dedicated penicillin manufacturing areas.

Case.No.04: **REGISTRATION OF DRUGS UNDER DRUGS ACT, 1976.**

The following products of M/s Himmel Pharmaceuticals (Pvt.) Ltd, Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore considered and deferred in 351st meeting of Registration Board as per following details: -

M-351			
1.	**HIMMEL PHARMACEUTICALS (PVT.) LTD,** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **Product License Holder:** **Manufacturer.** Beacon Pharmaceuticals PLC.- Kathali, Bhaluka , Mymensingh, - Bangladesh	**Abenix 200mg Tablet** Each film coated tablet contains Abemaciclib 200mg As per Innovators Specification 2 Year(s)Store below 30°C. YSJ-68H-6VT4	60's-As per SRO Non essential
Decision: **Deferred 351st meeting** Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life.			
2.	**-do-**	**Abenix 100mg Tablet** Each film-coated tablet contains Abemaciclib….100mg As per Innovators Specification 24 Months (s)Store below 30°C. 6UM-YEY-JUPT	60's-As per SRO Non essential
Decision: Deferred 351st meeting. Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life.			

The same products considered and rejected in 353rd meeting of Registration Board as per following details: -

1.	**HIMMEL PHARMACEUTICALS (PVT.) LTD,** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **Product License Holder:** **Manufacturer.** Beacon Pharmaceuticals PLC.- Kathali, Bhaluka , Mymensingh, - Bangladesh	**Abenix 200mg Tablet** Each film coated tablet contains Abemaciclib 200mg As per Innovators Specification 2 Year(s)Store below 30°C. YSJ-68H-6VT4	60's-As per SRO Non essential
Decision: Rejected The Registration Board rejected the present application after noting a discrepancy between the coated tablet weight recorded in the Batch Manufacturing Record (BMR) and the drug product details submitted in the CTD section 3.2.P.1 of the dossier. In addition, overwriting and alteration of dates were observed on multiple pages of the BMR; specifically, at two locations the year "2025" appears to have been cut and changed to "2022," raising serious concerns regarding data integrity. Moreover, several pages of the BMR indicate that the manufacturing process was carried out in the year 2025. Furthermore, the firm submitted BMRs for only two stability batches, which is insufficient to support the application.			
2.	**-do-**	**Abenix 100mg Tablet** Each film-coated tablet contains Abemaciclib….100mg As per Innovators Specification 24 Months (s)Store below 30°C. 6UM-YEY-JUPT	60's-As per SRO Non essential
Decision: Rejected The Registration Board decided to reject the instant application upon observing a variation in the weight of the coated tablet in all three BMRs compared to the drug product details submitted in the CTD section 3.2.P.1. Furthermore, the composition of all three stability batches also shows variations despite the same claimed batch size for each batch. Details of the observed variations are recorded in the evaluation remarks column.			

The same products were duplicate in the 353rd meeting of the Registration Board, presented by the Import & Vet Section, PE&R Division. Therefore, these products may be deleted as they have already been applied for through the e-application system. The same decision will be applicable as per the online application.

Decision:

The Board decided to delete repeated agenda item presented by Import & Vet Section 353rd meeting of registration Board of product Abenix 200mg Tablet & Abenix 100mg Tablet.

Case No. 5: Requirement of NOC for Change of Importer under PRVC Application

It is submitted for the consideration of the Registration Board that in cases where an importer intends to apply for a **Post Registration Variation Case (PRVC)** for a product that is already registered and being imported by another importer in Pakistan, the applicant shall be required to submit a **No Objection Certificate (NOC)** from the existing importer for the change of importer.

In the absence of the NOC from the existing importer, the application shall **not be processed under PRVC.** Instead, the case shall be treated as a **fresh registration application** and processed in accordance with the relevant DRAP guidelines on a **First-In-First-Out (FIFO) basis**.

Decision:

The Board deliberated on the matter and decided that for imported products, an application for change in marketing authorization holder/Importer shall accompany an NOC from existing MAH/Importer. In case the NOC is not available, the application shall be processed as a routine case unless it qualifies for priority consideration as defined in the 257th Meeting of the Registration Board or by the Authority from time to time**.** Furthermore, any application submitted **without NOC shall be taken up for consideration as a routine case after cancellation of registration of case of previous marketing authorization holder/importer due to termination of letter of authorization from product license holder /marketing authorization holder abroad.**

RRR Section

Case No.01: M/s AZ Pharmaceuticals Co. Ltd., address 4-KM, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338)

M/s AZ Pharmaceuticals Co. Ltd., submit the Form 5 Application with requisite fee and documents of already registered products of the previously under DML No. 000338, as per the following details, DML No. 000338 was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal.

The Central Licensing Board, 312th meeting held on 04 November 2025, considered the application for approval of Regrant the DML (by way of formulation) and DML has been received with issuance dated is. 14-11-2025.

The DRAP Authority in 199th meeting (held on 31st January, 3rd and 4th February 2025) after thorough deliberation, in continuation of its previous decision in 180th meeting exempted Form 5F to those products which were cancelled due to cancellation of DML on account of late/non submission of renewal.

Following applications are submitted in the light of above-mentioned decision:

1.	Brand Name + Dosage Form and Strength	Immunasol 5 % IV Infusion
	Composition	Each 1000ml contains:- Dextrose Anhydrous……..50gm
	Tracking ID and fee details	Challan No. 41469255 Rs. 38700 & Tracking ID WAT-EL2-D1Y3
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	500ml, 1000ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved.
	RRA status	MHRA Approved
	Remarks:	Immunasol 5% IV Infusion (014233) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025,

		due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml)
	Decision: Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
2.	Brand Name + Dosage Form and Strength	Immunasol 10% Intravenous Infusion
	Composition	Each 1000ml contains:- Dextrose Anhydrous……..100gm
	Tracking ID and fee details	Challan No. 719192064503 Rs. 38700 & Tracking ID 4TY-785-QG4H
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	500ml, 1000ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved.
	RRA status	MHRA Approved
	Remarks:	Immunasol 10% Intravenous Infusion (014234) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml)
	Decision: : Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
3.	Brand Name + Dosage Form and Strength	Immunasol NS IV Infusion
	Composition	Each 1000ml contains:- Sodium Chloride……..9gm
	Tracking ID and fee details	Challan No. 72652747972 Rs. 38700 & Tracking ID Q7M-7GB-GTNZ
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	500ml, 1000ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	MHRA Approved
	Remarks:	Immunasol NS IV Infusion (014235) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025,

		due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml)
	Decision: : Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
4.	Brand Name + Dosage Form and Strength	Immunasol DN Intravenous Infusion
	Composition	Each 1000ml contains:- Dextrose Anhydrous……..50gm Sodium Chloride…….9gm
	Tracking ID and fee details	Challan No. 63116404527 Rs. 38700 & Tracking ID: 1BD-1AU-R1J2
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	500ml, 1000ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	MHRA Approved
	Remarks:	Immunasol DN Intravenous Infusion (014236) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml)
	Decision: : Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
5.	Brand Name + Dosage Form and Strength	Immunasol-H IV Infusion
	Composition	Each 1000ml contains:- Sodium Chloride…….6.00gm Potassium Chloride ……..0.400gm Sodium Lactate …….....6.200gm Calcium Chloride $2H_2O$ ……..…0.27gm
	Tracking ID and fee details	Challan No. 3249846568 Rs. 38700 & Tracking ID: 5ZX-E87-9PMV
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	1000ml, 500ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	MHRA Approved

	Remarks:	Immunasol-H IV Infusion (015329) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml) The sodium lactate quantity is found different in RRA approved formulations. Moreover 50% and 60% concentration of sodium lactate is used in reference as well as generic product.
	Decision: Deferred for clarification/revision of formulation in line with RRA/innovator's product	
6.	Brand Name + Dosage Form and Strength	Immunasol-DN½ IV Infusion
	Composition	Each 1000ml contains:- Sodium Chloride B.P. ……...4.50gm Dextrose Anhydrous……50.00gm
	Tracking ID and fee details	Challan No. 039567001231 Rs. 38700 & Tracking ID: SMA-JU8-5TAN
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	1000ml, 500ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	USFDA Approved
	Remarks:	Immunasol-DN IV Infusion (015331) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml)
	Decision: : Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
7.	Brand Name + Dosage Form and Strength	Immunasol-HD IV Infusion
	Composition	Each 1000ml contains:- Dextrose Anhydrous……..50.00gm Sodium Chloride……..6.00gm Potassium Chloride……0.400gm

		Sodium Lactate …….....6.200gm Calcium Chloride 2H20……..…..0.27gm
	Tracking ID and fee details	Challan No. 509773754 Rs. 38700 & Tracking ID: H7N-VHA-TLA4
	Type of form	IV Infusion
	Finished product specifications	USP Specification
	Pack size and Demand Price	1000ml, 500ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	MHRA approved
	Remarks:	Immunasol-HD IV Infusion (015332) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal. 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml) Composition of reference product (Lactated Ringer's Injection, USP) is different from applied product
	Decision: Deferred for clarification/revision of formulation in line with RRA/innovator's product	
8.	Brand Name + Dosage Form and Strength	Immunasol Paed IV Infusion
	Composition	Each 1000ml contains:- Sodium Chloride B.P. ……1.8gm Dextrose Anhydrous B.P. ……43.00gm
	Tracking ID and fee details	Challan No. 01810853286 Rs. 38700 & Tracking ID: BET-81X-ZVHS
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	1000ml, 500ml
	RRA status	MHRA approved
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	Remarks:	Immunasol Paed IV Infusion (015333) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either

		500ml or 1000ml) Applied formulation is not found approved in RRA
	Approved with only one pack size (volume) and one presentation either with or without Eurocap.	
9.	Brand Name + Dosage Form and Strength	Immunatol I.V Infusion
	Composition	Each 100ml contains:- Mannitol B.P ……17.5gm Sorbitol…….2.5gm.
	Tracking ID and fee details	Challan No. 16456450311 Rs. 38700 & Tracking ID: 8U8-QZ7-1GWB
	Type of form	IV Infusion
	Finished product specifications	Manufacturer's specification
	Pack size and Demand Price	500ml, 1000ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	Not found
	Remarks:	Immunatol I.V Infusion (022079) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml) Approval status of applied formulation in RRA not found.
	Decision: Deferred for confirmation of approval status of applied formulation in RRA.	
10.	Brand Name + Dosage Form and Strength	Immunadialysis Concentrate Solution
	Composition	Each 1000ml contains: Sodium Chloride…….….199.2gm Sodium Acetate $3H_20$……..174.3gm Calcium Chloride $2H_20$……....6.4gm Magnesium Chloride 6H…….….5.3gm Potassium Chloride…….….6.8gm Dextrose MH……..96.3gm Water for Injection q.s
	Tracking ID and fee details	Challan No. 1908073212 Rs. 38700 & Tracking ID: 92A-98L-UV8S
	Type of form	IV Infusion
	Finished product specifications	BP Specification
	Pack size and Demand Price	100ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved

	RRA status	Not found
	Remarks:	Immunadialysis Concentrate Solution (022080) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal Approval status of applied formulation in RRA not found
	Decision: Deferred for confirmation of approval status of applied formulation in RRA	
11.	Brand Name + Dosage Form and Strength	Immunazole Injection
	Composition	Each 100ml contains:- Metronidazole B.P…….500mg
	Tracking ID and fee details	Challan No. 16456450311 Rs. 38700 & Tracking ID: QZY-XRA-G7RN
	Type of form	IV Infusion
	Finished product specifications	BP specification
	Pack size and Demand Price	100ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	MHRA Approved
	Remarks:	Immunazole Injection (022081) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal
	Decision: Approved	
12.	Brand Name + Dosage Form and Strength	Immuasol-NS IV Infusion
	Composition	Each 100ml contains:- Sodium Chloride…….0.9g (USP specification)
	Tracking ID and fee details	Challan No. 1908073212 Rs. 38700 & Tracking ID: QR9-5ZZ-LS4S
	Type of form	IV Infusion
	Finished product specifications	USP specification
	Pack size and Demand Price	100ml
	GMP Status	DML (afresh) granted dated 14th November 2025 Large volume parenteral (infusion) section is approved
	RRA status	USFDA Approved
	Remarks:	Immuasol-NS IV Infusion (084806) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide

		letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal
	Decision: : Approved with only one presentation as with or without Eurocap.	

Case No.02: M/s Macter International Ltd. F-216 SITE Karachi.

Following applications are submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Venticort Inhaler (200mcg+6mg)
	Composition	Each actuation contains:- Budesonide…….200mcg Formoterol Fumarate Dihydrate…….6mcg
	Tracking ID and fee details	Challan No. 12482966158 Rs. 38700 & Tracking ID 6TA-BB8-RUGA
	Type of form	Inhaler
	Finished product specifications	As per Innovator's Specifications
	Pack size and Demand Price	30's
	GMP Status	DML renewal inspection conducted on 13th and 18th August 2025
	RRA status	TGA Approved
	Remarks:	Firm has applied re-registration of Venticort Inhaler (200mcg+6mg) Reg.No.086110 due to non-submission of renewal application for year 2022. The label claim of reference product (SYMBICORT RAPIHALER) states delivered dose as under: Each delivered dose (the dose that leaves the mouthpiece) contains as active constituents: Budesonide 160µg/inhalation and formoterol 4.5 µg/inhalation.
	Decision: Approved with standardization of label claim as mentioned above along with fee (as per SRO) and availability of cascade impactor instrument.	
2.	Brand Name + Dosage Form and Strength	Venticort Inhaler (100mcg+6mg)
	Composition	Each actuation contains:- Budesonide…….100mcg Formoterol Fumarate Dihydrate…….6mcg
	Tracking ID and fee details	Challan No. 4560371112 Rs. 38700 & Tracking ID 5JQ-9P6-5PT1
	Type of form	Inhaler
	Finished product specifications	As per Innovator's Specifications
	Pack size and Demand Price	30's
	GMP Status	DML renewal inspection conducted on 13th and 18th August

		2025
	RRA status	TGA Approved
	Remarks:	Firm has applied re-registration of Venticort Inhaler (200mcg+6mg) Reg.No.086109 due to non submission of renewal application for year 2022. The label claim of reference product (SYMBICORT RAPIHALER) states delivered dose as under: Each delivered dose (the dose that leaves the mouthpiece) contains as active constituents: budesonide 80 µg/inhalation and formoterol 4.5 µg/inhalation
	Decision: Approved with standardization of label claim as mentioned above along with fee (as per SRO) and availability of cascade impactor instrument.	

Case No.03: M/s Al-Fazal Pharma Industries (Pvt) Ltd.16-Km Sheikhupura Road Lahore

Following applications are submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Fazotose Syrup
	Composition	Each 5ml contains:- Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron… 50mg
	Tracking ID and fee details	Challan No. 62500706 Rs. 38700 & Tracking ID 1PR-SXL-Y93B
	Type of form	Syrup
	Finished product specifications	Not mentioned
	Pack size and Demand Price	60ml and 120ml
	GMP Status	GMP Inspection Report Dated: 06.08.2024
	RRA status/generic product	Bisleri syrup by M/s Sami pharma, Karachi
	Remarks:	Firm has applied re-registration of Fazotose Syrup Reg.No.078900 due to non submission of renewal application Section approval letter by CLB is not provided
	Decision: Approved.	

2.	Brand Name + Dosage Form and Strength	Mizicine Capsule 250mg
	Composition	Each capsule contains:- Azithromycin as dihydrate… 250mg
	Tracking ID and fee details	Challan No 9902573546 Rs. 38700 & Tracking ID 1PR-SXL-Y93B
	Type of form	Capsule

	Finished product specifications	Not mentioned
	Pack size and Demand Price	1x10's
	GMP Status	GMP Inspection Report Dated: 06.08.2024
	RRA status/generic product	USFDA approved Zithromax
	Remarks:	Firm has applied re-registration of Mizicine Capsule 250mg Reg.No.078901 due to non submission of renewal application Section approval letter by CLB is not provided
	Decision: Approved	

Case No.04: M/s Neomedix Plot No. 5/N-5 National Industrial Zone, Rawat.

Following application is submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Leucodix Tablet 15mg
	Composition	Each Tablet contains:- Calcium Folinate Hydrate eq. to folinic acid……..15mg
	Tracking ID and fee details	Challan No. 9692316627 Rs. 38700 & Tracking ID NY2-EVH-J73U
	Type of form	Tablet
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10's, 14's, 20's, 30's and 56's
	GMP Status	GMP Inspection Report dated: 29.03.2024
	RRA status	MHRA Approved
	Remarks:	Firm has applied re-registration of Leucodix Tablet 15mg Reg.No.068829 due to non submission of renewal application
	Decision: Approved	

Case No.05: M/s. Convell Laboratories pharmaceutical manufacturing Saidu sharif swat Pakistan

Following applications are submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Veldox 40 mg Dry suspension
	Composition	Each oral suspension contains Cefpodoxime Proxetil…….40mg/5ml
	Tracking ID and fee details	NEL-9D1-5ZGQ Rs.37,000/-dated: 04-July-2025 (840505501647)
	Type of form	Fom-5
	Finished product specifications	USP Specification
	Pack size and Demand Price	As per SRO, 50 ml
	GMP Status	Not provided
	RRA status	HPRA approved

	Remark of the Renewal section	Firm has applied re-registration for Veldox 40 mg/5ml/50ml Dry suspension Reg.No. 032390 due to non-submission of renewal application Remarks: Label claim to be standardized in line with RRA along with fee as under: When reconstituted each 5ml volume contains: cefpodoxime (as cefpodoxime proxetil)……40mg The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Approved alongwith standardization of label claim.	
2.	Brand Name + Dosage Form and Strength	Conflox 200 mg tablet
	Composition	Each film coated tablet contains Ofloxacin……...200mg
	Tracking ID and fee details	V3V-DA7-R7PD Rs.37,000/-dated: 04-July-2025 (73539728814)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	USFDA approved
	Remark of the Renewal section	Firm has applied re-registration for Conflox 200 mg tablet Reg.No. 033718 due to non submission of renewal application The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP.	
3	Brand Name + Dosage Form and Strength	Crolid 125 mg/5ml oral suspension
	Composition	Each 5ml contains Clarithromycin ….125 mg
	Tracking ID and fee details	PPJ-YNQ-WJQN Rs.37,000/-dated: 04-July-2025 (8014241046638)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	MHRA
	Remarks	Firm has applied re-registration for Crolid 125 mg/5ml oral suspension (Reg.No. 032394) due to non-submission of renewal application

		The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP.	
4.	Brand Name + Dosage Form and Strength	Crolid 250 mg tablet
	Composition	Each film coated Tablet contains Clarithromycin……..250 mg
	Tracking ID and fee details	772-G6M-YNPU Rs.37,000/-dated: 04-july-2025 (55789777132)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	MHRA approved
	Remarks	Firm has applied re-registration for Crolid 250 mg tablet Reg.No. 032392 due to non submission of renewal application The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP.	
5.	Brand Name + Dosage Form and Strength	Crolid 500 mg tablet
	Composition	Each film coated tablet contains Clarithromycin……500 mg
	Tracking ID and fee details	ENV-XV3-JNMN Rs.37,000/-dated: 04-july-2025 (1825532480)
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	MHRA approved
	Remarks	Firm has applied re-registration for Crolid 500 mg tablet Reg.No. 032393 due to non submission of renewal application The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP.	
6.	Brand Name + Dosage Form and Strength	ETA syrup
	Composition	Each Syrup contains Acefylline piperazine B.P 45 mg

		Diphenhydramine HCl BP 8 mg
	Tracking ID and fee details	MQV-174-WTUP Rs.37,000/-dated: 04-july-2025 (622165473)
	Type of form	Fom-5
	Finished product specifications	USP Specification
	Pack size and Demand Price	As per SRO, 1x1 60 ml , 120ml
	GMP Status	Not provided
	RRA status	Not found
	Remarks	Firm has applied re-registration for ETA syrup 60 ml, 120ml Reg.No. 032396 due to non submission of renewal application. Firm has applied USP specification while applied formulation is not found available in any official monograph The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP.	
7.	Brand Name + Dosage Form and Strength	Niltus syrup 120 ml
	Composition	Each 5ml contains Aminophylline……32 mg Diphenhydramine HCl……..8 mg Ammonium chloride……30 mg Menthol……0.98 mg
	Tracking ID and fee details	8Y2-E58-SRQ9 Rs.37,000/-dated: 04-july-2025 (7216618389)
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specification
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	Not found
	Remarks	Firm has applied re-registration for Niltus syrup 120 ml Reg.No. 032397 due to non submission of renewal application. The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP	
8.	Brand Name + Dosage Form and Strength	Velcodin syrup 60 ml

	Composition	Each Syrup contains Promethazine HCl 1.5 mg Pholcodine 1.5 mg
	Tracking ID and fee details	2DW-XR6-JB5S Rs.37,000/-dated: 04-july-2025 (9609481299)
	Type of form	Fom-5
	Finished product specifications	BP specification
	Pack size and Demand Price	As per SRO
	GMP Status	Not provided
	RRA status	Not found
	Remark of the Renewal section	Firm has applied re-registration for Velcodin syrup 60 ml Reg.No. 032395 due to non-submission of renewal application. Firm has applied BP specification while applied formulation is not found available in any official monograph The DML renewal status/GMP is not clear yet since maintenance work is ongoing. Manufacturing facility/sections approval yet to be verified
	Decision: Deferred for confirmation of manufacturing facility and updated GMP	

Case No.06: <u>M/s. Barrett Hodgson Pakistan (Pvt.) Ltd F/423, SITE, Karachi-75700.</u>

Following application is submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	**MobiKare Gel**
	Composition	Each 100gm contains: Diclofenac diethylammonium salt corresponding to 1g diclofenac sodium
	Dairy No. date of R &I fee	Rs. 38,700/-Via Challan no. 9772944958 YN8-6LM-R5S1
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	GMP Certificate dated 02nd November, 2023
	RRA status	MHRA approved
	Remarks	Registration of MobiKare Gel tablet Reg No. (024007) Firm has applied afresh due to non- submission of renewal
	Decision: Approved	

Case No.07: <u>M/s. PDH Pharmaceuticals (Pvt.) Ltd. 19-KM Ferozepur Road, Lahore-Pakistan</u>

Following applications are submitted for grant of registration of below mentioned products as per decision of the DRAP Authority in its 180th meeting held on 07th March 2024.

1.	Brand Name + Dosage Form and Strength	Azirolide 250mg capsule
	Composition	Each capsule contains: Azithromycin (as dihydrate)…250mg
	Dairy No. date of R &I fee	Tracking ID# QR7-6WT-EH25

		Rs. 38,700/-Via Challan no. 5264515980
	Type of form	Fom-5
	Finished product specifications	(USP Specifications)
	Pack size and Demand Price	As per SRO, 12's
	GMP Status	DML renewal/Section approval letter granted on 23-01-2026
	RRA status	MHRA approved
	Remarks	Registration of Azirolide 250mg capsule (Reg No. 028055) is applied afresh due to non- submission of renewal
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Azirolide Suspension
	Composition	Each 5ml contains: Azithromycin (as Dihydrate)...200mg
	Dairy No. date of R &I fee	Tracking ID#3Z7-APW-8JHJ Rs. 38,700/-Via Challan no. 649951788
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	15ml
	GMP Status	DML renewal/Section approval letter granted on 23-01-2026
	RRA status	USFDA approved
	Remarks	Registration of Azirolide Suspension (Reg No. 028054) is applied afresh due to non- submission of renewal
	Decision: Approved	

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	CASE TITLE
1.	**AVAILABILITY OF COUNTERFEIT CEPHRADINE CAPSULES AGAINST BRAND VELOSEF CAPSULE MANUFACTURED BY GSK PAKISTAN LIMITED, REGISTRATION NO. 001863**
2.	**OOS INVESTIGATION OF SUBSTANDARD MELOVETZ 10 INJECTION, REG. NO. 102021 BATCH NO # 2599063 MANUFACTURED BY M/S. VETZ PHARMACEUTICALS (PVT.) LTD., PLOT # Q-1, S.I.T.E KOTRI, SINDH**

CASE NO.1: **AVAILABILITY OF COUNTERFEIT CEPHRADINE CAPSULES AGAINST BRAND VELOSEF CAPSULE MANUFACTURED BY GSK PAKISTAN LIMITED, REGISTRATION NO. 001863**

1. M/s Glaxo SmithKline (GSK) Pakistan Limited submitted an application dated 12-12-2025, wherein they stated that their product 'Velosef Capsule' has been duly registered under Registration No. 001863, with DRAP, and is also registered with the Trademarks Registry and the Intellectual Property of Pakistan. However, several Pharmaceutical Companies have been manufacturing and marketing products with packaging, design, artistic work, and color schemes that visually identical and deceptively similar to their product. the name of the companies and their respective products is given below:
    a. Farmaceutics International; Haradene
    b. Mediate Pharmaceuticals Pvt Ltd; Quin-safe
    c. Shawan Pharmaceuticals; Wadin
    d. Medicraft Pharmaceuticals Pvt Ltd; Velomed

2. The firm has attached scanned copies of IPO Tribunal Orders and infringing Products

3. The firm was asked to provide, commercial packs of above stated products as well as Velosef for comparison purposes; however, the firm was able to provide packs of Velomed Manufactured by Medicraft Pharmaceuticals Pvt Ltd and Velosef manufactured by GSK only.

4. The firm has requested to restrain the aforementioned companies from manufacturing, packaging, distributing, selling or offering for sale the said products. The firm has further requested assistance in recalling the infringing products from the market.

12 Capsules
500 mg
VELOSEF CAPSULES
(Cephradine)
Each capsule contains 500 mg
Cephradine U.S.P.
۵۰۰ ملی گرام
ویلوسیف کیپسول
6x2 Capsules
500mg
VELOMED
(Cephradine)
MEDICRAFT
VELOSEF CAPSULES
12 Capsules
250 mg
VELOSEF CAPSULES
(Cephradine)
Each capsule contains 250 mg
Cephradine U.S.P.
۲۵۰ ملی گرام
ویلوسیف کیپسول
6x2 Capsules
250mg
VELOMED
(Cephradine)
MEDICRAFT

12 Capsules
gsk
GlaxoSmithKline
500 mg
VELOSEF CAPSULES
(Cephradine)
Each capsule contains 500 mg
Cephradine U.S.P.
۵۰۰ ملی گرام
ویلوسیف کیپسول
VELOSEF CAPSULES ویلوسیف کیپسول
6x2 Capsules
500mg
VELOMED
(Cephradine)
MEDICRAFT

Decision: **Registration Board deferred the case for next meeting.**

CASE NO.2: **OOS INVESTIGATION OF SUBSTANDARD MELOVETZ 10 INJECTION, REG. NO. 102021 BATCH NO # 2599063 MANUFACTURED BY M/S. VETZ PHARMACEUTICALS (PVT.) LTD., PLOT # Q-1, S.I.T.E KOTRI, SINDH**

Federal Inspector of Drugs, Karachi during routine GMP inspection on 31-05-2021 took sample of following drug from premises of M/s Vetz Pharmaceuticals (Pvt.) Ltd., Kotri and sent to CDL for test and analysis. Details of CDL test and analysis report were as following

Product	Batch No.	Mfg. Date	Exp. Date	CDL Report
Melovetz 10 Injection 10mg /ml (Meloxicam) (Reg. # 102021)	2199017	05-2021	04-2023	Report No. KQ.161/2021 dated 27-07-2021 pH does not comply Results: 13.45 Ref. Range: 7.5-9.1

3. A notice of personal hearing was issued vide letter No. 03-18/2023-QC (326-RB) dated 08-03-2023. The firm replied vide their letter No. V/23004 dated 13-03-2024 stating that their product Melovetz Inj was in-house specification as per registration letter however CDL did not ask the manufacturer to provide the testing method as their method was developed as per in house specification. The firm further stated that they had revised our finished product specification as per pharmacopeia.

4. Case was placed before 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:

a. *Suspension of the Registration of Melovetz Injection, Registration No. 102021 under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.*
b. *The firm was advised to follow the Pharmacopoeial specifications in compliance to the specification rules.*
c. *Submission of RCA and CAPA by the firm.*
d. *Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT. During inspection the panel will also confirm the compliance to the specification rules.*

5. Letter for Suspension of Registration was issued bearing No. 03-18/2023-QC (326-RB) dated 26-05-2023, and letter No. 03-18/2023-QC (326-RB) dated 08-06-2023 for Product Specific Inspection by inspection panel, was issued.

6. Panel conducted PSI on 16.05.2024 and panel concluded that recommended that suspended registration of Melovetz Injection (Reg. No. 102021) may be resumed and first 2-3 batches of samples may be sent again to CDL for test/analysis before marketing. Also to submit batch validation reports of first three commercial batches with the revised formulation.

7. The Board in its 345th meeting held on 19th - 21st February 2025, after considering the facts of the case, keeping in view recommendations of panel of experts in its report dated 16.05.2024 and after thorough deliberations decided:

i. *"To resume the production of Melovetz 10 Injection, Registration No. 102021 of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Kotri, Sindh.*
ii. *Firm shall inform area FID to take sample from 1st commercial batch for the purpose of test/analysis by CDL Karachi and sale of the product is subject to the standard report by the Central Drugs Laboratory, Karachi and subsequent approval by Director (QA & LT).*
iii. *Also to submit batch validation reports of first three commercial batches with the revised formulation."*

8. The Federal Inspector of Drugs-II, DRAP, Karachi, during the inspection of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh dated 28th August, 2025, took samples of Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063 on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

declared Batch No. 2599063 of Melovetz Injection 50ml 10mg/1ml manufactured by M/s. Vetz P

Drug Sample	**Mfg. Date**	**Exp. Date**	**Tests**	**CDL Report No.**	**Manufacturer**
Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063	06/2025	05/2027	Sterility **Does not comply**	KQ-9-25-000125 dated 24th October 2025 The sample is of sub-standard quality under the Drugs Act 1976.	M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh

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10. FID-II, Karachi forwarded copy of the CDL report to the firm with show cause letter vide No.F.5-11/2025-FID-II(K) dated 5th November, 2025. Thereafter, the firm submitted its request for Appellate testing to the office of FID-II, Karachi vide letter No. VTZ 289 dated 21-11-2025.

11. In this regard, it is submitted that the Registration Board in its 313th meeting decided as under:

Proceedings and Decision of 313th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided as:
i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."

12. In light of the above-mentioned decision of the Board, the division of QA&LT vide letter F.No.03-07/2025-DDQALT-VI dated 02-01-2026, requested the Federal Government Analyst CDL Karachi and M/s. Vetz Pharmaceuticals (Pvt.) Ltd for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

13. The firm has submitted that total manufactured quantity was 1000 units of which were not marketed as CDL report was awaited as per directions of the Registration Board.

14. Summary of evaluation of Out of specification (OOS) investigation by the division of QA&LT is given as under:

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:
Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the BP Vet, 2024 test/analysis method and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Summary of OOS investigation submitted by M/s. Vetz Pharmaceuticals (Pvt.) Ltd

M/s. Vetz Pharmaceuticals (Pvt.) Ltd in their reply has provided OOS investigation of Melovetz Injection 50ml 10mg/1ml Reg# (102021) Batch No. 2599063 at the laboratory level along with relevant evidences and has claimed to rule out any chance of error in the manufacturing or testing of the product in question.

Technical Evaluation of OOS Investigation:

i. The product was declared by CDL as sub-standard on the basis of Sterility
ii. CDL performed Sterility Testing in accordance with BP Vet. 2024 whereas manufacturer referenced USP <71> for Sterility Test in OOS investigation.
iii. In the initial observation of OOS Investigation, the firm mentioned that the DRAP laboratory reported sterility test failure and that the observation reportedly was based on appearance of turbidity / crystalline particles in sterility test media. However, neither CDL test report nor OOS investigation from CDL, Karachi mentions crystalline particles; rather as per report, the test for visible particulate matter complies with BP vet 2024.
iv. Furthermore, Confirmatory / Retesting at Manufacturing Site performed by the manufacturer shows that retesting was performed on control/hold samples of the same batch. strictly as per USP <71> Sterility Test**.** Results of Retesting showed No microbial growth in either FTM or SCDM after completion of incubation period. However, under the heading of Additional Observation, the firm mentioned the presence of **Crystalline material** in sterility test media during incubation which were transparent/white, settled at the bottom, did not cause turbidity, and did not spread or increase over time.
v. Phase-I Laboratory Investigation conducted by the firm showed that no deficiencies were found in the reviewed Analyst training records, SOP for Sterility test was followed without deviation, Media preparation, sterilization, GPT, and environmental monitoring results reviewed were all within limits, Media Growth Promotion Test was passed, Incubator temperature records were found Within 20–25°C and 30–35°C limits, Sterility test isolator/LAF environmental monitoring also Complied. Therefore, after Phase-I investigation, the firm concluded that no laboratory error or contamination source was identified.
vi. Phase II – Full Scale Investigation (Root Cause Analysis) conducted by the firm consisted of Product & Formulation Review which observed that since Meloxicam is a poorly water-soluble drug, therefore, formulation relies on pH adjustment and solubilizing system. Change in pH or temperature can cause drug precipitation/crystallization. Furthermore, the firm noted under interaction with the Sterility test media i.e., FTM/SCDM that they have different pH range, aqueous environment, and incubation at elevated temperatures (30–35°C) which are not representative of product storage conditions and may induce supersaturation and crystallization of Meloxicam. Evaluation of crystals showed no growth on subculture and no proliferation upon incubation; also the microscopic examination of the crystals showed non-cellular crystalline structure. Based on these observations, it was confirmed that the crystals were non-microbial and that drug precipitation/crystal formation was misinterpreted as microbial growth.
vii. Based on foregoing, the firm found the Root Cause to be physicochemical precipitation/ crystallization of meloxicam in sterility test media due to solubility and pH differences therefore concluding that there was no impact on animal health, or on other batches of the product and the manufacturing process remained validated and Sterility Assurance Level remains maintained.

Decision: Registration Board deferred the case for next meeting.

Item No. IV Division of Biological Evaluation & Research

Case No. 1: Virtual Inspection of Manufacturer Abroad for Liraglid (Liraglutide) Solution for injection in prefilled Pen 18mg/3ml applied by M/s Getz Pharma (Pvt.) Ltd., Karachi approved in 351st meeting of Registration Board.

Following product of M/s Hivet Animal Health Business, Lahore was approved in 339th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 339th Meeting
M/s. Hangzhou Jiuyuan Genetic Biopharmaceutical Co., Ltd., East of No.8th Street, Hangzhou Economic and Technological Development Zone, Hangzhou, Zhejiang, China.	Liraglid 18mg/3mL Pre-Filled Pen Solution for Injection Each 3mL Pre-Filled Pen contains: Liraglutide.....18mg	1's Prefilled Pen 2 Years (2^0C -8^0C)	Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of fee for pre-registration change in name of bulk labelled Pens manufacturer. M/s Getz Pharma (Pvt.) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi shall be responsible for final batch release.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 22nd & 24th December, 2025:

1. Muhammad Zubair Masood, Deputy Director (BE&R) DRAP, Islamabad.
2. Adil Saeed, Deputy Director (PEC) DRAP Islamabad.

Following are the observations & conclusion of Panel:

Observations:

Sr. No.	Observation
1.	Use of same Workshop for the manufacturing of semaglutide & liraglutide drug substances. Section 18 of ICH Q7 addresses specific controls for drug substances manufactured by cell culture. Its subsection 18.44 states that, *"Additional controls, such as the use of dedicated chromatography resins or additional testing, may be appropriate if equipment is to be used for multiple products."* WHO good manufacturing practices for biological products Replacement of Annex 1 of WHO Technical Report Series, No. 822 subsection 12.7 gives following statement regarding reuse of components for different products; *"A wide variety of equipment and components (for example, resins, matrices and cassettes) are used for purification purposes. QRM principles should be applied to devise the control strategy regarding such equipment and associated components when used in campaign manufacture and in multi-product facilities. The reuse of components at different stages of processing of one product is discouraged but, if performed, should be validated. Acceptance*

	criteria, operating conditions, regeneration methods, lifespan and sanitization or sterilization methods, cleaning process, and hold time between the use of reused components should be defined and validated. ***The reuse of components for different products is not acceptable."*** Keeping in view the details mentioned above, panel has serious concerns regarding use of same lines for manufacturing 2 rDNA products as it increases risk of cross contamination of cell culture related impurities.
2.	The steps like dispensing of raw materials and their transfer to mixing area were being performed in class C area. The material was not protected from the class C environment by any means during transfer (No HEPA trolley or closed cabinet was being used). The firm has informed Semaglutide drug product is also being manufactured in the same facility. The panel also have serious concerns regarding dispensing and transfer of materials in class C area without any measures to ensure minimization of contamination, when the product being manufactured is a sterile product. The process till preparation of final solution is not considered aseptic by the manufacturer.
3.	The Laminar flow hoods used in raw material sampling, dispensing and lyophilization areas were open from the sides and were operating at negative pressure allowing entry of surrounding air inside the Laminar Flow Hoods. The firm informed that the negative pressure inside the hoods is for the safety of personnels (although in clarification regarding use of same line for manufacturing drug substance firm has claimed that liraglutide and semaglutide not highly sensitizing or have high pharmacological activity or toxicity).
4.	

Based on the virtual inspection conducted, the documents reviewed, the discussions held with technical personnel and representatives of the importing firm, the panel is of the view to **Not Recommend Registration of applied product i.e Liraglid (Liraglutide) Solution for injection in prefilled Pen 18mg/3ml.** The recommendations are based on following concerns of the panel;

i. Using same facility for manufacturing of Semaglutide and Liraglutide by rDNA technique.
ii. Relaxed contamination controls before sterile filtration.

It is pertinent to mention that M/s Getz Pharma (Pvt.) Ltd., Karachi is using Semaglutide Drug Substance of same source for their registered products.

Decision:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided as follows:

- **To give opportunity of personal hearing to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.**
- **To issue a show-cause notice to the firm, requiring them to explain their stance regarding manufacturing of their registered Semaglutide-containing formulations in light of the finding of dosage-form-specific inspection of Liraglutide Injection as the Semaglutide API was also being manufactured on the same equipment and premises.**

Case No. 2: Product Specific Inspection of M/s Macter International Limited, Karachi.

Following products of M/s Macter International Limited, Karachi were approved in 352nd meeting of Registration Board subject to the Product Specific Inspection (PSI) of the manufacturer:

1. **Zepatide Single Dose Vial 2.5mg**
2. **Zepatide Single Dose Vial 5mg**
3. **Zepatide Single Dose Vial 7.5mg**
4. **Zepatide Single Dose Vial 10mg**
5. **Zepatide Single Dose Vial 12.5mg**
6. **Zepatide Single Dose Vial 15mg**
7. **Zepatide Multi Dose Pen 20mg**
8. **Zepatide Multi Dose Pen 40mg**
9. **Zepatide Multi Dose Pen 60mg**

Accordingly, following panel of inspectors of DRAP conducted the inspection on 08-12-2025:

1. Hafiz. M. Ali Tayyab (Additional Director, PE&R)
2. M. Zubair Masood (Deputy Director, BE&R)

Following are the observations and conclusion of Panel:

Observations/ Remarks:

i. With reference to submitted documents in registration application, regarding procurement of API Tirzepatide, firm has imported 21.25gm of API. During inspection, calculations were performed which transpired that total quantity of API used in manufacturing was 72.82gm. Then the firm has also intimated and provided invoice of 55gm API for which no DRAP clearance and intimation was presented at the time of inspection. Firm stated that this API was imported through DHL. Any import document e.g. DRAP Clearance / Bill of Landing / Custom Clearance / LC / Custom Invoice, etc. confirming import of API was presented neither at the time of inspection nor later on even after specific query. However, the firm has submitted a precedence of Registration Board wherein only DHL invoice was considered by the Board.

ii. Remaining stability batches of both Zepatide Single Dose Vials and Multi Dose Pen were placed in stability chamber without any primary labelling in secondary packing of another product namely Epo. Label was only pasted on outer carton.

iii. Firm has not provided record of Zepatide production and testing in any of the log books except Microbial Limit Testing.

iv. **During the physical audit of the HPLC system for Tirzepatide Single Dose Injection,** significant discrepancies / variations were observed between the chromatographic data provided in the CTD dossier submitted to DRAP and the data available at the firm's premises. The processing and acquisition date, time, retention times and area values of the chromatograms had significant differences at various time points. Few of the examples are as under:

   a. In the case of Zepatide 2.5mg single dose injection at the initial time point, the firm recorded an area of 80477 with retention time of 29.581 whereas the data submitted to DRAP reported 19471427 with retention time of 26.309.
   b. In the case of Zepatide 5mg single dose injection at the 06th month time point, the firm recorded an area of 51886304 with retention time of 26.001 along with two impurities whereas the data submitted to DRAP reported 20303400 with retention time of 26.283 along with one impurity. Moreover, acquisition and processing times are also different.
   c. In the case of Zepatide 7.5mg single dose injection at the 06th month time point, the firm recorded an area of 53269392 with retention time of 25.960 along with two impurities

whereas the data submitted to DRAP reported 20051135 with retention time of 26.534 along with one impurity. Moreover, acquisition and processing times are also different.

d. In the case of Zepatide 12.5mg single dose injection at the 06th month time point, the firm recorded an area of 46919906 with retention time of 25.791 along with two impurities whereas the data submitted to DRAP reported area of 19931812 with retention time of 26.582 along with one impurity. Moreover, acquisition and processing times are also different.

e. In the case of Zepatide 15mg single dose injection at the 09th month time point, the firm recorded an area of 42287211 with retention time of 20.983 along with three impurities whereas the data submitted to DRAP reported area of 51129566 with retention time of 20.953 along with two impurities. Moreover, acquisition and processing times are same.

f. The firm has submitted CoA of API indicating Polymer testing while they have not used the method for Polymer testing of API manufacturer as they don't have requisite impurity standard i.e. G27-IM122. Furthermore, the firm has also performed Polymer testing of finished products during stability studies although they don't have requisite impurity standard i.e. G27-IM122.

v. The firm informed that the requisite reference standard is required for performance of system suitability but on the other hand system suitability of Polymer testing was not performed.

It is pertinent to mention that USP monograph of Chromatography <621> states the following:
"The system suitability tests represent an integral part of the analytical procedure and are used to ensure adequate performance of the chromatographic system."
"Compliance with the system suitability criteria is required throughout the chromatographic procedure."
It is evident from above statement of USP that as the firm has not performed system suitability, hence, their method is not ensuring the adequate performance of the chromatographic system in quantifying the amount of High Molecular Weight Proteins (HMWPs) which are directly related to immunogenicity of product.

Conclusion:

In the light of above, the panel concluded the following:

i. Discrepancies between the quantity of procured documented API and API used in manufacturing of the stability batches were observed. Firm has imported 21.25gm of API for which DRAP clearance was available. During inspection, calculations were performed which revealed that total quantity of API used in manufacturing of APIs was 72.82gm. Then the firm has also intimated and provided invoice of 55gm API for which no DRAP clearance and intimation was presented at the time of inspection. Firm stated that this API was imported through DHL. Neither any import document e.g. DRAP Clearance / Bill of Landing / Custom Clearance / LC / Custom Invoice, etc. confirming import of API was presented neither at the time of inspection nor later on even after specific query. However, the firm has submitted a precedence of Registration Board wherein only DHL invoice was considered by the Board.

ii. For Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg), keeping in view previous practice, the panel recommended the firm to procure Impurity standard of Polymer from the API manufacturer, to conduct complete polymer testing of the drug products using this standard at the next stability study time point and submit a comprehensive report along with chromatograms, raw data sheets, and procurement documents for the standard. The firm then submitted procurement documents including DRAP clearance certificate along with Import License, invoice and Airway bill vide tracking ID: 952-N94-M1QT. The firm also submitted chromatograms of polymer testing for Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg) vide tracking ID: QLD-UQ7-PSY1 and the results were found to be within limits of specifications. Moreover, the Assay and Impurity data of Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg) was satisfactorily verified on-site.

iii. For Zepatide Single Dose Vial range (Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg), discrepancies were observed between the chromatogram area values, retention times, processing and acquisition times available onsite and those submitted to DRAP in the CTD dossiers. These differences, observed in multiple chromatograms across all strengths and multiple time points, including initial, 3rd month, 6th month and 9th month stability studies. These discrepancies raised concerns about the authenticity and reliability of the submitted data. Hence, these observations of the panel regarding Zepatide Single Dose Vial range may be placed before Registration Board.

In light of above report, the registration letters for Tirzepatide Multi-dose pens 20mg, 40mg & 60mg has been issued while case of Zepatide Single Dose Vial range is placed before Registration Board for discussion please.

Decision of 353rd meeting:
Keeping in view the observations of panel of inspectors of DRAP; Registration Board decided to give opportunity of personal hearing to the firm to explain their position regarding discrepancies observed by panel of inspectors of DRAP between the chromatogram area values, retention times, processing and acquisition times available onsite and those submitted to DRAP in the CTD dossiers of Zepatide Single Dose Vial range (Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg).

Accordingly, letter was issued to the firm.

Proceedings of the meeting:

Dr. Fida Hussain, MD and Dr. Farooq Mustafa, DQO & Biotech appeared before the Board on behalf of M/s Macter International Limited, Karachi. They informed that the differences observed in the chromatographic data in CTD dossier submitted to DRAP and the data available at the firm's premises was due to analyst handling of data and are within limits of specifications of products. They further informed that they have now implemented LIMS in their QC Laboratory and in future such mishandling will not happen.
The Board also heard the panel members who presented their observations in the report regarding the discrepancies in the chromatographic data in the dossier and which they verified physically.

Decision:

Keeping in view the recommendations of the panel and proceedings of Registration Board above; the Board rejected the below mentioned applications of M/s Macter International Limited, Karachi :

1. **Zepatide Single Dose Vial 2.5mg**
2. **Zepatide Single Dose Vial 5mg**
3. **Zepatide Single Dose Vial 7.5mg**
4. **Zepatide Single Dose Vial 10mg**
5. **Zepatide Single Dose Vial 12.5mg**
6. **Zepatide Single Dose Vial 15mg**

Case No.4: <u>TERMINATION OF SOLE AGENCY/ DISTRIBUTION AGREEMENT BY M/S BIOPHARMA PLASMA LLC, UKRAINE</u>

M/s Amgomed, Office No.4, 1st Floor, Ghousia Plaza, Main Jinnah Avenue, Blue Area Islamabad has submitted an application vide Tracking ID: G79-GU4-RU5A & RRM-SG7-DVEX dated 24.09.2025 for transfer of ownership of following registered drugs in name of M/s SMS Corporation, 13 B/1, Block-6, PECHS, Karachi under Post Registration Variation Guidelines Edition 2 (Variation No. MiV-PA8, Change of importer/ MA holder in Pakistan). Details are as under:

Sr. No.	Reg. No.	Brand Name & Composition & Pack Size	Product License Holder & Manufacturer
1.	111123	**Albumin-Biopharma 20%** (Solution for Injection) Each ml contains: Total Protein (of which Human Albumin is >95%).....200mg Ph. Eur. Specifications (50ml Vial)	**Product License Holder & Manufacturer:** M/s Biofarma Plasma Limited Liability Company, 37 Kyivska Str., Bila Tserkva, Kyiv region, 09100, Ukraine. **Secondary Packaging & Batch Release:** M/s Biofarma Plasma Limited Liability Company, 9M. Amosova, Str., Kyiv, 03680, Ukraine.)
2.	111124	**Albumin-Biopharma 20%** (Solution for Injection) Each ml contains: Total Protein (of which Human Albumin is >95%).....200mg Ph. Eur. Specifications (100ml Vial)	

2. In the aforementioned application, the applicant, M/s Amgomed Islamabad, has submitted a letter dated 14.10.2025 from M/s Biopharma Plasma LLC, Ukraine wherein it has been declared that the distribution agreement with the former registration holder, M/s SMS Corporation, 13 B/1, Block-6, PECHS, Karachi has been terminated with immediate effect for the mentioned products and other related items.

3. The termination of sole agency agreement by the manufacture abroad, invokes the provisions of Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976. Under the circumstances, you are required to show the cause in writing as to why the registration of your above-mentioned drugs may not be cancelled with immediate effect in your name.

Accordingly, M/s SMS Corporation, 13 B/1, Block-6, PECHS, Karachi vide letter No. F. 3-164/2018-AD(BD)(Vol-I) dated 23rd December 2015 was advised to explain their position in this regard. M/s SMS Corporation vide TID: 9LA-ZB2-ZEDU dated 29th December 2025 submitted their response which is as under:

"It is hereby notified that we, SMS Corporation, based in Karachi Pakistan, are an independent distribution company that made its first contract with M/s Biopharma in 2017, after which we had started the registration process with DRAP under an agreement with the supplier. We received the final registration of products in 2023, during which period all the expenses were borne by us, including the DRAP fees, updating the application at various stages when our application was deferred due to lack of several documents. SMS Corporation has helped Biopharma at each stage of registration, providing guidance in terms of documentation required by DRAP, planning for plant visit twice before Covid break out and later the price negotiations with DRAP, Urdu labeling of the product and production of QR codes for all products as per DRAP directives. It is not true that SMS Corporation did not import sufficient quantities, rather the first order was made after due consultation and agreement with the supplier. We cooperated with the supplier in each step of import through a third country due to the ongoing war between Ukraine and Russia during the time. It was the supplier's bad logistic situation during their war with Russia that it had started forcing us to buy a huge volume all at once so it can save itself from routine shipments, as practice within the industry. We had explained to them that the product needs special storage and has a shelf life, so it is not possible for us to buy large volumes at once and sell within the shelf-life requirement by DRAP regulations. The firm has also requested to be heard in person before the Registration Board.

It is also incorrect that SMS Corporation made an agreement with any other international company for the same products for which we have signed distribution agreement with M/s. Biopharma LLC - Ukraine, which can be verified by your system records. It is unfair on part of the supplier to call any of the above as 'breach of agreement" and terminate distribution without consulting us or giving us in writing that they are not happy with any of the above points raised now. The supplier has been visiting Pakistan during these years but never once visited our office despite our requests. They have been meeting with other parties in

Islamabad; the only city they have visited several times during the registration process. We have also arranged for their visit to the CEO DRSP office to make them understand about the delay in registration, and that most of the delay was due to their own changes they have been making over all these years, including change of facility address, change of name, change in IVIG formulation etc. Each time we have helped them with repeated applications for the said changes with DRAP. Based on our above concerns about the notification, we would like to request to be heard in person before the registration board. Kindly allocate a time and date for our meeting thereof".

A personal hearing notice has also been issued to the firm vide DRAP letter F. 3-164/2018 AD(BD)(Vol-I) dated 23.2.2026. Submitted please.

Proceedings of the Board:

Mr. Muhammad Asim, Regulatory Affairs Manager of M/s SMS Corporation appeared before the Registration Board on behalf of the firm and informed that they have filed a civil suit No. 520/2025 before the court of 1st Senior Civil Judge at Karachi South and also submitted copy of ciurt order dated 02-03-2026 which is reproduced as under:

"Whereas the Plaintiff above named has instituted a Civil Suit against you for Declaration, Compensation & Permanent Injunction along with Application U/O 39 Rule 1 & 2 CPC.
You are hereby summoned to appear in this court in person, or by a pleader duly instructed and able to answer all material questions, on 13-04-2026 at 8:30 AM to answer the claim. You are also directed to produce on that day all documents upon which you intend to rely in support of your defence and to file your written statement on the said date.
Take notice that in default of your appearance on the day mentioned above, the suit will be heard and determined in your absence.
Also take notice that in default of filing an address for service on or before the date mentioned above, you are liable to have your defence struck out.
Given under my hand and seal of the court this 02-03-2026."

The Board noted that there is no restraining order in the above mentioned court order and advised the DBE&R to submit a report on behalf of DRAP before the honorable court as per directions. The Board further noted that the Albumin Injection is lifesaving drug and it has been reported many times regarding the non-availability of this product in the market.

Decision of Registration Board:

Keeping in view proceedings of Registration Board, the Board made the following decisions:

1. **Cancelled the registrations of Albumin-Biopharma 20% (50 ml) vide Reg. No: 111123 and Albumin-Biopharma 20% (100 ml) vide Reg. No: 111124 under Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976 in name of M/s SMS Corporation, 13 B/1, Block-6, PECHS, Karachi manufactured by M/s Biofarma Plasma Limited Liability Company, 37 Kyivska Str., Bila Tserkva, Kyiv region, 09100, Ukraine in light of termination of sole agency agreement dated 14.10.2025.**
2. **Granted the registrations of Albumin-Biopharma 20% (50ml) and Albumin-Biopharma 20% (100ml) manufactured by M/s Biofarma Plasma Limited Liability Company, 37 Kyivska Str., Bila Tserkva, Kyiv region, 09100, Ukraine in name of M/s Amgomed, Office No.4, 1st Floor, Ghousia Plaza, Main Jinnah Avenue, Blue Area Islamabad in light of sole agency authorization dated 02.09.2025 subject to the compliance of Import Policy for Finished Drugs.**

Case No:5 **TERMINATION OF SOLE AGENCY/ DISTRIBUTION AGREEMENT BY M/S NINGBO RONGAN BIOLOGICAL PHARMACEUTICAL CHINA IN NAME OF M/S.3A DIAGNOSTICS, LAHORE**

M/s Mediflow Pharmaceutical (Pvt) Ltd. Plot No. 100 Sector 30 Korangi Industrial Area Karachi, has submitted an application vide Tracking ID: 3NW-M4M-XT3J for transfer of ownership of your following registered drugs in name of M/s.3A Diagnostics, Pakistan Lahore under Post Registration Variation Guidelines Edition 2 (Variation No. MiV-PA8, Change of importer/ MA holder in Pakistan). Details are as under:

Sr. No.	Reg. No.	Product Name	Product License Holder & Manufacturer
1.	103762	**OLAVAXTAR-RAB VACCINE** (Rabies vaccine (Vero Cell) Freeze-dried) Each dose contains: Rabies Virus Antigen……2.51U (Ph. Eur Specifications)	M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd. No. 21, Chuangye Avenue, Free Trade West Zone, Ningbo, China.

M/s Mediflow Pharmaceutical (Pvt) Ltd. Karachi has submitted a letter dated 19.02.2025 from M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd, China wherein it has been declared that the cooperation relationship with the former registration holder, M/s.3A Diagnostics, Pakistan is terminated with immediate effect from 19.02.2025.

Accordingly show cause notice was issued to M/s. 3A Diagnostics, 12-F1 Block, Johar Town, District Lahore on 03.11.2025 as the termination of sole agency agreement by the manufacture abroad, invokes the provisions of Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976.

With reference to above letter the M/s 3A Diagnostics Lahore requested to kindly allow some time to resolve their issue with the manufacturer amicably as we have pending dues and claims from the manufacturer. They also informed that they are already in discussion with the manufacturer Therefore, requested DRAP to maintain the current status of our sole agency and refrain from making any modifications in the records until the matter is resolved in accordance with their contract. The firm requested an extension of at least one month period to enable us to settle the things lawfully.

Registration Board, in its 352nd meeting held on 19–20 November 2025, deliberated upon the request submitted by M/s Mediflow Pharmaceutical (Pvt) Ltd., Karachi. regarding the change of registration status OLAVAXTAR-RAB VACCINE (Rabies Vaccine [Vero Cell], Freeze-Dried), (Registration No. 103762) registered in your name , in view of the termination of the sole agency agreement by manufacturer abroad i.e., M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd., China, vide their termination letter dated 19 February 2025.

Considering the above facts, Registration Board decided to issue a final show cause notice to M/s. 3A Diagnostics, 12-F1 Block, Johar Town, District Lahore under provisions of Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in light of their termination of sole agency agreement Olavaxtar-Rab Vaccine by M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd. China. The said notice has been issued vide DRAP letter No. F. No. 9-9/2022AD(BD)(PRV) dated 21st January 2026 wherein M/s 3A Diagnostics, Lahore is advised to explain their position.

A personal hearing notice has also been issued to the firm vide DRAP letter F. No. 9-9/2022AD(BD)(PRV) dated 23.2.2026.

Proceedings of the Board:

Mr. Shabih Haider, Regulatory Affairs Manager of M/s 3A Diagnostics, Lahore appeared before the Registration Board on behalf of the firm and informed that multiple financial matters for the said product are pending with the manufacturer and they are negotiating for their resolution. The firm demanded some time for their amicable solution. The representative of the firm also informed that have filed a suit in the Lahore High Court, Lahore, however, didn't provide any copy of aforesaid suit or order of Honorable court.

Decision of Registration Board:

Keeping in view proceedings of Registration Board, the Board made the following decisions:

1. **Cancelled the registrations of Olavaxtar-Rab Vaccine vide Reg. No: 103762 under Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976 in name of M/s 3A Diagnostics, Lahore manufactured by M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd. No. 21, Chuangye Avenue, Free Trade West Zone, Ningbo, China in light of termination of sole agency agreement dated 19.02.2025.**
2. **Granted the registrations of Olavaxtar-Rab Vaccine manufactured by M/s Ningbo Rongan Biological Pharmaceutical Co., Ltd. No. 21, Chuangye Avenue, Free Trade West Zone, Ningbo, China in name of M/s Mediflow Pharmaceutical (Pvt) Ltd. Plot No. 100 Sector 30 Korangi Industrial Area Karachi in light of sole agency authorization dated 13.05.2025 subject to the compliance of Import Policy for Finished Drugs.**

Case No. 6: Request of M/s AMB HK (Pvt) Limited Lahore for permission of bulk import and local repacking Human Chorionic Gonadotrophin Hormone (HCG) Injection Reg No. 131657 by M/s M/s English Pharmaceutical, Lahore

AMB HK Enterprises (Private) Limited 2nd Floor Plaza 60, Commercial Block-K Phase 1 DHA, Lahore was granted the registration of "Human Chorionic Gonadotrophin Hormone (HCG) Injection" (Reg. No. 131657). They have requested to grant them permission to import bulk labelled vials of "Human Chorionic Gonadotrophin Hormone (HCG) Injection" (Reg. No. 131657) from their principal manufacturer i.e M/s Qingdao Guanlong Biopharmaceutical Co Ltd., No. 9, Zhuzhou Road, Laoshan District, Qingdao City, Shandong Province, China and local repacking in secondary unit cartons from M/s English Pharmaceutical, Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore along with insertion of registered local diluent of M/s English Pharmaceutical, Lahore, holding registration number (074239). They have informed that all these activities will be perform in the premises of M/s English Pharmaceutical, Lahore. The details of the product are as below:-

S.NO.	REG. NO.	NAME OF PRODUCT	NAME OF PRINCIPAL MANUFACTURER
1.	131657	Human Chorionic Gonadotrophin Hormone (HCG) Injection Each vial contains: Chorionic Gonadotropin ..... 5000 Units (Manufacturer USP Specifications)	M/s Qingdao Guanlong Biopharmaceutical Co. Ltd., No. 97, Zhuzhou Road, Laoshan District, Qingdao City. Shandong Province, China

They have provided following documents:

1. Copy of registration letter.
2. Copy of registration of diluent issued to M/s English Pharmaceutical, Lahore, (Reg.No.074239).

3. Copy of DML of M/s English Pharmaceutical, Lahore., (Lic. no. 000339)
4. Copy of GMP of M/s English Pharmaceutical, Lahore.
5. Copy contract manufacturing agreement between M/s AMB HK Enterprises (Pvt) Ltd Pakistan and M/s English Pharmaceutical, Lahore, Pakistan.
6. Paid Fee Challan Copy.
7. Undertakings and documents as per MaV-15 Inclusion or replacement of the solvent/diluent for the drug product Guideline.

Decision:

Registration Board acceded to the request of the firm for change in registration status of Human Chorionic Gonadotrophin Hormone (HCG) Injection (Reg. No. 131657) from finished import to bulk labelled vials Import, local secondary packaging at M/s English Pharmaceutical, Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore (contract manufacturing) along with addition of Pngsol Injection 0.9%v/w (Sodium Chloride 5ml Ampoule) vide Reg. No. 074239. The final batch release shall also be performed at M/s English Pharmaceutical, Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.

Case No. 7: Registration of imported biological product deferred in 350th meeting imported by M/s Amgomed Islamabad:

Sr. No. 01	
Name, address of Applicant / Importer	**M/s AMGOMED, Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue arejn a Islamabad Pakistan**
Details of Drug Sale License of importer	License No: DSL-002-ICT/2013 Address: Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. Validity: 30-01-2024 Status: Drug License by way of Wholesale
Name and address of marketing authorization holder (abroad)	M/s Gennova Biopharmaceuticals Limited, Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
Name, address of manufacturer(s)	M/s **Gennova Biopharmaceuticals Limited,** Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP**: Firm has submitted original CoPP certificate (CoPP/CERT/PD/110860/2022/11/39406/ 191298) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 14-07-2022.
Details of letter of authorization / sole agency agreement	The firm submitted notarized letter of authorization whereby M/s Gennova Biopharmaceuticals Limited, India authorized M/s Amgomed to apply for registration, for marketing, distribution and sale of below mentioned product;
Status of the applicant	

	Status of application	Hamsyl 3750 IU / 5ml Injection Each 5 ml vial contains: Pegasparagase (Pegylated L- Asparaginase) HIS 3750 IU The authorization letter is valid till 06-05-2022. Manufacturer ☒ Importer Is involved in none of the above (contract giver) New Drug Product (NDP) ☒ Generic Drug Product (GDP) ☒ Domestic sale Export sale Domestic and Export sales ☒ Finished Pharmaceutical product import Bulk import and local repackaging Bulk import and local repackaging for export purpose only
	Intended use of pharmaceutical product	
	For imported products, specify one the these	
	Dy. No. and date of submission	Dy. No. 26085 Dated: 30-07-2018
	Details of fee submitted	PKR 100,000 (Slip number : 0778294)
	Proposed proprietary name / brand name	Hamsyl 3750 IU / 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Pegaspargase (Pegylated L-Asparginase) ..... 3750 IU
	Pharmaceutical form of applied drug	Solution for IV / IM Administration
	Pharmacotherapeutic Group of (API)	Antineoplastic agents ATC- code: 01XX24
	Finished product specifications	In-house
	Proposed Pack size	1's vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 2 °C to 8 °C
	The status in reference regulatory authorities	Oncaspar Injection 3,750 IU / 5ml vial of M/s Sigma Tau (USFDA approved).
	For generic drugs (me-too status)	Pegaspargase (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	DMF Holder Address: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China. Name and Address of the manufacturer: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Gennova Biopharmaceuticals limited do not intend to store the API manufactured. It is immediately transfer for fill finish activities. Hence formal stability study for Pegaspargase Bulk is not intended as there is no change in the composition of Bulk and Finished product. Its only containerization process. Hence, we have carried out hold time study for bulk and finished product stability study is reflective for API stability as well.
	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 data of Pharmaceutical Equivalence: Hamsyl 3750 IU /5ml Injection and reference product Oncaspar by Sigma Tau Corporation, USA.
	Analytical method validation / verification of product	The firm has submitted relevant data including analytical method validation for the drug product including the impurities.
	Container closure system of the drug product	Pegaspargase Injection is filled in USP Type I Glass vial. One such labelled vial is placed in Plastic Tray and which is packed in Monocarton along with leaflet. Primary packaging materials conform to specifications.
	Stability study data of drug product, shelf life and storage conditions	Real time stability (Long term) studies have been conducted at 5°C ± 3°C for 24 months of 3 batches. Accelerated stability studies is conducted at 25 °C ± 2 °C / 60% ± 5% RH for 6 months of 3 batches.

		431401H01 431402H02 431403H03
	Non-Clinical (Module IV)	**Single dose toxicity** Acute Intravenous toxicity study in Swiss Albino mice Acute Intravenous toxicity study in Sprague Dawley rat **Multiple Dose** Subchronic intravenous toxicity study in the Swiss Albino Mouse Subchronic intra venous toxicity study in the Sprague Dawley Rat
	Module V	A prospective, open label, randomized, active control, parallel design, comparative pharmacokinetics study of intramuscular pegaspargase (Hamsyl) of M/s Gennova Biopharmaceuticals Ltd versus intramuscular Oncaspar in pediatric patients with **relapsed cases** of Acute Lymphoblastic Leukemia (ALL). **Twenty-four** (24) Pediatric patients diagnosed with Acute Lymphoblastic Leukemia (ALL) in relapsed stage enrolled in 1:1 ratio in two arms randomly. To demonstrate the pharmacokinetic comparability of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase) given intramuscularly during induction in patients with ALL therapy. To compare the immunogenicity and toxicity of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase).

Remarks of Evaluator:

The submitted original CoPP is not legalized however, the firm has submitted undertaking that we will submit legalized original copy of CoPP after attestation. Meanwhile, we request you to please include our product in DRB meeting.

Evaluation by BE&R:

Sr.No.	Decision of 324th meeting	Response by the firm

1.	Submission of Phase I, II, III clinical study data for the proposed indication since already submitted study is a pharmacokinetic comparison of applied product with reference product.	Hamsyl is a pegylated version of native- asparaginase. Hamsyl was approved as an 'Orphan drug' in India in the second line of treatment of relapsed Acute Lymphoblastic Leukemia (ALL). This approval was based on a bioequivalency study (PK) against the reference product (Oncaspar) in patients with ALL in India. The serum asparaginase activity (> 100 IU/L) has been considered as a surrogate marker for efficacy1 and has been used for the approval of asparaginase formulations worldwide. For instance, *Erwinia asparaginase* US-FDA approval was based on the nadir serum asparaginase activity >100 IU/L. Hamsyl was found to be 'Bioequivalent' to Oncaspar. Importantly, both drugs maintained a nadir serum L-asparaginase activity> 100 IU/L. The secondary endpoints of the study included comparison of the L• asparaginase antibodies response profile and changes in L-asparagine and glutamine amino acids levels. No statistically significant differences were observed in the secondary endpoints. Based on these results, Hamsyl was approved and Phase III study was waived off. Hamsyl has been available in India for therapeutic use since 2014. Various independent investigators have published their experience of treatment with Hamsyl as retrospectivestudies with no new significant concerns.
2.	Details of pharmaceutical comparison with reference product Oncaspar Injection 3750 IU / 5ml.	The firm has submitted comparability evaluation report of Oncaspar (ON3066X2) and Hamsyl injection (3750 IU/vial) for the identified critical quality attributes.
3.	Legalization of CoPP	**CoPP**: Firm has submitted original Legalized CoPP certificate CoPP/CERT/PD/1108776/2022/11/41643/ 204858) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 09-07-2025.

Decision: Registration Board decided to refer the case to Pharmacy Services Division for opinion on firm's justification for exemption of Phase III clinical study data.

The subject matter was placed before Clinical Studies Committee (CSC) in its 50th meeting held on 11th July 2024. The Committee decided the case as follows:

The CSC after detailed deliberation and discussion advised to forward following decision to the BE&R Division:

The CSC notified and work under the Bio-Study Rules, 2017 for Clinical Trial Oversight in the country and instant application is not for the conduct of any clinical trial / study hence its not the mandate of CSC.

However, the Committee is of the view that Pharmacokinetic study is one of the parts of the Phases of the Clinical Trials and can't substitute Phase-I, II and III studies, as already mentioned in the Registration Board. Moreover, Registration Board may decide the application as per merit of the case

Previous Decision M-339:

Registration board after detailed deliberation decided on the recommendation of pharmacy services division deferred the case and give the final opportunity to submit the complete pharmacokinetic studies as it is the parts of the phases of the clinical studies.

Decision of 347th meeting of Registration Board:

The Registration Board, after detailed deliberation and upon the recommendation of Pharmacy Services Division, decided to defer the case and grant a final opportunity to submit the complete clinical studies data in accordance with the WHO biosimilarity guidelines.

Evaluation by BE&R:

Decision of the Board (M-347)	Reply of the firm
"The Registration Board, after detailed deliberation and upon the recommendation of Pharmacy Services Division, decided to defer the case and grant a final opportunity to submit the complete clinical studies data in accordance with the WHO biosimilarity guidelines".	**Hamsyl PEG is designated as an "Orphan Drug" by USFDA. Orphan drugs are medications developed to treat rare diseases or conditions, are incentivized through programs like the Orphan Drug Act to encourage their development.** **Worldwide, Asparaginase is registered with limited clinical trials (Pharmacokinetics, and efficacy markers). There are always fewer patients suffering from the rare disease. Therefore, numbers of selected patients are always low for the trials of orphan drug. We have developed the product by completing all the necessary parameters and testing of surrogate efficacy makers.** **Hamsyl PEG is used to treat acute lymphoblastic leukemia in children. There is only one or two brands available in Pakistan.** **Complete Pharmacokinetic studies (Cmax, AUC, tmax, t1/2, Vd and Cl) which also includes surrogate efficacy markers i.e. L-asparaginase activity, Plasma anti L asparaginase antibodies, Plasma anti- L asparaginase amino acid estimation, L- glutamine amino acid estimation in all patients attached below."**

Remarks by BE&R:

Firm has submitted "Periodic Safety Update Report" from 28th September 2014 to 27th March 2015 and conclusion is as below:

"This Periodic Safety Update Report (PSUR) presents data on safety and adverse events reported for Pegaspargase injection. There were two spontaneous reports to manufacturer. In the first case, abnormality in liver function tests (LFTs) were demonstrated but later the patient's LFTs normalized and he received further

recommended therapy. In the second case, the patient experienced hepatic encephalopathy and septicemia and died on 10/Feb/2015, the cause of which was unassessable. There were no serious unexpected adverse events neither published for pegaspargase injection in Springer's Pharmacovigilance Insight Database or in the published literature nor reported to the manufacturer. Safety and tolerability of concomitant use of pegaspargase injection for the treatment of acute lymphoblastic leukemia is well established. After an analysis of available information from various sources, it is concluded that Pegaspargase injection has an acceptable benefit: risk ratio in the treatment of ALL."

However, Complete clinical studies data is still not provided.

Decision of 350th meeting of RB:

The Registration Board deferred the case and provided final opportunity to submit the complete non-clinical and clinical study data in compliance with ICH guidelines.

Remarks of evaluator:

The firm has submitted a reply as under;

"We have established biosimilarity of the Hamsyl with Oncaspar at all three aspects and based on the query received, we have structured the response into three parts to demonstrate the comparability of Hamsyl to Oncaspar in terms of quality, safety and efficacy.

Following parameters are tested;

• open-label, parallel-group, comparative pharmacokinetic study in paediatric patients with relapsed ALL (Acute lymphoblastic leukemia). (Report is attached)

• Immunogenicity (Report is attached).

• Pharmacodynamics i.e. L-asparaginase activity, Plasma anti-L asparaginase antibodies, Plasma anti- L asparaginase amino acid estimation, L- glutamine amino acid estimation in all patients (Report is attached).

Asparaginase has been used the treatment of ALL for decades. Based on the abundance of clinical data, pharmacokinetic (PK) and pharmacodynamic (PD) markers have been established for asparaginase. This is advantageous in clinical development because using established PK and PD markers as a surrogate for efficacy simplify clinical trials (more sensitive) and obviate the need to assess long and costly endpoints.

Following documents are attached in response to the query;

Justification letter.

Clinical Comparability (PK, PD (Surrogate efficacy markers, Immunogenicity) with reports."

Decision of 353rd meeting:

Registration Board deferred the application for submission of following by the firm:

- *Clarification whether the applied product was registered in country of origin without pivotal Safety and Efficacy data, along with assessment report issued by regulatory authority of country of origin indicating waiver of Safety and Efficacy data.*
- *Evidence of registration of product in other countries along with evidence that the product was registered in those countries on the basis of same justification as provided by the firm in instant case.*

Evaluation by BE&R:

Firm has submitted following;

- Registration letters of Hamsyl injection in Sirilanka and Bolivia.
- PSUR from Dec.2024 to Nov.2025.
- Study synopsis of Phase IV clinical study and the study is ongoing.

Decision:

Registration Board deferred the case till submission of phase IV clinical study report of applied product.

Case No. 8: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s Highnoon Laboratories, Lahore approved in 349th meeting of Registration Board.

Following product of M/s Highnoon Laboratories, Lahore was approved in 349th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of 349th meeting
M/s Beximco Pharmaceuticals Ltd, 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh.	**Cleven 20 Injection** Each 0.2ml prefilled syringe contains: Enoxaparin sodium 2000 IU eq. to enoxaparin 20mg **Cleven 40 Injection** Each 0.4ml prefilled syringe contains: Enoxaparin sodium 4000 IU eq. to enoxaparin 40mg **Cleven 60 Injection** Each 0.6ml prefilled syringe contains: Enoxaparin sodium 6000 IU eq. to enoxaparin 60mg **Cleven 80 Injection** Each 0.8ml prefilled syringe contains: Enoxaparin sodium 8000 IU eq. to enoxaparin 80mg	The Registration Board after thorough deliberation approved the case subject to the submission of the data in accordance with the guidelines approved by the Board in 289th meeting and its approval by the Chairman, Registration Board.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 01-01-2026:

1- Madam Saima Hussain, Deputy Director, PE&R
2- Madam Iqra Aftab, Deputy Director, PE&R

Following are the observations & conclusion of Panel:

Observations

The observation noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is as under;

Observation	Impact on quality and GMP compliance
There is no dedicated and self -contained facilities for the production of biological product "Enoxaparin" on the basis of following key findings: • **Shared raw material store** for biological and non-biological products. • **Shared corridor** between Vision (Non-Biological) and PFS (Biological) units. • **Shared dispensing booth** for Ampoule (Non-Biological) and PFS (Biological) units. • Same AHU unit serving PFS (Biological) and Ampoule (Non-Biological) areas.	The manufacturing layout does not ensure physical and operational dedication required for biological products. Shared warehousing, dispensing areas, corridors, and HVAC systems significantly increase the risk of cross-contamination, product mix-ups, and airborne contamination. ***In order to minimize the risk of a serious medical hazard due to cross contamination, dedicated and self-contained facilities must be available for the production of biological product.***
List of registered products under License No. 119 (Biological & Special Products) includes	The inclusion of pharmaceutical products such as penicillin under a license designated for biological

pharmaceutical products (e.g., penicillin and others) along with biological products and no clarification submitted by the applicant.	and special products raises concerns regarding regulatory classification and facility dedication.
No ion chromatography system for determination of free sulfate content in **finished product.** Absence of NMR for identification testing. No gel chromatography for molecular weight determination.	Firm has not complied USP standard, since they don't have specialized instrument for performing these critical tests for structural identity, molecular weight and free sulphate content on DP.

Conclusion

Based on the virtual inspection of M/s Beximco Pharmaceuticals Ltd., 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh, as well as the documents reviewed and interviews conducted with management and technical personnel, the panel of inspectors concludes that the grant of registration for the below-mentioned biological products is **not recommended** due to the absence of a dedicated and self-contained facility for the manufacture of the biological product enoxaparin, along with the observations noted in Paragraph 4.

- **Cleven 20 Injection**
- **Cleven 40 Injection**
- **Cleven 60 Injection**
- **Cleven 80 Injection**

Decision:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided to give opportunity to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.

Case No. 9: Virtual Inspection of Manufacturer Abroad for Rabies Vaccine applied by M/s CLOUD AGRI PAKISTAN, Lahore approved in 350th meeting of Registration Board.

Following product of M/s CLOUD AGRI PAKISTAN, Lahore was approved in 350th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Decision of 350th meeting
M/s BIOGENESIE BAGO S.A.-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOUS AIRES, ARGENTINA.	**Biorabia Vaccine Rabies Vaccine, Inactivated** Each ml contains: Inactivated rabies virus antigen, Pasteur Strain PV.....≥1 IU	Approved subject to compliance of current Import Policy for finished drugs along with submission of following documents by the firm: • Original Legalized FSC. • Original Letter of Authorization. • Proposed pack

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 4-12-2025 and 5-12-2025:

1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.

2. Mrs. Sara Mehreen, Assistant Director (PE&R), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observations

The observation noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is tabulated below;

Observations	Impact on quality and GMP compliance
The firm had provided a common production area for the manufacture of inactivated bacterial and viral vaccines including FMD vaccine, rabies vaccine etc. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing are performed within the same area.	The use of a shared area for emulsification/formulation and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.
No cleaning validation was conducted for the reactors or tanks used in formulation/emulsification of inactivated vaccines.	The lack of cleaning validation for formulation reactors/tanks represents a **major GMP compliance gap**, as it fails to demonstrate that equipment is consistently cleaned to prevent cross-contamination. This increases the risk of product contamination.

Conclusion

Based on the virtual inspection of **M/s BIOGENESIE BAGO S.A.-RUTA PANAMERICANA, 38.5 KM. (B16191EA) GARIN, BUENOUS AIRES, ARGENTINA** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned cell cultured inactivated virus vaccines is **not recommended**, taking into consideration the potential risk of cross-contamination and mix-ups as detailed in paragraph 7.

Biorabia Vaccine Rabies Vaccine, Inactivated

Each ml contains:

Inactivated rabies virus antigen, Pasteur Strain PV.....≥1 IU

Decision:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided to give opportunity to the firm to explain their position regarding non-recommendation of dosage form specific inspection by panel of inspectors of DRAP.

PERSONAL HEARING CASES:

Case No. 10: Virtual Inspection of Manufacturer Abroad for Sinvac IBD Vaccine applied by M/s Hivet Animal Health Business, Lahore approved in 339th meeting of Registration Board.

Following product of M/s Hivet Animal Health Business, Lahore was approved in 339th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 339th Meeting
M/s. Beijing Sinder-Vet Technology Co., Ltd. Address: Beijing Tianzhu Airport	Sinvac IBD Each dose contains: Infectious Bursal Disease Antigen (B87	1000 doses 18 months (2^0C -8^0C)	On the basis of recommendations of Sub-committee on Veterinary Drugs,

Economic Development Zone, Shunyi District, Shunyu Road No.118, Shunyi District, Beijing, China.	strain)…..≥10(3.0) ELD50/dose before freeze drying (0.0012ml/dose)		Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 31-10-2025:

2- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.

2. Ms. Aqsa Hashmi, Deputy Director (Pharmacy Services), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observations:

The observations noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance are tabulated below;

Sr.No.	Observations noted during virtual audit	Potential Impact on GMP compliance
1	During the inspection, it was observed that in the inoculation room, there was an open area within the room where a table was positioned under a **laminar flow unit without side curtains.** In this area, eggs were manually disinfected, inoculated, and sealed.	The absence of side curtains around the laminar airflow ceiling may compromise the unidirectional airflow pattern and may increase the risk of environmental contamination during the handling and inoculation process. Proper segregation and enclosure of critical activities are recommended to maintain aseptic conditions.
2	The firm reported that inoculation activities are conducted in a Grade A laminar airflow unit without curtains, situated within a **Grade C background** in the same room.	Performing critical aseptic operations in a Grade A laminar airflow unit without curtains inside a Grade C area reduces the level of environmental protection. In this case the Grade A zone is more exposed to Grade C air, which has higher particulate and microbiological limits.
3	Disinfection, Inoculation and sealing activities were performed manually on the same table under a laminar airflow unit without segregation and **no dedicated equipment** was installed for the inoculation process.	Performing multiple critical steps in the same unsegregated workspace increases the likelihood of cross-contamination between activities. Without proper equipment designed for inoculation, the process may lack precision, reproducibility, and environmental protection.
4	During the virtual audit, it was observed that the **aseptic filling machine was open**, and multiple personnel were present inside the area during filling process at the time of virtual audit. It was also noted that there was	The lack of online particle monitoring and the absence of documented evidence supporting the claimed Grade A classification of the entire room raise concerns regarding the adequacy of

	no online particle monitoring system installed in the area. The firm stated that the entire room is classified as Grade A; however, HVAC validation report does not support this statement/ claim of the firm.	environmental controls and compliance with aseptic processing standards.
5	In the **solution preparation room,** a **tank** was used for the preparation of the solution. After completion of the preparation process, the tank was **manually transferred to the filling room** for the filling operation. It was observed that there were **no fixed transfer lines or transfer pipes** installed between the preparation and filling areas.	The absence of a closed or fixed transfer system may increase the risk of contamination or mix-up during the manual transfer process. The use of a validated, closed transfer line is recommended to ensure product integrity and maintain aseptic conditions.
6	**Airlocks** were not provided prior to entry into Grade A areas.	The absence of airlocks increases the risk of contamination entering Grade A (critical) cleanroom environments. Without proper pressure differentials and controlled transitions between lower and higher grade areas, personnel and materials can introduce particulates, microorganisms, and other contaminants.

Conclusion

Based on the virtual inspection of **M/s Beijing Sinder-vet Technology Co., Ltd. No.118, Shunyu Roard, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China** conducted, documents reviewed, interview of the management and technical personnel conducted, **panel of inspectors is of the view, not to recommend Good Manufacturing Practices (GMP) compliance for below products due to critical observations contained in paragraph 7.**

Sinvac IBD

Each dose contains:

Infectious Bursal Disease Antigen (B87 strain)……..…..≥10(3.0)ELD50/dose before freeze drying (0.0012ml/dose)

In the light of above decision, a personnel hearing letter was issued to M/s Hivet Animal Health Business, Lahore.

Proceedings of the Board:

Following representatives of the firm appeared before the Registration Board for deliberation on the matter:

1. **Dr. Asif Masood Rana** (Business Director)
2. **Dr. Suhaib Afzaal** (Regulatory Manager)

The representatives of the firm submitted certain documents for clarification. The Board reviewed all the submitted documents; however, they did not adequately justify the observations noted by the panel.

Decision:

After detailed deliberation, the Board decided to reject the case, in view of the observations recorded by the panel during the virtual inspection. The Board was not satisfied with explanations provided by the applicant during the personal hearing.

Case No. 11: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Agriprom Pakistan (Pvt.) Ltd., Lahore approved in 347th meeting of Registration Board.

Following products of M/s Agriprom Pakistan (Pvt.) Ltd., Lahore were approved in 347th meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 347th Meeting
M/s. Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China.	CENTRE-NDFLU H9 Each dose (0.5 ml) contains: Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... 10^8.175 EID50 Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... 10^7.175 EID50	250ml/500 doses 18 months (2^0C -8^0C)	Keeping in view the legalized GMP & 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.
	CENTRE-NIEA H9 Each dose (0.5 ml) of vaccine contains: Newcastle Disease Virus, Strain La Sota ..... ≥ 10^8.5 EID50 Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50 Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50	250ml/500 doses 18 months (2^0C -8^0C)	Keeping in view the legalized GMP & 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.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 5th to 6th November, 2025:

2- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
3- Mrs. Najia, Deputy Director (PE&R), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

1. **Observations**

The observation noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is as under;

Observation	Impact on quality and GMP compliance
The firm had provided a common production area for the manufacture of inactivated virus and bacterial vaccines. Antigen production activities	The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of

were carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing were performed within the same area.	operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.

2. Conclusion

Based on the virtual inspection of **M/s Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned embryo cultured inactivated virus vaccines is **not recommended** because of the manufacturing (emulsification and filling operations) of inactivated virus and bacterial vaccine within the same area.

i) CENTRE-NDFLU H9

Each dose (0.5 ml) contains:
Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... 10^8.175 EID50
Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... 10^7.175 EID50

ii) CENTRE-NIEA H9

Each dose (0.5 ml) of vaccine contains:
Newcastle Disease Virus, Strain La Sota ..... ≥ 10^8.5 EID50
Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50
Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units
Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50

In the light of above decision, a personnel hearing letter was issued to M/s Agriprom Pakistan (Pvt.) Ltd., Lahore.

Proceedings of 354th Meeting:

The following representatives of the firm appeared before the Registration Board for deliberation on the matter:

i. Dr. Ali Aun
ii. Dr. Ahsan

The representatives of the firm provided justifications/clarifications regarding the observations noted by the panel during the virtual audit.

Decision:

After deliberation, the Registration Board decided to defer the case for further consideration in the next meeting.

Case No. 12: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore approved in 347th meeting of Registration Board.

Following products of M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore was approved in 347th meeting of Registration Board as per following details:

i. Polimun SALMO (vaccine against avian salmonellosis, polyvalent, inactivated)

One dose (0.5 ml) contains;
Inactivated antigens in the titer before inactivation:
Salmonella enteritidis strain SE-15 at least 10^8 CFU
Salmonella typhimurium strain ST-15 at least 10^8 CFU
Salmonella gallinarum strain SG-15 at least 10^8 CFU

ii. **POLIMUN ND Hitchner B1 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

Each dose contains:

Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50

Avian Infectious Bronchitis, strain H-120 ≥ 10^3.5 EID50

iii. **Polimun POX (**vaccine against fowl pox, live)

Each dose (1ml) contains:

Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50

Solvent contains:

Glycerol HOCH2CH(OH)-CH2OH (kh.h) – 250 ml

Brilliant blue dye E 133 - 0.5 g

Phosphate-buffered saline (PBS) - up to 1000 ml

iv. **Polimun ND CLON 124 (**vaccine against Newcastle disease of poultry, live)

Each one dose contains:

Virus of Newcastle disease, strain "La-Sota" DK-124 ≥ 10^6.0 EID50 per dose, obtained on SPF chicken embryos.

v. **Polimun ND Clone 124 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

One dose of the vaccine contains;

Newcastle disease virus, strain "La-Sota" DK-124 ≥ 10^6.0 EID50

Avian infectious bronchitis virus, strain H-120 ≥ 10^3.5 EID50.

vi. **Polimun ND inac (**vaccine against Newcastle disease, inactivated)

Each dose (0.1 ml) contains:

Newcastle disease virus strain "La Sota" DK-124 ≥ 10^9 EID50 before inactivation.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 31-10-2025:

1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2- Mr. Nafees ur Rehman, Deputy Director (H&OTC), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observation

The observations noted by the panel members during virtual inspection and its potential impact on quality of product and GMP compliance is tabulated below;

Observations	**Impact on quality and GMP compliance**
The firm has provided a common production area for the manufacture of inactivated viral and bacterial vaccines. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing are performed within the same area.	The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.
The firm has one live bacterial vaccine among its registered products. Upon inquiry, the firm stated that this product is manufactured once per year and that no segregated area is available for live bacterial vaccine production. Instead, mixing of the live bacterial vaccine is carried out in the Antigen	Live viral and live bacterial products present a high risk of **biological cross-contamination**, particularly when mixing, filling, and lyophilization activities are performed in **non-segregated areas.**

Preparation Room (1-2107). For filling operations, a semi-automatic filling machine installed in the live virus vaccine mixing room (1-2133) is used, and the lyophilizer is shared for the manufacture of both live virus and live bacterial vaccines.	
During a virtual inspection, it was observed that inoculation and harvesting were carried out in a **laminar flow cabinet without side curtains**. Eggs were manually disinfected, inoculated, and subsequently harvested. The firm stated that the area under the laminar flow cabinet was classified as Grade A, with the surrounding environment classified as Grade B. However, without side curtains, maintaining Grade A conditions during manufacturing is challenging.	Without side curtains, **Grade A air cannot be reliably maintained** over the critical zone. Risk of **particulate and microbial contamination** increases during inoculation and harvesting. Proper segregation and enclosure of critical activities are recommended to maintain aseptic conditions.

Conclusion

Based on the virtual inspection of **M/s "BIOTESTLAB" LLC-1/3, Listrovoho Oleksandra St., Vasylkiv, Obukhiv District, Kyiv Region, 08600-Ukraine** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned products is **not recommended** taking into consideration the potential risk of cross-contamination and mix-ups as detailed in paragraph 7.

i. **Polimun SALMO (**vaccine against avian salmonellosis, polyvalent, inactivated)

One dose (0.5 ml) contains;
Inactivated antigens in the titer before inactivation:
Salmonella enteritidis strain SE-15 at least 10^8 CFU
Salmonella typhimurium strain ST-15 at least 10^8 CFU
Salmonella gallinarum strain SG-15 at least 10^8 CFU

ii. **POLIMUN ND Hitchner B1 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

Each dose contains:
Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50
Avian Infectious Bronchitis, strain H-120 ≥ 10^3.5 EID50

iii. **Polimun POX (**vaccine against fowl pox, live)

Each dose (1ml) contains:
Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50
Solvent contains:
Glycerol HOCH2CH(OH)-CH2OH (kh.h) – 250 ml
Brilliant blue dye E 133 - 0.5 g
Phosphate-buffered saline (PBS) - up to 1000 ml

iv. **Polimun ND CLON 124 (**vaccine against Newcastle disease of poultry, live)

Each one dose contains:
Virus of Newcastle disease, strain "La-Sota" DK-124 ≥ 10^6.0 EID50 per dose, obtained on SPF chicken embryos.

v. **Polimun ND Clone 124 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

One dose of the vaccine contains;

Newcastle disease virus, strain “La-Sota” DK-124 ≥ 10^6.0 EID50
Avian infectious bronchitis virus, strain H-120 ≥ 10^3.5 EID50.

vi. Polimun ND inac (vaccine against Newcastle disease, inactivated)

Each dose (0.1 ml) contains:
Newcastle disease virus strain "La Sota" DK-124 ≥ 10^9 EID50 before inactivation.

In the light of above decision, a personnel hearing letter was issued to M/s Hi Tech Pharmaceuticals, Lahore. Moreover, following applications have been applied by other firms on E-App from same manufacturer:

i. POLIMUN ND+IB inac– vaccine against Newcastle disease and avian infectious bronchitis,
ii. BOVIMUN 4
iii. POLIMUN REO 1133 inac – vaccine against poultry viral arthritis (tenosynovitis)
iv. POLIMUN REO 1133 – vaccine against poultry viral arthritis
v. POLIMUN La-Sota + H120 – vaccine against Newcastle disease and avian infectious bronchitis, live
vi. BOVIMUN LSD – vaccine against lumpy skin disease, live
vii. BOVIMUN NEO - vaccine against rotavirus, coronavirus infection, escherichiosis and clostridiosis in cattle, inactivated
viii. POLIMUN IBD light – vaccine against avian infectious bursal disease, Live
ix. POLIMUN ND IB EDS – vaccine against Newcastle disease virus, avian infectious bronchitis, and egg drop syndrome, inactivated
x. POLIMUN ND Hitchner B1– vaccine against Newcastle disease of poultry, live
xi. POLIMUN La-Sota – vaccine against Newcastle disease of poultry, live
xii. BOVIMUN MAST – vaccine against bovine mastitis, polyvalent, inactivated
xiii. POLIMUN IB H120

Proceedings of 354th meeting:

Following representative of firm appeared before Registration Board for deliberation on the matter:

1. Brig. Khalid Mahmud Akhter(Retd) (Group head planning, int'l business development & Regulatory Affairs, Hi-Tech)
2. Dr. Ali Afzal (Pharmacist, Hi-Tech)
3. Maksim Vorohobin (Head of the Regulatory Affairs Department, Biotestlab Ukraine)
4. Maria Sinchuk, (Head of the Quality Department — Biotestlab Ukraine)

The representatives of the firm provided justifications/clarifications regarding the observations noted by the panel during the virtual audit.

Decision:

After deliberation, the Registration Board decided to defer the case for further consideration in the next meeting.

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

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Item No. V Applications received on e-app.

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(339-Y28-D9VQ, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-11-28,
	The proposed proprietary name / brand name	**Axavon 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vonoprazan Fumarate Equivalent to Vonoprazan .....10 mg (The Finish Product Complies with Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Vonozan 10mg Tablet by Getz Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Jingsheng Pharmaceutical Co., Ltd., No.27, Donghai 5th Avenue, Taizhouwan Economic and Technical Development Zone, Linhai, Taizhou City, Zhejiang province, China.
	Detail of stability batches of drug product	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm Imported Material against DIL, Form-6# DIL-C-95D19E and Clearance Certificate# RO-FADEF7 (09-04-2025) Complete Import Document Attached in MOD-III
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Vonozan 10mg Tablet by Getz Pharma Karachi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months
	The status in reference regulatory authorities	Takecab Tablet 10mg by Takeda Pharmaceutical Company PMDA Approved

	GMP status of the firm	GMP Certified and New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evidence of approval of manufacturing facility	New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evaluation Remarks	
	The application fullfils codal formalities and submitted for consideration of the Registration Board.	
	Decision	
	Approved Approved subject to GMP Inspection report.	
2	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(3EY-PR7-UR9T, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-28,
	The proposed proprietary name / brand name	**Axasten Extra Cream**
	Label Claim	Each unit contains: Clotrimazole (USP) .....1% w/w Hydrocortisone (USP) ..... 1% w/w The Finish Product Complies with BP Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	15gm-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C.
	For generic drugs (me-too Status)	Hydrozole Cream (R. No. 103151) by Haleon Pakistan Limited.
	Pharmacotherapeutic Group of (API)	Anti-Fungal and Anti-Inflammatory
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Halcyon Private Limited, 405-408, NAVBHARAT State, B wing, 4th Floor, Zakaria Bunder Road. Sewri(West) Mumbai, 400015,,Tianjin Jinjin Pharmaceutical Co., Ltd, No. 08 of Jingfu Road, Industrial Zone of Zhangjiawo Town, xiqing District Tainjin,
	Detail of stability batches of drug product	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm Imported Material against DIL, Form-6# K-32480284268 and Clearance Certificate# E-454980286384 Complete Import Document Attached in MOD-III
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE Conducted against Hydrozole Cream (R. No. 103151) by Haleon Pakistan Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data

		is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months
	The status in reference regulatory authorities	Canesten HC Cream by Bayer PLC MHRA APPROVED DRUG
	GMP status of the firm	GMP Certified and New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evidence of approval of manufacturing facility	New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the GMP Inspection report.	
3	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Carer Pharmaceuticals industries** Plot no.27, Main Road Rawat Industrial Estate, Rawat **(000925)**
	Application Form Dy. No / Tracking ID & date of submission	(4PH-SNM-P2NU, 2026-01-27)
	Detail of Fee Submitted	38700.0, 2025-08-07,
	The proposed proprietary name / brand name	**Rosvasta 20mg tablet**
	Label Claim	Each film coated tablet Contains: Rosuvastatin calcium eq. to Rosuvastatin .....20mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15C-30C
	For generic drugs (me-too Status)	ROVISTA TABLETS 20mg M/S Getz Pharma
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA07
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	S Livmore Life Sciences Pvt. Ltd
	Detail of stability batches of drug product	03 batches on long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed against Rovista 20 mg by Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on long term and accelerated conditions
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate dated 24.02.2025
	Evidence of approval of manufacturing facility	DML dated 18.03.2021
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

	Approved	
4	Case Category	Priority As Per 257-M of RB (Abdul Mughees)
	Name, address of Applicant.	**ATCO LIFE SCIENCES (PRIVATE) LIMITED** B-18 S.I.T.E. Karachi **(051)**
	Application Form Dy. No / Tracking ID & date of submission	(SAE-9RM-XZZ7, 2025-09-16)
	Detail of Fee Submitted	300000.0, 2025-07-07,
	The proposed proprietary name / brand name	**OSIMATAB 80mg Tablet**
	Label Claim	Each film coated tablet contains Osimertinib Mesylate INN equivalent to Osimertinib 80 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3×10's -De-Controlled
	Shelf Life (Unit)	24 Month(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	TAGRISSO 80 mg film-coated tablets by AstraZeneca Pakistan
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile performed against TAGRISSO® 80 Film Coated Tablets by AstraZeneca
	Name, address of Marketing Authorization Holder:	Eskayef Pharmaceuticals Limited, Murapara, Rupganj, Narayanganj 1464, Bangladesh., Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	GMP of manufacturer by DGDA: DGDA/6-214/2671 dated 06.03.2025 COPP: DGDA/6-214/15318 dated 28.08.2024
	Details of Authorization Letter :	NIL
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at longterm and accelerated conditions
	The status in reference regulatory authorities	TAGRISSO 80 mg film-coated tablets by AstraZeneca UK Limited
	Evaluation Remarks	
	The applciation fulfills codal formalities and is submitted for consideration of the Registration Board.	
	Decision	
	Approved Approved subject to the submission of finished drug stability data including chromatograms and Batch Manufacturing Records for finished product stability batches	
5	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(AJ5-W3N-WUH3, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-15,

	The proposed proprietary name / brand name	**GOSOFT 40mg Capsule**
	Label Claim	Each capsule contains: Omeprazole (as enteric coated pellets).....40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-Controlled,28's-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	RISK GET
	Pharmacotherapeutic Group of (API)	A02BC01; Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	03 batches on accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Bio-Mark Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Risek 40 mg Capsule Batch No.: 779D18 Each capsule contains: Omeprazole (as enteric coated delayed release pellets)….40 mg Manufactured by: Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on accelerated and long-term conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificated dated 11.06.2025
	Evidence of approval of manufacturing facility	Section Approval Letter dated 20.06.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
6	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(QEE-XR7-PPLY, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	**GOSOFT 20mg Capsule**
	Label Claim	Each capsule contains: Omeprazole (as enteric coated pellets).....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-Controlled,28's-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Risek Capsules (GETZ Pharma)
	Pharmacotherapeutic Group of (API)	A02BC01; Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	03 batches on accelerated and long-term conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Bio-Mark Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: Risek 20 mg Capsule Batch No.: 883C19 Each capsule contains: Omeprazole (as enteric coated delayed release pellets)….20 mg Manufactured by: Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on accelerated and long-term conditions
	The status in reference regulatory authorities	US FDA Approved
	GMP status of the firm	GMP certificated dated 11.06.2025
	Evidence of approval of manufacturing facility	Section Approval Letter dated 20.06.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
7	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(RG1-ARY-G9L1, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-31,
	The proposed proprietary name / brand name	**Brisonox 150mg Capsule**
	Label Claim	Each Hard Gelatin Capsule containing: Itraconazole.....
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Icon capsule Ferozsons laboratories PVT ltd.
	Pharmacotherapeutic Group of (API)	Azole Antifungals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan
	Detail of stability batches of drug product	03 batches on accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Bio-Mark Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Icon 100 mg, FEROZSONS LABORATORIES LIMITED, Batch 230579
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on accelerated and long-term conditions
	The status in reference regulatory authorities	Sporanox Capsule (JANSSEN PHARMS) Hard Capsule is USFDA approved
	GMP status of the firm	GMP certificated dated 11.06.2025
	Evidence of approval of manufacturing facility	Section Approval Letter dated 20.06.2025
	Evaluation Remarks	

	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
8	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(YQQ-TY7-4SSH, 2025-10-03)
	Detail of Fee Submitted	37000, 2025-07-15,
	The proposed proprietary name / brand name	**VLAX 200mg Capsule**
	Label Claim	Each Capsule contains: Sustained release pellets of Mebeverine hydrochloride eq. to mebeverine.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Mebever MR Capsule
	Pharmacotherapeutic Group of (API)	ATC A03AA04: synthetic anticholinergics; musculotropic antispasmodic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VISION PHARMACEUTICALS, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	03 batches on accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Bio-Mark Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Colopas Capsules, Nabiqasim Industries, Batch PSG003
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on accelerated and long-term conditions
	The status in reference regulatory authorities	Attached
	GMP status of the firm	GMP certificated dated 11.06.2025
	Evidence of approval of manufacturing facility	Section Approval Letter dated 20.06.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
9	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(BS2-G6A-26V5, 2025-10-02)
	Detail of Fee Submitted	38700, 2025-09-15,

	The proposed proprietary name / brand name	**Tamsu 0.4mg Capsule**
	Label Claim	Each capsule contains: Tamsulosin Hydrochloride (as SR pellets) ..... 0.4 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Tamsolin (0.4mg) Capsules GETZ Pharma
	Pharmacotherapeutic Group of (API)	BPH,Alpha blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	03 batches on accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Bio-Mark Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flomax Capsule 0.0.4mg; Manufactured by Astellas, Pharma Inc. Batch # FLO9562
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on accelerated and long-term conditions
	The status in reference regulatory authorities	Flomax Capsules Astellas, Pharma Inc. USFDA Approved
	GMP status of the firm	GMP certificated dated 11.06.2025
	Evidence of approval of manufacturing facility	Section Approval Letter dated 20.06.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Aprroved subject to API loan verification	
10	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(P3N-MGJ-NE1X, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Zeegap Capsules 100mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, -As per SRO, 2x 5's, -As per SRO, 3x10's,-As per SRO, 4x14's-As per SRO,1x14's, -As per SRO,1x5's,-As per SRO,1X7's, -As per SRO,2x10's,-As per SRO,2x14's -As per SRO,4x7's,-As per SRO,7's, 2x -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 100mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan form Hilton; DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of JUL 2018 around 250 Kg on long-term and accelrated conditions
	The status in reference regulatory authorities	Lyrica Capsules 100mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML no. 001001 issued on 02.12.2024
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
11	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(VZR-RJQ-U7ST, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Zeegap Capsules 75mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x10's, -As per SRO,1x10's, -As per SRO,1x14's, -As per SRO,1x5's, -As per SRO,1X7's, -As per SRO,2x 5's, -As per SRO,2x 7's, -As per SRO,2x14's-As per SRO,3x10's-As per SRO,4x14's-As per SRO,4x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 75mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan form Hilton; DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsules 75mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la

	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	dml no. 001001
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
12	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(PJ7-HSB-E9RZ, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Zeegap Capsules 150mg**
	Label Claim	Each capsule contains: Pregabalin, USP.....150mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x14's -As per SRO, 4x14's-As per SRO,1X 7's, -As per SRO,1x10's, -As per SRO,1x14's,-As per SRO,1x5's, -As per SRO,2x 5's,-As per SRO,2x 7's-As per SRO,2x10's, -As per SRO,3x10's, -As per SRO,4x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Gabica 150mg, (Getz Pharma)
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan form Hilton; DIL -C-19CF52
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsules 150mg ; (Pfizer) https://www.accessdata.fda.gov/drugsatfda_docs/la
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	dml no. 001001
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
13	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP)

		(001001)
	Application Form Dy. No / Tracking ID & date of submission	(L2G-YJ3-P1D7, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	**Flux Capsules 20mg**
	Label Claim	Flux Capsules 20mg Each capsule contains: Fluoxetine Hydrochloride, USP eq. to Fluoxetine.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x14's -As per SRO, 4x14's-As per SRO,1X 7's, -As per SRO,1x10's, -As per SRO,1x14's,-As per SRO,1x5's, -As per SRO,2x 5's,-As per SRO,2x 7's, -As per SRO,2x10's, -As per SRO,3x10's, -As per SRO,4x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Dericap 20mg capsules (Nabiqasim)
	Pharmacotherapeutic Group of (API)	anti depressents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	--
	Detail of stability batches of drug product	03 batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Hilton; DIL -C-DD91A0
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Prozac Capsule 20mg (Eli Lilly and Company, Indianapolis, IN 46285, USA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	dml no. 001001
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
14	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**HINUCON (Pvt.) Ltd.** Plot No. IT-03-A3 & IT-04-A3, Korangi Creek Industrial Park (KCIP) **(001001)**
	Application Form Dy. No / Tracking ID & date of submission	(EY3-MV4-BH1H, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Dulan Capsules 60mg**
	Label Claim	Each delayed release capsule contains: Duloxetine HCl enteric coated pellets equivalent to Duloxetine 60mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	2x 5's,-As per SRO, 2x14's-As per SRO, 4x14's-As per SRO, 7's, -As per SRO,1x10's, -As per SRO,1x14's,-As per SRO,1x5's,-As per SRO,2x 7's, -As per SRO,2x10's, -As per SRO,3x10's, -As per SRO,4x7's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	Getz Pharma : Lyta 20mg capsule
	Pharmacotherapeutic Group of (API)	anti depressents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	procured locally (Surge laboratories pvt ltd) pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Cymbalta Capsule 60mg Manufacturer: Eli Lilly and Company, Indianapolis, IN 46285, USA accessdata.fda (.gov) https://share.google/W99UGWRdU0G8MNYSe
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	dml no. 001001
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
15	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(VED-ZSW-2NLP, 2025-10-10)
	Detail of Fee Submitted	38700.0, 2025-09-01,
	The proposed proprietary name / brand name	**Zetigen 50mg Tablets**
	Label Claim	Each film coated tablet contains; Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Suzet Tablets 50mg manufactured by Helix Pharma (Pvt)., Ltd
	Pharmacotherapeutic Group of (API)	Non-opioid analgesics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CHONGQING ASINCAN BIOTECH CO., LTD
	Detail of stability batches of drug product	070T25,071T25,072T25

	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
16	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(ZY1-LG1-9H8A, 2025-09-02)
	Detail of Fee Submitted	75000.0, 2025-02-14,
	The proposed proprietary name / brand name	**Avenox 200mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Avanafil.....200mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA Approved

	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
17	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(LPL-9V4-1Y7H, 2025-09-02)
	Detail of Fee Submitted	75000.0, 2025-02-14,
	The proposed proprietary name / brand name	**Avenox 50mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Avanafil.....50mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
18	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(992-3EH-26B3, 2025-09-02)
	Detail of Fee Submitted	75000.0, 2025-02-14,

	The proposed proprietary name / brand name	**Avenox 100mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Avanafil.....100mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
19	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(YVA-V5R-6TT2, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Suzemax 50mg Tablets**
	Label Claim	Suzetrigine 50mg/Tablets
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Suzetrigine is a selective $Na_v1.8$ voltage-gated sodium channel blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Attached in Module 3 in section 3.2.P.8
	Documents for the procurement of API with approval from DRAP	Attached in Module 3 in section 3.2.P.8

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Module 3 in section 3.2. P.2.2
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Module 3 in section 3.2. S.7
	The status in reference regulatory authorities	JOURNAVX (Suzetrigine) tablets, for oral use Tablets: 50 mg, Initial U.S. Approval: 2025 Manufactured for Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210
	GMP status of the firm	Attached in Module 1 in section 1.3.5
	Evidence of approval of manufacturing facility	Attached in Module 1 in section 1.3.5
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
20	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(UBB-XGT-D762, 2025-08-22)
	Detail of Fee Submitted	75000.0, 2025-07-18,
	The proposed proprietary name / brand name	**Suzene Tablets 50mg**
	Label Claim	Each film coated Tablet contains: Suzetrigine...50mg As per Innovator's specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Tablets-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 ºC at cool and dry place
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	A class of drugs that inhibit the activation of voltage-gated sodium channels.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Neutan Pharma (Anhui) Co., Ltd.
	Detail of stability batches of drug product	SZT-001, SZT-002, SZT-003 Each of 1200 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Jouravx Tablet 50mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Both Accelerated and real time stability studies performed

	The status in reference regulatory authorities	US FDA
	GMP status of the firm	w.e.f 04-07-2025
	Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
21	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(Q3M-8PD-BJTJ, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-01-29,
	The proposed proprietary name / brand name	**CEF-X 400mg CAPSULE**
	Label Claim	CEF-X 400mg capsule Each capsule contains: Cefixime as Trihydrate eq. to Cefixime 400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	CEFSPAN Capsules
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Available; Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Available; Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Available; Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Available; Attached
	The status in reference regulatory authorities	Suprax Capsule 400MG (USFDA Approved)
	GMP status of the firm	GMP certificate dated 01/07/2025 for Govt Institutes only
	Evidence of approval of manufacturing facility	Additional Section Capsule (Ceph) New approval letter dated 20.06.2025
	Evaluation Remarks	
	The application fullfils codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

	Approved	
22	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(QJ4-6Q9-QDQ3, 2026-01-13)
	Detail of Fee Submitted	37000.0, 2025-07-31,
	The proposed proprietary name / brand name	**Nispore Capsule**
	Label Claim	Each Hard Gelatin Capsule containing: Fluconazole 150mg (JP Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Diflucan Capsule - Pfizer laboratories (PVT) LTD
	Pharmacotherapeutic Group of (API)	Azole antifunga
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HEMA PHARMACEUTICAL PVT. LTD. Plot No :- 6201/A&B, GIDC ESTATE, Opp. EW AC ALLOY LTD, ANKLESHWAR-393002.GUJARA T-INDIA
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Valid upto 13/06/2028
	Evidence of approval of manufacturing facility	New Section Approval Letter Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
23	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(93R-21R-S9YB, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-09-24,
	The proposed proprietary name / brand name	**NEPCO 100mg CAPSULE**
	Label Claim	Each hard gelatin capsule contains: Pregabalin.....100mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	14's-De-Controlled,28's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Gabica (GETZ)
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life sciences Pvt. Ltd. Progress Life Sciences Pvt. Ltd., J-311,Bhosari MIDC, Pune - 400 026 Maharashtra, India
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Lyrica (Pfizer Gloval Research & Development)
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
24	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(HTS-AAY-J4BU, 2025-11-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	**DXLO DDR 30mg Capsule**
	Label Claim	Each hard gelatin capsule containing: Dual Delayed Release pellets of Dexlansoprazole equivalent to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Razodex Capsule (Getz Pharma)
	Pharmacotherapeutic Group of (API)	nonsteroidal aromatase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Pvt. Ltd, Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Detail of stability batches of drug product	3 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached

	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP against razodex by Getz pharma; batch number 117C47
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Dexilant Capsule (Takeda Pharmaceutical, USA)
	GMP status of the firm	GMP certificate dated 13.06.2025
	Evidence of approval of manufacturing facility	DML dated 16.10.2024 Additional Section dated 20.06.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
25	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(DPV-3R7-H9E6, 2025-11-03)
	Detail of Fee Submitted	38700, 2025-10-01,
	The proposed proprietary name / brand name	**DXLO DDR 60mg Capsul**
	Label Claim	Each hard gelatin capsule containing: Dual Delayed Release pellets of Dexlansoprazole equivalent to Dexlansoprazole 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's -De-Controlled,14's -De-Controlled,20's -De-Controlled,28's -De-Controlled,30's -De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Razodex Capsule (Getz Pharma)
	Pharmacotherapeutic Group of (API)	nonsteroidal aromatase inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Pvt. Ltd, Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Dexilant Capsule (Takeda Pharmaceutical, USA)
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	

26	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(H69-SHW-PWEH, 2025-09-17)
	Detail of Fee Submitted	38700.0, 2025-09-03,
	The proposed proprietary name / brand name	**Sylonex 30mg Capsule**
	Label Claim	Each capsule contains: Duloxetine HCl Enteric Coated Pellets (17%) eq. to Duloxetine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Cymbalta Capsules (Eli Lilly & Company)
	Pharmacotherapeutic Group of (API)	serotonin norepinephrine reuptake inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	New Section Letter Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
27	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(H1U-EMZ-AUNB, 2025-09-17)
	Detail of Fee Submitted	38700.0, 2025-09-03,
	The proposed proprietary name / brand name	**Delight 20mg Capsule**
	Label Claim	Each capsule contains: Duloxetine HCl Enteric Coated Pellets (17%) eq. to Duloxetine.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled

	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Cymbalta Capsules (Eli Lilly & Company)
	Pharmacotherapeutic Group of (API)	serotonin norepinephrine reuptake inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	New Section Letter Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
28	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(A9Y-NW8-JA9X, 2025-09-17)
	Detail of Fee Submitted	38700.0, 2025-09-03,
	The proposed proprietary name / brand name	**Sylonex 60mg Capsule**
	Label Claim	Each capsule contains: Duloxetine HCl Enteric Coated Pellets (17%) eq. to Duloxetine.....60mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,28's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Cymbalta Capsules (Eli Lilly & Company)
	Pharmacotherapeutic Group of (API)	serotonin norepinephrine reuptake inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	New Section Letter Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
29	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(QA3-2QZ-X1A8, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	**Ignis 40mg Capsule**
	Label Claim	Each capsule contains: Esomeprazole as Magnesium Trihydrate (as enteric coated pellets) 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-De-Controlled,28's-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	NEXUM (GETZ)
	Pharmacotherapeutic Group of (API)	proton pump inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Valid upto 13/06/2028
	Evidence of approval of manufacturing facility	new Section approval Attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
30	Case Category	New Section (Abdul Mughees)

	Name, address of Applicant.	**Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)**
	Application Form Dy. No / Tracking ID & date of submission	(BJZ-QUT-G4LL, 2025-08-04)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	**Ignis 20mg Capsule**
	Label Claim	Each capsule contains: Esomeprazole as Magnesium Trihydrate (as enteric coated pellets) 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	NEXUM (GETZ)
	Pharmacotherapeutic Group of (API)	proton pump inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid upto 13/06/2028
	Evidence of approval of manufacturing facility	New Section Approval attached
	Evaluation Remarks	
	Firm could not retrieve pictures of reference pack against which CDP was performed.	
	Decision	
	Approved Approved with the condition that manufacturer will perform CDP with comparator before marketing of the product.	
31	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(V9R-XSR-TW51, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-12-29,
	The proposed proprietary name / brand name	**Axavon 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vonoprazan Fumarate Equivalent to Vonoprazan .....20 mg (The Finish Product Complies with Innovato'rs Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO

	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Vonozan 20mg Tablet by Getz Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Jingsheng Pharmaceutical Co., Ltd., No.27, Donghai 5th Avenue, Taizhouwan Economic and Technical Development Zone, Linhai, Taizhou City, Zhejiang province,
	Detail of stability batches of drug product	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm Imported Material against DIL, Form-6# DIL-C-95D19E and Clearance Certificate# RO-FADEF7 (09-04-2025) Complete Import Document Attached in MOD-III
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Vonozan 20mg Tablet by Getz Pharma Karachi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months
	The status in reference regulatory authorities	TAKECAB 20mg TABLETS BY Takeda Pharmaceutical Company Limited, JAPAN. PMDA APPROVED
	GMP status of the firm	GMP Certified and New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evidence of approval of manufacturing facility	New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to GMP Inspection Report	
32	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(67B-MWN-LWV8, 2025-08-20)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	**Roxudo Tablet 70mg**
	Label Claim	Each Film Coated tablet contains: Roxadustat .....70mg.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-

		Controlled,30's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30C.
	For generic drugs (me-too Status)	Rodus 70mg Tablet PHARMEVO (PVT) LTD.
	Pharmacotherapeutic Group of (API)	Dr. Reddy's Laboratories Limited.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	THREE BATCHES: ROXD-T1-24, ROXD-T2-24, ROXD-T3-24 (1000 TABLETS)
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-10632044883714, 20.09.2024, BATCH NO. AFQH009345
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against EVRENZO TABLET 70MG. Batch # 22C1945
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	THREE BATVHES: AFNH000682, AFNH000683, AFNH000684 As per zone IVa
	The status in reference regulatory authorities	Evrenzo (Roxadustat) Tablet 70mg Astellas Pharma Ltd, MHRA.
	GMP status of the firm	Valid till 31.12.2027
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
33	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(DNJ-985-D8J8, 2025-10-01)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	**Roxudo Tablet 150mg**
	Label Claim	Each Film Coated tablet contains: Roxadustat 150mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30C.
	For generic drugs (me-too Status)	Rodus 150mg Tablet PHARMEVO (PVT) LTD.
	Pharmacotherapeutic Group of (API)	Dr. Reddy's Laboratories Limited.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	THREE BATCHES: ROXE-T1-24, ROXE-T2-24, ROXE-T3-24 (1000 TABLETS)

	Documents for the procurement of API with approval from DRAP (in case of Import)	E-10632044883714, 20.09.2024, BATCH NO. AFQH009345
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against EVRENZO TABLET 150MG. Batch # 22C1045
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	THREE BATCHES: AFNH000682, AFNH000683, AFNH000684 As per zone IVa
	The status in reference regulatory authorities	Evrenzo (Roxadustat) Tablet 150mg, Astellas Pharma Ltd, MHRA.
	GMP status of the firm	Valid till 31.12.2027
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
34	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(MZG-9R1-QLJY, 2025-02-14)
	Detail of Fee Submitted	75000.0, 18000.0 2024-05-24, 2024-10-09
	The proposed proprietary name / brand name	**Zevxime 200mg/5mL Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as trihydrate.....200mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Evofix Suspension 200mg (Reg No. 050396) Manufactured by PharmEvo Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Suprax Suspension 200mg (USFDA Approved)
	Detail of previous approval	Ze-Xim Suspension 200mg in 106th PRVC Meeting
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
35	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(EYJ-BSP-9VV8, 2025-04-05)

	Detail of Fee Submitted	93000.0, 2024-09-09,
	The proposed proprietary name / brand name	**Cefno Injection 1gm**
	Label Claim	Each vial contains: Cefoperazone Sodium eq. to Cefoperazone.....500mg + Sulbactam Sodium eq. to Sulbactam.....500mg (JP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Sulzone 1 gm Injection (Manufactured by Biocare Pharmaceutica Lahore)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-
	The status in reference regulatory authorities	Cefobid Injection 1gm (Manufactured by Pfizer Pvt. Ltd.) FDA Approved
	Detail of previous approval	Mectrum 1gm Injection in 106th Meeting of PRVC
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
36	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	**Med Asia Pharmaceuticals (Pvt) Ltd** Plot No. 7, NowsheraIndustrial Estate (SIZ) Risalpur **(000690)**
	Application Form Dy. No / Tracking ID & date of submission	(P2T-E41-RA6M, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Med-D 5mg/ml Injection**
	Label Claim	Each ampoule contains: Cholecalciferol (200,000IU) 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 C.
	For generic drugs (me-too Status)	Brand Name: Novel-D Injection Oral/ I.M Registration holder: DANAS Pharmaceuticals Islamabad Registration Number: 073183
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA approved drug
	Detail of previous approval	Seraf-D Injection , Meeting No :PRVC 119th
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	

37	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Mexolab (Pvt) Ltd** Qila Sitar Shah Sheikhupura Road Lahore **(000965)**
	Application Form Dy. No / Tracking ID & date of submission	(1MP-3JX-4LQZ, 2025-06-17)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	**Ironmex**
	Label Claim	Each 5ml Ampoule Contains: Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5mlx5's/5mlx1's-As per SRO
	Shelf Life (Unit)	2 Year15-30 Degree Centigrade
	For generic drugs (me-too Status)	Venofer 5ml Injection by Searle Pakistan Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	TGA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
38	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	**Oncogen Pharma (Pvt) Limited** WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) **(000960)**
	Application Form Dy. No / Tracking ID & date of submission	(94Z-DG4-ATJR, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-31,
	The proposed proprietary name / brand name	**Platigen (Carbplatin) Injection 150mg/15ml**
	Label Claim	Each 15ml contains: Carboplatin.....150mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Do not refrigerate or freeze. Protect from heat & light
	For generic drugs (me-too Status)	Kemocarb Injection 150mg/15ml
	Pharmacotherapeutic Group of (API)	L01XA02 Anti-neoplastic agent
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability studies of 03 batches i.e. P11.NP.ST.001, P11.NP.ST.002 & P11.NP.ST.003 is enclosed.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Carboplatin Injection 150mg/15mL is equivalent to the reference product Kemocarb Injection 150mg/15mL B. No. 87240333AD
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 18months
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Last GMP Inspection was carried on 07th December 2023 and found good
	Evidence of approval of manufacturing facility	Liquid injectable(with lyophilizer facility) (Oncology) approved on 02-11-2023
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved	
39	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	**Oncogen Pharma (Pvt) Limited** WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) **(000960)**
	Application Form Dy. No / Tracking ID & date of submission	(DED-YB1-5LHG, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-31,
	The proposed proprietary name / brand name	**Platigen (Carboplatin) Injection 450mg/45ml**
	Label Claim	Each 45ml contains: Carboplatin.....450mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Do not refrigerate or freeze. Protect from heat & light
	For generic drugs (me-too Status)	Kemocarb Injection 450mg/45ml
	Pharmacotherapeutic Group of (API)	L01XA02 Anti-neoplastic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability studies of 03 batches i.e. P10.NP.ST.001, P10.NP.ST.002 & P10.NP.ST.003 is enclosed.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 and clearance certificate is attached in module 3
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Carboplatin Injection 450mg/45mL is equivalent to the reference product Kemocarb Injection 450mg/45mL B. No. 87240414AE
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of 18months is enclosed in module 3
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Last GMP Inspection was carried on 07th December 2023 and found good

	Evidence of approval of manufacturing facility	Liquid injectable(with lyophilizer facility) (Oncology) approved on 02-11-2023
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved	
40	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**AMB HK ENTERPRISES (PVT) LTD, LAHORE** 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. **(05-352-0058-104514D)**
	Application Form Dy. No / Tracking ID & date of submission	(VM5-5UX-DGSB, 2025-11-03)
	Detail of Fee Submitted	300000.0, 13500 2025-07-18, 2026-02-18
	The proposed proprietary name / brand name	**Lovacor**
	Label Claim	Each capsule contains: Omega-3-Acid Ethyl Esters 1000 mg eq. to; 840 mg ethylesters of eicosapentaenoic acid (EPA 465 mg) and docosahexaenoic acid (DHA 375 mg).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	BOX OF 30'S: AS PER SRO-As per SRO
	Shelf Life (Unit)	36 Year(s)STORE BELOW 30 DEGREES CELSIUS
	For generic drugs (me-too Status)	NEW DRUG PRODUCT
	Pharmacotherapeutic Group of (API)	C10AX06 Other lipid modifying agents
	Name, address of Manufacturing site:	Humanwell PuraCap Pharmaceutical (Wuhan) Co Ltd.-No.99, Shendun 2nd Road, East Lake New Technology Development Zone, Wuhan-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is perfomed against Lovaza capsules, Mfg GSK Norway
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES(PVT) LTD, 2ND FLOOR PLAZA 60, COMMERCIAL BLOCK-K, PHASE-1, DHA, LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of inspection results dated 13.09.2024 are submitted. GMP inspection was conducted by Hubei Provincial Medical product administration. The inspection conclusion reported is, "The inspection confirms compliance with GMP guidelines. Results are hereb
	Details of Authorization Letter :	Copy of Distribution agreement and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II, upto 24 months.
	The status in reference regulatory authorities	FDA APPROVED
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:-	

	i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
41	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(HQ2-1MS-TQRE, 2026-01-22)
	Detail of Fee Submitted	75000, 2025-11-11,
	The proposed proprietary name / brand name	**UBROF Extra 400mg/100mg Tablet**
	Label Claim	Each film coated tablet contains: Ibuprofen .....400mg Caffeine.....100mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 12's, 14's, 20's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	M01AE51 Anti-inflammatory drug and caffeine combination
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2000 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificates are submitted for both drug substances. 50kg Caffeine is mentioned and Ibuprofen is being imported in bulk for already registered products.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Iprafeine 400mg+100mg Tablet B. No. 241687 Mfg Opella Healthcare Product.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Caffeine: Zone IVa upto 60 months Ibuprofen Zone IVb upto 72 months.
	The status in reference regulatory authorities	ANSM of France - IPRAFEIN 400 mg/100 mg film-coated tablet
	GMP status of the firm	Valid until 30.06.2027
	Evidence of approval of manufacturing facility	Copy of renewal letter dated 13.10.2023 is submitted wherein Tablet (General) Section is mentioned.
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	

42	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(3QB-G4A-81MN, 2025-10-14)
	Detail of Fee Submitted	75000.0, 2025-09-01,
	The proposed proprietary name / brand name	**Delgotib 2% Cream**
	Label Claim	Each gram contains: Delgocitinib.....20mg(2%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm-As per SRO,15gm-As per SRO,30gm-As per SRO,5gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	D11AH11 Agents for dermatitis, excluding corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S SHANDONG KEHUI PHARMACEUTICAL CO., LTD. NO.9A1, TIANHENG ROAD, GAOQING CITY, SHANDONG PROVINCE, CHINA.
	Detail of stability batches of drug product	3 batches, 250 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 100grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Anzupgo 20mg/g Cream B. no. D33047 Mfg Leo Laboratories Ireland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 5 ± 3C (24 Months), Accelerated: 25C ± 2oC and 60% ± 5% RH (6 Months)
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Renewal letter dated 22.03.2024 is submitted.
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
43	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**

	Application Form Dy. No / Tracking ID & date of submission	(VA8-MW8-AGEW, 2026-02-06)
	Detail of Fee Submitted	75000, 2026-01-21,
	The proposed proprietary name / brand name	**Delgo Cream 2%**
	Label Claim	Each gram of cream contains: Delgocitinib.....20mg (2.0%) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at controlled room temperature 20 °C to 25 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	D11AH11 Agents for dermatitis, excluding corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian Pharmaceutical Technology Co., Ltd.
	Detail of stability batches of drug product	3 batches, 500 packs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 of 250grams drug substance is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Anzupgo Cream2% Mfg Leo Pharma Denmark
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa, up to 24 months.
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	w.e.f 13-04-2021 requested for renewal 27-10-2022
	Evidence of approval of manufacturing facility	Renewal letter dated 30.04.2024 is submitted wherein Ointment cream gel general section is mentioned.
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
44	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Amgomed** Office No. 4, First Floor, Ghousia Plaza,Main Jinnah Avenue, Blue Area **(037/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(5EP-BTY-JJ4H, 2025-09-22)

	Detail of Fee Submitted	313500.0, 2025-08-21,
	The proposed proprietary name / brand name	**Lenvicap 4 mg capsules**
	Label Claim	Each Capsule contains: Lenvatinib mesylate eq. to Lenvatinib ..... 4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 capsules-De-Controlled
	Shelf Life (Unit)	24 Month(s)30 degree
	For generic drugs (me-too Status)	Lenvanix 4 mg capsules
	Pharmacotherapeutic Group of (API)	01EX08 Other protein kinase inhibitors
	Name, address of Manufacturing site:	M/s Zhejiang Jianfeng Co.,Ltd-Building X02, 2nd Floor, Office Quality Inspection Building, No. 58 Gaofan Section, Baitangxia Line, Wucheng District, Jinhua City, Zhejiang Province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lenvima 4mg, B. Nos. 127402, 128136, 128137 Eisai Europe Ltd. Canada.
	Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of conclusion of inspection dated 05.07.2024 is submitted. Inspection was conducted by Zhejiang Medical Products Administration.
	Details of Authorization Letter :	Letter of authorization and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term conducted at refrigerated conditions.
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved As per policy for inspection abroad.	
45	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan **(DSL 0655)**
	Application Form Dy. No / Tracking ID & date of submission	(5N1-X7B-AWBU, 2026-02-09)
	Detail of Fee Submitted	300000, 2025-04-29,
	The proposed proprietary name / brand name	**Lenvib Capsules 4mg**
	Label Claim	Each capsule contains: Lenvatinib Mesylate equivalent to Lenvatinib.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	LENVIMA Capsules 4mg by M/s Hilton Pharma (Pvt.) Ltd.

	Pharmacotherapeutic Group of (API)	L01EX08 Protein Kinase Inhibitors (Other protein kinase inhibitors)
	Name, address of Manufacturing site:	Laboratorio Eczane S.A., Argentina-Laprida 43 – Avellaneda – (Postal Code 1870C), Buenos Aires - Argentina.-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been performed on Lenvatib Capsules 4mg manufactured by M/s Laboratorio Varifarma S.A., Argentina
	Name, address of Marketing Authorization Holder:	Getz Pharma (Pvt.) Limited., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate issued by ANMAT Argentina dated 20.03.2024 valid upto 12 months is submitted. Certificate No. CE-2024-29387490-APN-DTC#MRE
	Details of Authorization Letter :	Letter of Authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2~8C upto 36 months.
	The status in reference regulatory authorities	Lenvima Capsules 4mg by Eisai Inc., USA (US-FDA Approved)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved As per policy for inspection abroad.	
46	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan **(DSL 0655)**
	Application Form Dy. No / Tracking ID & date of submission	(Y36-BZV-V45L, 2026-02-09)
	Detail of Fee Submitted	300000, 2025-04-29,
	The proposed proprietary name / brand name	**Lenvib Capsules 10mg**
	Label Claim	Each capsule contains: Lenvatinib Mesylate equivalent to Lenvatinib....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	LENVIMA Capsules 10mg by M/s Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Protein Kinase Inhibitors (Other protein kinase inhibitors)
	Name, address of Manufacturing site:	Laboratorio Eczane S.A., Argentina-Laprida 43 – Avellaneda – (Postal Code 1870C), Buenos Aires - Argentina.-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been performed on Lenvatib Capsules 10mg manufactured by M/s Laboratorio Varifarma S.A., Argentina
	Name, address of Marketing Authorization Holder:	Getz Pharma (Pvt.) Limited., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi.,

		Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted GMP Certificate of M/s Laboratorio Eczane S.A., Argentina.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Lenvima Capsules 10mg by Eisai Inc., USA (US-FDA Approved)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved As per policy for inspection abroad.	
47	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(TMA-46W-3QES, 2025-04-21)
	Detail of Fee Submitted	75000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Revoler 10mg Tablet**
	Label Claim	Each film coated tablet contains: Bepotastine besilate 10mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place below 30°C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Antiallergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Precise Chemipharma Pvt. Ltd. C-384, T.T.C.INDUSTRIAL AREA , M.I.D.C. , NAVI MUMBAI, PAWANE - 400703, Dist. THANE-ZONE7,INDIA
	Detail of stability batches of drug product	3 batches, 1200 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice of 70 gram drug substance along with impurities is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Talion 10mgTablets B. No. F715 M/s Mitsubishi tanabe pharma Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency (PMDA)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.01.2023 is submitted,
	Evidence of approval of manufacturing facility	Renewal letter dated 03.03.2023 is submitted.
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	

	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
48	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(53Z-W5X-HM18, 2026-02-06)
	Detail of Fee Submitted	75000, 2025-12-02,
	The proposed proprietary name / brand name	**Etra 2mg Tablets**
	Label Claim	Each film-coated tablet contains: Etrasimod Arginine eq. to Etrasimod 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	L04AE05 Sphingosine-1-phosphate (S1P) receptor modulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	3 batches, 4000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 40 grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velsipity 2mg tab B. No. 028552 Mfg Pfizer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 24 months.
	The status in reference regulatory authorities	VELSIPITY (Etrasimod) tablets, for oral use Tablets: 2 mg, Initial U.S. Approval: 2023 Distributed by: Pfizer Labs Division of Pfizer Inc. New York, NY 10001
	GMP status of the firm	GMP certificate valid upto 10.01.2027 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 01.03.2010 is submitted.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

Approved

Approved subject to the submission of:-

i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026.

ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.

49	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(87M-NS6-NWVZ, 2026-02-12)
	Detail of Fee Submitted	75000, 2025-09-16,
	The proposed proprietary name / brand name	**Etrava 2mg Tablet**
	Label Claim	Each film-coated tablet contains: Etrasimod arginine eq. to Etrasimod.....2mg (Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Packed in Alu alu blister pack of 7's, 10's, 14's,- De-Controlled
	Shelf Life (Unit)	24 Year(s)store below 30ºC
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	L04AE05 Immunosuppressants, sphingosine 1-phosphate (S1P) receptor modulators.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Ailead Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 30 grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velsipity 2mg Tablet of Pfizer Limited Belgium . B. No. 028552
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa
	The status in reference regulatory authorities	MHRA approved.
	GMP status of the firm	GMP certificate dated 3-06-2025 based on inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Section approval/ renewal letter dated 01.08.2025 is submitted.
	Evaluation Remarks	
	The application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved Approved subject to the submission of:-	

	i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
50	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Al Qasim Enterprises** House No.134-E, Street #01, Sabzazar, Range Road Rawalpindi **(01-374-0176-039416D)**
	Application Form Dy. No / Tracking ID & date of submission	(1VJ-A7D-D2GR, 2026-02-23)
	Detail of Fee Submitted	313500, 2025-12-01,
	The proposed proprietary name / brand name	**Pomalidomide**
	Label Claim	Each capsule contains; Pomalidomide 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21-As per SRO
	Shelf Life (Unit)	36 Year(s)30
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Immuno Suppressants Anatomical Therapetic Chemical, ATC Code : L04AX06
	Name, address of Manufacturing site:	Synthon Hispania S.L.- c/ castello, 1, 08830 Sant Boi de Llobregat, Barcelona, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Imnovid 4mg B. No. C0033AB
	Name, address of Marketing Authorization Holder:	Synthon B.V., Microweg 22 6545 CM Nijmegen The Netherlands, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	Synthon Hispania Spain, Eudra GMP.
	Details of Authorization Letter :	COPP issued by Netherlands is submitted. As per COPP product is manufactured by Synthon Hispania Spain And MA holder is Synthon BV Netherlands. The finished product is placed on market of Netherlands for free sale. Agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone II upto 60 months.
	The status in reference regulatory authorities	Attach in Module 1
	Evaluation Remarks	
	The application fulfills codal formalities and is recommended for consideration of board.	
	Decision	
	Approved Approved subject to the policy for inspection abroad and submission of :- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	

51	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**FAAS Pharmaceuticals (Pvt)Ltd** F-748 L, S.I.T.E, Karachi **(000767)**
	Application Form Dy. No / Tracking ID & date of submission	(42E-DL4-V621, 2024-07-08)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	**KETRO 30mg/ml Injection**
	Label Claim	Each ml contains: Ketorolac tromethamine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 C.
	For generic drugs (me-too Status)	Brand Name: Toralac 30mg/ml injection Registration holder: Global Pharmaceuticals Pakistan
	Pharmacotherapeutic Group of (API)	M01AB15 Acetic acid derivatives and related substances
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	FDA approved drug
	Detail of previous approval	351st Rb meeting. Toralak 30mg Injection. For Solaris Life Sciences.
	Evaluation Remarks	
	Data already approved in 351st Rb meeting. Toralak 30mg Injection. For Solaris Life Sciences.	
	Decision	
	Approved	
52	Case Category	Short Availability Drugs (Adil Saeed)
	Name, address of Applicant.	**Health Hub Pakistan** House# 397, South Service Road Sector I-14/4 Islamabad Pakistan **(whole sale/8c-2T2Mu8p4)**
	Application Form Dy. No / Tracking ID & date of submission	(5NS-3H1-YQQP, 2025-09-30)
	Detail of Fee Submitted	300000.0, 2025-05-21,
	The proposed proprietary name / brand name	**Imiro 350**
	Label Claim	iohaxol 350 mg/5ml USP
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Omnipaque
	Pharmacotherapeutic Group of (API)	Contrast Media
	Name, address of Manufacturing site:	Popular Pharmaceuticals PLC.-164, Tongi Industrial Area, Gazipur 1711 -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Module 5
	Name, address of Marketing Authorization Holder:	HEALTH HUB PAKISTAN, House# 397, South Service Road I-14/4 Islamabad Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	Module 5

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Module 3
	The status in reference regulatory authorities	MYANMAR
	Evaluation Remarks	
	Although applicant have submitted Module 1 2 & 3 but has filled and signed Form 5A instead of Form 5F. As per current Rules, firm cannot apply on Form 5A for registration of imported drug until any relaxation is granted by the Authority. In this case there is no relaxation and applicant has applied on an incorrect form. Further firm has not submitted COPP. 3.2.P.2.2 pharmaceutical equivalence is not submitted. An explanation is attached in dossier wherein its mentioned that they have used same formulation as innovator product except HCl for pH adjustment and both products are same, indicating firm has not performed pharmaceutical equivalence. 3.2.P.8 Claimed shelf life is 24 months, stability data only up to 18 months is submitted.	
	Decision	
	Deferred Deferred for submission of requisite information.	
53	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(XLX-G3W-UJ5B, 2025-09-04)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Vnosil 100mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....100mg (Product complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	----------
	Pharmaceutical Equivalence and Comparative Dissolution Profile	--------
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid Till 12 Dec, 2027
	Evidence of approval of manufacturing facility	Tablet General Section, section approval letter is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of the Registration Board.	
	Decision	
	Approved	

54	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi **(000838)**
	Application Form Dy. No / Tracking ID & date of submission	(TBG-1UZ-7HEQ, 2024-03-27)
	Detail of Fee Submitted	75000.0, 2024-02-02,
	The proposed proprietary name / brand name	**Voxeto 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vortioxetine Hydrobromide eq. Vortioxetine..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Vorbo 20mg Tablet
	Pharmacotherapeutic Group of (API)	N06AX26 Other antidepressants
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
	Name & address of API manufacturer	M/S PORTON PHARMA LIMITED SOLUTIONS LTD. 1 FINE CHEMICAL ZONE, CHONGQING CHEM, IND PARK, CHANGSHOU, CHONGQING, 401221, CHINA
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Brintellix 20mg tablet batch No. 5928361
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP inspection report dated 17.10.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 05.05.2010 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of the Registration Board.	
	Decision	
	Approved	
55	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Bio-Next Pharmaceuticals** plot no 50 street no S-10 RCCI Rawat **(000910)**
	Application Form Dy. No / Tracking ID & date of submission	(VG2-LRS-126E, 2024-06-13)
	Detail of Fee Submitted	75000.0, 2021-10-12,
	The proposed proprietary name / brand name	**Ceftam 1gm Injection**
	Label Claim	Each vials contains: Sulbactam sodium eq.to sulbactam....500mg Cefoperazone Sodium eq, to Cefoperazone....500mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	01 Vials-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30
	For generic drugs (me-too Status)	2SUM Injection 1gm
	Pharmacotherapeutic Group of (API)	J01DD62 cefoperazone and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-
	Name & address of API manufacturer	Suzhou Dawnrays Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 4545 packs each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 100kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	2SUM 1g Injection B. No. AOK015 Mfg Sami Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24 months.
	The status in reference regulatory authorities	Pfizer Japan
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection report dated 09.10.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 27.02.2011 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of Board.	
	Decision	
	Approved	
56	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Bio-Next Pharmaceuticals** plot no 50 street no S-10 RCCI Rawat **(000910)**
	Application Form Dy. No / Tracking ID & date of submission	(RYH-7UA-XUT1, 2024-06-13)
	Detail of Fee Submitted	75000.0, 2021-10-12,
	The proposed proprietary name / brand name	**Ceftam 2g Injection**
	Label Claim	Each vials contains: Sulbactam sodium eq.to sulbactam....1000mg Cefoperazone Sodium eq, to Cefoperazone....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	01 Vials-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30
	For generic drugs (me-too Status)	2SUM Injection 2gm
	Pharmacotherapeutic Group of (API)	J01DD62 cefoperazone and beta-lactamase inhibitor
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-
	Name & address of API manufacturer	Suzhou Dawnrays Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 2272 packs each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 100kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	2SUM 2g Injection B. No. APK073 Mfg Sami Pharmaceuticals

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24 months.
	The status in reference regulatory authorities	Pfizer Japan
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection report dated 09.10.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 27.02.2011 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
57	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(EZA-6Q7-Z7QP, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-04-18,
	The proposed proprietary name / brand name	**SILTRATE-SUB 50mg Sublingual TABLET**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 4590 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	taken loan from M/s Wnsfeild and Form 6and clearance are not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Wafesil 50mg Tablet B. No. VF3600
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section letter dated 05.05.2010 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Applicant has requested to withdraw their application.	
	Decision	
	Rejected Rejected as withdrawn	
58	Case Category	Any Other (Adil Saeed)

	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(PL5-689-5DAW, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-04-18,
	The proposed proprietary name / brand name	**SILTRATE-SUB 25mg Sublingual TABLET**
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....25MG (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 450 tabs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan, import documents are not submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Wafesil Tablet25mg B No. VS2408
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	TGA Australia
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section, section approval letter is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Applicant has requested to withdraw their application.	
	Decision	
	Rejected Rejected as withdrawn	
59	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(75V-JYX-M51P, 2025-09-30)
	Detail of Fee Submitted	38700, 2025-09-05,
	The proposed proprietary name / brand name	**Virexo 100mg Tablets**
	Label Claim	Each Film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store belou, 30C prcltect tiom moisture
	For generic drugs (me-too Status)	Hilagra 100mg Tablets, Hilton Pharma Pvt. Ltd.,

	Pharmacotherapeutic Group of (API)	G04BE03 phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	3 batches, 500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	----------
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hilagra 100mg Tablets, Hilton Pharma Pvt. Ltd., B No. 159999
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Sildenafil 100mg film-coated tablets Each Film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil .....….. 100mg PL 36687/0364 Torrent Pharma (UK) Ltd. 3rd Floor, Nexus Building 4 Gatwick Road Crawley West Sussex RH10 9BG United Kingdom
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 14.04.2022 is submitted
	Evidence of approval of manufacturing facility	Tablets section approved vide letter dated 14.06.2008
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
60	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(LT8-JUZ-MYD8, 2025-09-04)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Vnosil-CH 50mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....50MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSFeild. Verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sildenafil 50mg chewable tablet B. No. 0108XRA Mfg M/s Cinfa

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Renewal in 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of registration board.	
	Decision	
	Approved	
61	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(B9W-BSP-H72A, 2025-09-04)
	Detail of Fee Submitted	75000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Vnosil-CH 25mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....25MG (Product complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSFeild, verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Product Name Sildenafilo Cinfa 25mg Comprimidos Masticables EFG Manufacturer Cinfa Laboratories, Batch number 0134XRB
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Renewal in 2025
	Evidence of approval of manufacturing facility	Renewal letter dated 06.02.2025 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of Registration Board.	
	Decision	
	Approved	
62	Case Category	Any Other (Adil Saeed)

	Name, address of Applicant.	**Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)**
	Application Form Dy. No / Tracking ID & date of submission	(6QP-NV9-59EW, 2025-09-30)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Viridio Chewable Tablet 50mg**
	Label Claim	Each chewable tablet contains: Sildenafil Citrate equivalent to Sildenafil 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,25's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Stability data of 3 batches on Zone IV-A provided 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed against innovator product "Direktan 50mg Chewable Tablet Mfg. by GEROT LANNACH" B. No/ 231408
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches on Zone IV-A provided
	The status in reference regulatory authorities	Sildenafil STADA 50mg Chewable tablets (HPRA - Ireland Approved)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 15.08.2024 is submitted
	Evidence of approval of manufacturing facility	Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of Registration Board.	
	Decision	
	Approved	
63	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(JXS-BSR-Y9W3, 2026-02-09)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**POMYDA Capsule 4.0mg**
	Label Claim	Each capsule contains: Pomalidomide..... 4mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	21's Blister Pack-As per SRO
	Shelf Life (Unit)	48 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	NA- New Drug Product
	Pharmacotherapeutic Group of (API)	Other immunosuppressants ATC Code: L04AX06
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator's product (IMNOVID Capsule 4mg B. No. C2164AB) with QILU's Pomalidomide capsule 4.0mg
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., 8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Eudra GMP Certificate No. ES/046HV/25
	Details of Authorization Letter :	COPP and agency agreement are submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study of Pomalidomide by drug substance manufacturer for three batches (8001L51E, 8002L51E &8003L51E) based on 6 months of accelerated stability data (40 ± 2°C / 75% ± 5% RH) and 48 months of long- term stability data (30 ± 2°C / 65% ± 5% RH) for six stability batches (8001L51E, 8002L51E, 8003L51E, 3001L51E, 3002L51E & 3003L51E). Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	Imnovid Capsule 4.0 mg, MHRA Approved
	Evaluation Remarks	
	The application fulfills codal formalities. Recommended for consideration of the Registration Board.	
	Decision	
	Approved As per policy for inspection abroad and subject to the submission of :- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
64	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**NZ Pharmaceutical** Suite # 802, 8th Floor, Vital Foakh Tower, Main Shahrah-e-Faisal, Karachi **(0848)**
	Application Form Dy. No / Tracking ID & date of submission	(4M6-6H6-V7Q1, 2026-01-05)
	Detail of Fee Submitted	300000.0, 2025-05-21,
	The proposed proprietary name / brand name	**Lenvatiz 4**
	Label Claim	Each hard gelatin capsule contains: LenvatinIb Mesylate eq. to Lenvatinin.....4mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	30-As per SRO
	Shelf Life (Unit)	2 Year(s)30 °C
	For generic drugs (me-too Status)	Lenvanix 4mg Capsule
	Pharmacotherapeutic Group of (API)	01EX08 Other protein kinase inhibitors
	Name, address of Manufacturing site:	Tizig Pharma Pvt. Ltd-Maligaun-5, Kathmandu, Nepal.-Nepal
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Name, address of Marketing Authorization Holder:	Tizig Pharma Pvt. Ltd, Maligaun-5, Kathmandu, Nepal., Nepal
	Details of Certificates (CoPP/FSC/cGMP):	GMP attached
	Details of Authorization Letter :	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months
	The status in reference regulatory authorities	LENVIMA 4 mg Eisai Europe Limited European Knowledge Centre Mosquito Way Hatfield AL10 9SN United Kingdom
	Evaluation Remarks	
	The COPP submitted has a typographic error i.e. no option is checked stating whether product is on free sale in country of origin or not. The firm was asked to clarify this issue. In response they have submitted copy of same COPP corrected by relevant authority in Nepal. Further free sale status is verifiable from Nepal Drug Administration's website. Applicant has also stated that they will submit new COPP as soon as they receive it from the principal manufacturer. The application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad. Letter shall be issued after submission of legalized COPP.	
65	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Amgomed** Office No. 4, First Floor, Ghousia Plaza,Main Jinnah Avenue, Blue Area **(037/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(NP3-G2A-VRY5, 2025-10-14)
	Detail of Fee Submitted	300000.0, 2025-07-15,
	The proposed proprietary name / brand name	**Oxaliplatin Kemex 100 mg Lyophilized powder for Injection**
	Label Claim	Each lyophilized Vial contains: Oxaliplatin .... 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial in unit carton-As per SRO
	Shelf Life (Unit)	24 Year(s)30 degree
	For generic drugs (me-too Status)	Oxaltie 100 mg Injection, Oxol 100 mg injection
	Pharmacotherapeutic Group of (API)	Anti neoplastic agent
	Name, address of Manufacturing site:	Kemex Laboratorio S.A.-Nazarre 3446/54 Ciudad Autónoma de Buenos Aires - República Argentina-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxaltie Lyophlized powder for injection B. no. BILX000 Bioprofarma Bago SA

	Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Plant certificate issued by Authority of Argentina is submitted and COPP mentions GMP status
	Details of Authorization Letter :	COPP and agency agreement are submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH upto 60 months
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of the Registration Board.	
	Decision	
	Approved As per policy for inspection abroad.	
66	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Amgomed** Office No. 4, First Floor, Ghousia Plaza,Main Jinnah Avenue, Blue Area **(037/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(1SA-5RN-E6PW, 2025-10-14)
	Detail of Fee Submitted	300000.0, 2025-07-15,
	The proposed proprietary name / brand name	**Oxaliplatin Kemex 50 mg lyophilized Powder for Injection**
	Label Claim	Each lyophilized vial contains Oxaliplatin..... 50 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial in unit carton-As per SRO
	Shelf Life (Unit)	24 Year(s)30 degree
	For generic drugs (me-too Status)	Oxaltie 50 mg Injection, Oxol 50 mg injection
	Pharmacotherapeutic Group of (API)	L01XA03 Platinum compounds
	Name, address of Manufacturing site:	Kemex Laboratorio S.A.-Nazarre 3446/54 Ciudad Autónoma de Buenos Aires - República Argentina-Argentina
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxaltie Lyophlized powder for injection Bioprofarma Bago SA
	Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Plant certificate issued by Authority of Argentina is submitted and COPP mentions GMP status
	Details of Authorization Letter :	COPP and agency agreement are submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached, studies conducted at 25C / 60 % RH upto 60 months
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	

	As per policy for inspection abroad.	
67	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Genix Pharma (Pvt) Ltd,** Plot No. 44-45-B, Korangi Creek Road, Karachi **(0640)**
	Application Form Dy. No / Tracking ID & date of submission	(31R-VLG-YXAX, 2025-09-16)
	Detail of Fee Submitted	300000.0, 2025-04-18,
	The proposed proprietary name / brand name	**Docshil 20mg/1ml**
	Label Claim	Each 1ml vial contains: Docetaxel..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	01 Glass Vial-As per SRO
	Shelf Life (Unit)	2 Year(s)15°C - 30°C
	For generic drugs (me-too Status)	Taxotere
	Pharmacotherapeutic Group of (API)	L01CD02 Taxanes
	Name, address of Manufacturing site:	Shilpa Medicare Limited -Plot No. S-20 to S26, Pharmaceutical formulations SEZ, TSIIC, Green Industrial Park, Polepally, Jadcherla, Telangana, 509301, India -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	TAXOTERE® (Docetaxel) Injection concentrate 20mg/ml B. No. D2A774 Sanofi-Aventis U.S. LLC
	Name, address of Marketing Authorization Holder:	Genix Pharma (Pvt) Ltd. Karachi, 44,45-B Korangi Creek Road, Karachi 75190 Pakistan , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. INS-482698-100932923-19191069 issued by BASG Austria issued on basis of inspection concluded on 26.01.2024 is submitted. As per Eudra GMP data, Austria again inspected the faicility on 18-10-2024.
	Details of Authorization Letter :	Finished Product Import
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	5C upto 36 months.
	The status in reference regulatory authorities	Docetaxel
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad.	
68	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(457-E3W-SJVH, 2026-02-12)
	Detail of Fee Submitted	, 313500 , 2026-01-26
	The proposed proprietary name / brand name	**Imaxen 400mg tablet**
	Label Claim	Each film coated tablet contains Imatinib Mesilate equivalent to Imatinib..... 400 mg.
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	GLIVEC 400mg tablet (Imatinib Mesylate)
	Pharmacotherapeutic Group of (API)	L01EA01 BCR-ABL tyrosine kinase inhibitors
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited. -Plot No.:B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Glivec® 400 mg film-coated M/s Novartis JV102
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited. , Rahman's Regnum Center (11th Floor) 191/B Tejgaon C/A, Dhaka-1208, Bangladesh , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate dated 01.10.2024 valid till 29.09.2026 issued by drug administration Dhaka Bangladesh is submitted.
	Details of Authorization Letter :	Letter of Authorization and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 24 months.
	The status in reference regulatory authorities	GLEEVEC ® (imatinib mesylate) 400mg tablets,
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad.	
69	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(7A9-1BM-WS63, 2026-02-12)
	Detail of Fee Submitted	, 313500 , 2026-01-19
	The proposed proprietary name / brand name	**Imaxen 100mg tablet**
	Label Claim	Each film coated tablet contains Imatinib Mesilate equivalent to Imatinib..... 100 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x30"s-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C
	For generic drugs (me-too Status)	GLIVEC by Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	L01EA01 Bcr-Abl tyrosine kinase inhibitor
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Glivec® 100 mg film-coated M/s Novartis JV093
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited, Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate dated 01.10.2024 valid till 29.09.2026 issued by drug administration

		Dhaka Bangladesh is submitted.
	Details of Authorization Letter :	Letter of Authorization and COPP is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 24 months.
	The status in reference regulatory authorities	Brand name: GLEEVEC 100 mg tablet (Imatinib Mesylate) Manufactured by: Novartis Pharma Stein AG Stein, Switzerland Brand name: Imatinib 100 mg film-coated tablets Manufactured by: Amarox Limited Congress House, 14 Lyon Road Harrow, Middlesex HA1 2EN United Kingdom
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad.	
70	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(QDE-VBQ-1GZA, 2026-02-12)
	Detail of Fee Submitted	313500, 2025-12-23,
	The proposed proprietary name / brand name	**Caboxen 20mg Capsule**
	Label Claim	Each capsule contains Cabozantinib S-Malate equivalent to Cabozantinib..... 20 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	90's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Cabozanix 20mg Capsule (Himmel Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	L01EX07 Other protein kinase inhibitors
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	COMETRIQ 20 mg hard Capsules B. No. C22001
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhala-1208, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate dated 01.10.2024 valid till 29.09.2026 issued by drug administration Dhaka Bangladesh is submitted.
	Details of Authorization Letter :	COPP and letter of authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 24 months
	The status in reference regulatory authorities	COMETRIQ 20mg Hard Capsules (Germany)
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved As per policy for inspection abroad.	
71	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Amgomed** Office No. 4, First Floor, Ghousia Plaza,Main Jinnah Avenue, Blue Area **(037/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(5ZR-WTM-U6BB, 2025-12-11)
	Detail of Fee Submitted	313500, 2025-11-11,
	The proposed proprietary name / brand name	**Amphosom 50mg**
	Label Claim	Each Vial contains: Liposomal Amphotericin B ..... 50 mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1 vial in unit carton-Controlled
	Shelf Life (Unit)	24 Year(s)25C / 60 % RH
	For generic drugs (me-too Status)	Anfogen 50 mg M/s Ferozsons
	Pharmacotherapeutic Group of (API)	J02AA01 ANTIMYCOTICS FOR SYSTEMIC USE
	Name, address of Manufacturing site:	Donkook Pharmaceuticals Co., Ltd-No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	RLD (Ambisome) 042308AD, 006514D1, 005599D
	Name, address of Marketing Authorization Holder:	Amgomed Pharma, Office No. 4 First Floor, Ghausia Plaza, Jinnah Avenue, Blue Area, Islamabad, Pakistan 44000, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate issued by Daejeon Regional office of Food and Drug Safety valid upto 23.02.2028 is submitted.
	Details of Authorization Letter :	COPP and Letter of Authority is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2 - 8°C upto 36 months.
	The status in reference regulatory authorities	EMA, USFDA
	Evaluation Remarks	
	Priority as per decision of 211th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad.	
72	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore **(000228)**
	Application Form Dy. No / Tracking ID & date of submission	(GHA-W8B-69J6, 2025-11-10)
	Detail of Fee Submitted	37000.0, 1700 2025-07-21, 2025-09-16
	The proposed proprietary name / brand name	**Pazo 200mg**

	Label Claim	Each film-coated tablet contains: Pazopanib hydrochloride eq. to pazopanib.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10, 20, 30, 50, 60 and 100's packed in HDPE Bottle-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Votrient tablet 200mg by Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	L01EX03 Other protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-7156748488295 Clearance certificate mentioning 1.5kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Votrient 200mg (Glaxo Operations UK Limited.) B. No. 6D2B
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 36 months.
	The status in reference regulatory authorities	Votrient tablet 200mg by Novartis Pharmaceuticals UK Limited
	GMP status of the firm	GMP certificate valid till 05.07.2028 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 01.08.2025 is submitted wherein Tablet Section anticancer is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
73	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore **(000228)**
	Application Form Dy. No / Tracking ID & date of submission	(VDV-T37-2PLA, 2025-11-10)
	Detail of Fee Submitted	37000.0, 1700 2025-07-21, 2025-09-16
	The proposed proprietary name / brand name	**Pazo 400mg**
	Label Claim	Each film-coated tablet contains: Pazopanib hydrochloride eq. to pazopanib.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10, 20, 30, 50, 60 and 100's packed in HDPE Bottle-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Votrient tablet 400mg by Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	L01EX03 Other protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-7156748488295 Clearance certificate mentioning 1.5kg drug substance is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Votrient 400mg (Glaxo Operations UK Limited.) B. No. 8K5V
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 36 months.
	The status in reference regulatory authorities	Votrient tablet 400mg by Novartis Pharmaceuticals UK Limited
	GMP status of the firm	GMP certificate valid till 05.07.2028 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 01.08.2025 is submitted wherein Tablet Section anticancer is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
74	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(Y87-9PG-NTLS, 2025-10-01)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**TAGRO 80mg Tablet**
	Label Claim	Each Film coated Tablet Contains: Osimertinib Mesylate equivalent to Osimertinib 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3*10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Product Name:: Tagrisso 80mg, Registration No: 122400, Company Name: AstraZeneca Pharmaceuticals Pakistan Private Limit
	Pharmacotherapeutic Group of (API)	L01EB04 Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xierkangtai Pharmaceutical Co.,
	Detail of stability batches of drug product	03 Stability study batches(NPD/OSM/80-001, NPD/OSM/80-002, NPD/OSM/80-003) kept on stability studies at 07.10.2024 as per zone IV(a).
	Documents for the procurement of API with approval from DRAP (in case of Import)	For Product development API (B# 2022102501) 250 gm, purchase from Shandong Xierkangtai Pharmaceutical Co., Ltd. Form 6 # K-1512362085697 Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed on Pre formulation study trial having Batch# T-001 against Comparator Product Tagrix 80mg Tablet Batch# 2910194 (Marketed by Himmel Pharmaceuticals (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The Drug Substance Manufacturer has been conducted stability studies of 03 Batches(B#2019010601, 2019011001, 2019011401) as per Zone IV(a).
	The status in reference regulatory authorities	FDA Approved Tagrisso 80mg Tablet
	GMP status of the firm	GMP certificate# F.3-55/2020-Addle.Dir. (QA<-1)56 , Issue Date 03.07.2024, Valid till

		19.02.2027
	Evidence of approval of manufacturing facility	The Oncology Tablet section has been approved since June 13, 2017, under reference CLB M-253
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of Board	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
75	Case Category	New Molecule/Formulation (Dr. Farhad Ullah)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(PMB-58M-QP5B, 2025-10-14)
	Detail of Fee Submitted	75000.0, 2025-03-10,
	The proposed proprietary name / brand name	**ACNIVEL 1.2%/0.15%/3.1% Gel**
	Label Claim	Each gram contains: Clindamycin Phosphate .....12mg (Equivalent to 10mg clindamycin) Adapalene.....1.5mg Benzoyl Peroxide 31mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Don't store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-infectives for treatment of acne
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Bal Pharma Limited (Unit – II) ,Cambrex Karlskoga AB ,Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 75 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 01-04-2024 specifying 300gm Clindamycin Phosphate. Firm has also submitted copy of invoice and Fedex courier slip. Firm has submitted copy of form 6 issued dated 08-05-2024 specifying 0.1000kg Adapalene. Firm has also submitted copy of commercial invoice and courier slip. Firm has submitted copy of final clearance certificate issued dated 10-06-2024 specifying 01kg Benzoyl Peroxide Hydrous.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against CABTREO Gel by M/s Bausch Health, Canada Inc.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV

	The status in reference regulatory authorities	CABTREO (clindamycin phosphate, adapalene, and benzoyl peroxide) Topical Gel - USFDA Approved
	GMP status of the firm	Valid until 30.06.2027
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 13-10-2023 specifying Cream/Ointment/Gel (General) section.
	Evaluation Remarks	
	The application fulfills codal formalities	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
76	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(44H-A4P-86J5, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	**ASP 50mgTablet**
	Label Claim	Each Tablet contains Amisulpride.....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Aisul 50mg Tablet M/s Siam Pharmaceuticals Registration #106988
	Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
	Detail of stability batches of drug product	930 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 50mg Tablets)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Solian 50mg Tablets M/s Sanofi-Winthrop Industrie, United Kingdom (HPRA Approved)

	GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
	Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section
	Evaluation Remarks	
	The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
77	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(5T6-U9X-U5G4, 2024-04-24)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	**ASP 100mg Tablet**
	Label Claim	Each Tablet contains Amisulpride.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Aisul 100mg Tablet M/s Siam Pharmaceuticals Registration #105654
	Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
	Detail of stability batches of drug product	930 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 100mg Tablets)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Solian 100mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
	GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
	Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	

	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
78	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(622-LV4-MUWW, 2024-03-26)
	Detail of Fee Submitted	75000.0, 2024-02-27,
	The proposed proprietary name / brand name	**Evista 60mg tablet**
	Label Claim	Each Film Coated Tablet contains: Raloxifene Hydrochloride 60mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's,2x10's,2x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30 degree celcius
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Selective estrogen receptor modulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s.Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002. Gujarat, INDIA
	Detail of stability batches of drug product	Stability studies both accelerated and real time for three batches of drug product are submitted by firm as per conditions of zone IVA.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Form 6 with following statement: “we have released the shipment on Form-6 basis.”
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies both accelerated and real time for three batches of drug substance are submitted by firm as per conditions of zone IVA.
	The status in reference regulatory authorities	Raloxifene Hydorchloride 60mg tablet by M/s Aspire Pharma Ltd 4 Rotherbrook Court, Bedford Road,Pete
	GMP status of the firm	GMP certificate issued to the firm based on inspection carried out on 0.3.04.2023
	Evidence of approval of manufacturing facility	Tablet General Section mentioned on GMP certificate.
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected	

	On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
79	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(7SP-NHV-459J, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	**Empamet 5/1000mg XR Tablet**
	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Xenglu-Met 5mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Synjardy 5mg/1000mg XR tablet by M/s Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
80	Case Category	Routine (Dr. Farhad Ullah)

	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(GY4-242-X6BM, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	**Empamet 12.5mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)**
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....12.5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Empaa M XR(Empagliflozin + Metformin HCl) 12.5mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided for 3 batches long-term and accelerated as per Zone IV-a
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not complete report
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs
	The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 12.5mg/1000mg M/s BOEHR
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
81	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(J31-8S2-A29E, 2024-03-12)

	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	**Empamet 25mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)**
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....25mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Empaa M XR(Empagliflozin + Metformin HCl) 25mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated studies at Zone IV-a
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not the report
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs
	The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 25mg/1000mg M/s BOEHRIN
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
82	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(JXW-TZH-AS56, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	**Empamet 10/1000mg XR Tablet**

	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....10mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Xenglu-Met 10mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated at Zone IV-a
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but no report
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs
	The status in reference regulatory authorities	Synjardy 10mg/1000mg XR tablet by M/sBoehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
83	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(ZXH-H5B-XWSP, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	**ASP 200mg Tablet**
	Label Claim	Each Tablet contains: Amisulpride.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30

	For generic drugs (me-too Status)	Amiride200mg Tablet M/s Shrooq Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
	Detail of stability batches of drug product	930 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 200mg Tablets)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Solian 50mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
	GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
	Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section
	Evaluation Remarks	
	Deferred in 353rd meeting of RB. The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Wimits Pharma, Mr. Atta Ullah Malik (Director Technical) and Mr. Misbahul Islam (Product Development Manager) appeared before the Registration Board. It was admitted that the HPLC software was not 21 CFR compliant, therefore, the audit trail could not be verified by the panel. Furthermore, the remaining quantities of stability batches placed on stability studies were not available. In view of the above, the Registration Board decided to reject the application.	
84	Case Category	New License (Dr. Farhad Ullah)
	Name, address of Applicant.	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore **(000563)**
	Application Form Dy. No / Tracking ID & date of submission	(NBT-6S8-72SV, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-04-24,
	The proposed proprietary name / brand name	**Levocare 250 mg**
	Label Claim	Each film coated tablet contains:Levofloxacin Hemihydrate equivalent to Levofloxacin.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Effiflox 250mg Tablets, M/s SAMI Pharmaceuticals, Reg. No. 037709.
	Pharmacotherapeutic Group of (API)	Fluoroquinolones. ATC code J01MA12.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Limited.
	Detail of stability batches of drug product	03 batches having batch size of 1500 Tablets each.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased from City Pharma.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against the comparator product i.e. Effiflox Tablets 250mg, B. No: 003K, Mfg. 02-2023, Exp: 01-2025 manufactured by M/s Sami pharmaceuticals and both comparator and applied formulation have shown similar release in in all the three medium and values of F2 are in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted both real time and accelerated stability studies of the drug substance for 6 months and 48 months respectively as per Zone IV A.
	The status in reference regulatory authorities	Levofloxacin 250 mg & 500 mg film-coated tablets, MHRA approved.
	GMP status of the firm	Copy of GMP certificate No. 146/2023-DRAP (AD-8890970234) dated 28-08-2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. 1-19/99-Lic (Vol-II) dated 13-07-2023 Tablet (General) (Revised) section.
	Evaluation Remarks	
	Deferred in 350th meeting of RB for PSI. The firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Care Pharma, Mr. Shehzada Khurram Gul (QCM) and Ms. Misbah Mehmood (QA Manager) appeared before the Registration Board. They informed that the system Windows was corrupted and after reinstallation of the software, data recovery was incomplete and some data were lost. Manual integration of chromatograms was performed, which led to differences in peak area and retention time between the data submitted to DRAP and the data available with the firm. In view of the above and the observations of the panel inspection report, the Board decided to reject the application.	
85	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore **(000563)**
	Application Form Dy. No / Tracking ID & date of submission	(UDH-9XB-5YX6, 2024-07-19)
	Detail of Fee Submitted	30000.0, 2024-04-24,
	The proposed proprietary name / brand name	**Levocare 500 mg**
	Label Claim	Each film coated tablet contains: Levofloxacin Hemihydrate equivalent to Levofloxacin.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Effiflox 500mg Tablets, M/s SAMI Pharmaceuticals, Reg. No. 037710.
	Pharmacotherapeutic Group of (API)	Fluoroquinolones. ATC code J01MA12.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	03 batches having batch size of 1500 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased from City Pharma.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against the comparator product i.e. Leflox 500mg Tablets, batch No: F02068, Mfg.: 02-2023, Exp: 02- 2026 and both comparator and applied formulation have shown similar release in in all the three medium and values of F2 are in acceptable range.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted both real time and accelerated stability studies of the drug substance for 6 months and 48 months respectively as per Zone IV A.
	The status in reference regulatory authorities	Levofloxacin 250 mg & 500 mg film-coated tablets, MHRA approved.
	GMP status of the firm	Copy of GMP certificate No. 146/2023-DRAP (AD-8890970234) dated 28-08-2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. 1-19/99-Lic (Vol-II) dated 13-07-2023 Tablet (General) (Revised) section.
	Evaluation Remarks	
	Deferred in 350th meeting of RB for PSI. The firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected On behalf of M/s Care Pharma, Mr. Shehzada Khurram Gul (QCM) and Ms. Misbah Mehmood (QA Manager) appeared before the Registration Board. They informed that the system Windows was corrupted and after reinstallation of the software, data recovery was incomplete and some data were lost. Manual integration of chromatograms was performed, which led to differences in peak area and retention time between the data submitted to DRAP and the data available with the firm. In view of the above and the observations of the panel inspection report, the Board decided to reject the application.	
86	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(96G-R9M-WYGE, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	**Painzol Injection 30mg/ml**
	Label Claim	Each 1ml Ampule contains: Ketorolac Tromethamine.....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x 5Ampule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	TORADOL INJECTION 30MG/ML (MARTIN DOW)
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt. Ltd.

	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted loan letter by MedPharm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	TORADOL INJECTION 30MG/ML (ATNAHS PHARMA UK Ltd)
	GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)
	Evidence of approval of manufacturing facility	Drug Manufacturing Liscence attached (000884)
	Evaluation Remarks	
	Deferred in 351st meeting of RB for PSI. The firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected No representative of M/s Hi-Med Pharma appeared before the Registration Board to defend the case. The Board considering the panel inspection report that the submitted data could not be verified due to the unavailability of the HPLC system (Shimadzu LC-10AD) which was sent to the supplier for repair, decided to reject the application.	
87	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(DVG-8EL-9GVR, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-14,
	The proposed proprietary name / brand name	**Painzol Injection 10mg/ml**
	Label Claim	Each 1ml Ampoule contains: Ketorolac Tromethamine.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	Monak Injection 10mg/ml (English Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Satyadivis Pharmaceuticals Pvt. Ltd.
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan documents by Med Pharma Are submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	TORADOL INJECTION 10MG/ML (ATNAHS PHARMA UK Ltd)
	GMP status of the firm	GMP Certificate attached (Valid till 22-09-2027)

	Evidence of approval of manufacturing facility	Drug Manufacturing Liscence attached (000884)
	Evaluation Remarks	
	Deferred in 351st meeting of RB for PSI. The firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected No representative of M/s Hi-Med Pharma appeared before the Registration Board to defend the case. The Board considering the panel inspection report that the submitted data could not be verified due to the unavailability of the HPLC system (Shimadzu LC-10AD) which was sent to the supplier for repair, decided to reject the application.	
88	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(8BZ-JRN-6N2Y, 2024-07-14)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Genpru 2mg Tablet**
	Label Claim	Film coated Tablet containing: Prucalopride as Succinate.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10-As per SRO,20-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	P Pride tablet Wilshire Laboratories Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot No 527, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Motegrity ® TAKEDA PHARMS USA. Approved in USFDA.
	Detail of previous approval	PruMark 2mg Tablet in 340th meeting of RB
	Evaluation Remarks	
	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 340th meeting of the Registration Board and submitted module I, undertaking and extract of minutes.	
	Decision	
	Approved	
89	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(HES-US7-HDEJ, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	**Citojet Injection 1000mg/4ml**
	Label Claim	Each 4ml Contains: Citicoline Sodium.....1000mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	CITOLIN 1G INJECTION (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratries Ltd
	Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Citolin 1g Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	GEROLIN 1gm/4ml solution for injection AIFA approved
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
	Evaluation Remarks	
	Approved in 351st meeting of RB subject to product specific inspection. Certain observations were noted during the inspections and the firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected No representative of M/s Hi-Med Pharma appeared before the Registration Board to defend the case. The Board considering the panel inspection report that the submitted data could not be verified due to the unavailability of the HPLC system (Shimadzu LC-10AD) which was sent to the supplier for repair, decided to reject the application.	
90	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(V28-J6Z-AUWS, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	**Citojet Injection 500mg/4ml**
	Label Claim	Each 4ml Contain: Citicoline Sodium..... 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4ml x 10 Ampules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at below 25 degree celcius
	For generic drugs (me-too Status)	Cerecolin Injection 500mg/4ml (Pharmasol Pvt. Ltd.)

	Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratries Ltd
	Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Neurizer Injection 500mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	GEROLIN 500mg/4ml solution for injection AIFA approved
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
	Evaluation Remarks	
	Approved in 351st meeting of RB subject to product specific inspection. Certain observations were noted during the inspections and the firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected No representative of M/s Hi-Med Pharma appeared before the Registration Board to defend the case. The Board considering the panel inspection report that the submitted data could not be verified due to the unavailability of the HPLC system (Shimadzu LC-10AD) which was sent to the supplier for repair, decided to reject the application.	
91	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(WJQ-JWN-85T7, 2025-07-17)
	Detail of Fee Submitted	37000.0, 9400 2025-05-14, 2025-09-17
	The proposed proprietary name / brand name	**Citojet Injection 250mg/2ml**
	Label Claim	Each 2ml contains: Citicoline Sodium.....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius
	For generic drugs (me-too Status)	Citolin 250mg Injection 2ml (Global Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Psychostimulants and nootropics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Dhanuka Laboratories Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 800 ampoules each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan letter from M/s Wimits pharmaceuticals for procurement of API along with intimation of borrowing of API letter to PE&R division DRAP. Firm has also submitted copy of final clearance certificate issued dated 20-02-2025 specifying 25kg Citicoline sodium
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Citolin Injection 250mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	CIDILIN 250mg/2ml solution for injection AIFA approved
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional section dated 02-12-2024 specifying Liquid Injectable (Small Volume Parenteral) (General)-New.
	Evaluation Remarks	
	Approved in 351st meeting of RB subject to product specific inspection. Certain observations were noted during the inspections and the firm has been given an opportunity of Personal Hearing for observations noted during product specific inspection	
	Decision	
	Rejected No representative of M/s Hi-Med Pharma appeared before the Registration Board to defend the case. The Board considering the panel inspection report that the submitted data could not be verified due to the unavailability of the HPLC system (Shimadzu LC-10AD) which was sent to the supplier for repair, decided to reject the application.	
92	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(Y35-2VA-A7HQ, 2024-07-08)
	Detail of Fee Submitted	75000.0, 2024-05-22,
	The proposed proprietary name / brand name	**Actapen 250mg ER Tablet**
	Label Claim	Each film coated Extended release Tablet contains: Tapentadol HCl e.q. to Tapentadol 250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x10's, 2x7'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Nucynta ER 250mg Tablet (: M/s Collegium Pharmaceutical, Inc)
	Detail of previous approval	Tofradol 250mg ER Tablet approved in 347th RB meeting
	Evaluation Remarks	

	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 347th meeting of the Registration Board and submitted undertaking and extract of minutes. The application fulfills codal formalities	
	Decision	
	Approved	
93	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(QP8-E8G-EDY8, 2024-06-25)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Rozimibe Tablet**
	Label Claim	Each Film Coated Tablet contains: Rosuvastatin as Calcium Salt (USP).....5MG Ezetimibe (USP) .....10MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Rovista EZ 5mg+10mg Tablet by Getz pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	352nd meeting of RB (Rozimibe 5mg + 10mg Tablet)
	Evaluation Remarks	
	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 352nd meeting of the Registration Board and submitted undertaking, module I and extract of minutes. The application fulfills codal formalities	
	Decision	
	Approved • Approved with following label claim; Each Film Coated Bilayer Tablet contains: Rosuvastatin as Calcium Salt (USP)……5MG Ezetimibe (USP) ….....10MG • Firm shall submit applicable fee for revision of label claim.	
94	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(TSH-2PH-JYDZ, 2024-05-28)
	Detail of Fee Submitted	75000.0, 2024-01-11,

	The proposed proprietary name / brand name	**Tacrowin 0.03% Ointment**
	Label Claim	Each gm Contains: Tacrolimus (as Monohydrate).....0.3mg (0.03%w/w) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Aimus Ointment by Aims Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Approved in 353rd meeting of RB (Tacrowin Ointment 0.03%)
	Evaluation Remarks	
	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 353rd meeting of the Registration Board and submitted undertaking, module I and extract of minutes. The application fulfills codal formalities	
	Decision	
	Approved	
95	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(29R-VXN-56BD, 2025-10-07)
	Detail of Fee Submitted	38700, 2025-09-17,
	The proposed proprietary name / brand name	**Tadralis**
	Label Claim	Each film coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,4's-De-Controlled,5's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	Fildil 20mg tablet (Highnoon Labortories Ltd)
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: RD/PR25-060/T1S1,RD/PR25-060/T1S2,RD/PR25-060/T1S3 (Batch size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate# RO-0E259D dated 15-03-2025 for 1kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP applicable and attached performed against Fildil Tablet by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-11-2023.
	Evidence of approval of manufacturing facility	Tablet Section (General)is approved
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
96	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(M86-X2B-4QXL, 2025-10-10)
	Detail of Fee Submitted	38700, 2025-09-17,
	The proposed proprietary name / brand name	**Tadralis**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-De-Controlled,10's-De-Controlled,14's-De-Controlled,4's-De-Controlled,5's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	Fildil 5mg tablet (Highnoon Labortories Ltd)
	Pharmacotherapeutic Group of (API)	Tablet General Section is approved.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: RD/PR25-061/T1S1,RD/PR25-061/T1S2,RD/PR25-061/T1S3 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate# RO-0E259D dated 15-03-2025 for 1kg f material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been conducted against Fildil by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Cialis by Eli Lilly and Company Indianapolis, IN 46285, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-11-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
97	Case Category	Any Other (Farooq Aslam)

	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(N9T-R9A-ZUZH, 2025-10-07)
	Detail of Fee Submitted	38700, 2025-09-17,
	The proposed proprietary name / brand name	**Tadralis**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's -De-Controlled,20's-De-Controlled,4's-De-Controlled,5's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
	For generic drugs (me-too Status)	Fildil 5mg tablet (Highnoon Labortories Ltd)
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: RD/PR25-069/T1S1,RD/PR25-069/T1S2,RD/PR25-069/T1S3 (Batch size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate# RO-0E259D dated 15-03-2025 for 1kg f material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been conducted against Fildil by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-11-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
98	Case Category	Short Availability Drugs (Farooq Aslam)
	Name, address of Applicant.	**Nimrall Laboratories** Plot No. 24, Street SS-3, Rawat Industrial Estate, Rawat **(000611)**
	Application Form Dy. No / Tracking ID & date of submission	(BR1-9NB-EEMZ, 2025-07-18)
	Detail of Fee Submitted	75000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Rhythm 200mg Capsules**
	Label Claim	Each Capsule contains: Mexiletine HCl.....200mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	100's in HDPE bottle with secure cap-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	NDP
Pharmacotherapeutic Group of (API)	Anti Arrhythmic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Alembic Pharmaceuticals
Detail of stability batches of drug product	Module 3 (3.2.P.8.3), 2 batches of 7500 Capsules/Units each, as per DRAP Guidelines.
Documents for the procurement of API with approval from DRAP (in case of Import)	Attached module 3, from Alembic Pharmaceuticals, India.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Module 3 (3.2.P.2.2.1)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Module 3 (3.2S.7.3)
The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/in event=overview.process&ApplNo =074377
GMP status of the firm	GMP Certified. Valid Certificate issued by DRAP. 28-10-2025
Evidence of approval of manufacturing facility	DML 000611 Validity 21-03-2027

Evaluation Remarks

The applicant was asked to clarify: 1. Signed copy of Analytical method verification as per claimed specifications 2. Signed copy of Comparative Dissolution Profile Report along with relevant data including chromatograms. 3. Evidence of FTIR 4. The HPLC documents attached from page 171 to page 215 in Module 3 does not show any peak. Please clarify. 5. As per information provided by you on page 108 of submitted module 3, the stability batches of your product were manufactured in 02-2024 using API lot 2302027465 with the stability initiation date 02-2024, whereas the accelerated stability table on the same page shows stability time points date as 02-2022 for 0 months, 05-2023 for 03 months and 08-2024 for 06 months. Please justify how you have tested a batch before its manufacturing? 6. Also provide stability summary as per applicable CTD guidelines along with relevant data including chromatograms for testing on all time points. They have submitted response to the queries and for point 5 they have informed "this was a typo error", Remarks: Registration Board approved the product in its 351st meeting subject to Product Specific Inspection (PSI) for verification of submitted data by a panel constituted by the Chairman, Registration Board. The panel conducted the inspection and the conclusion is hereby reproduced below: Conclusion: The panel concluded not to recommend registration of Rhythm Capsule 200mg based on the following critical and major observations: The stability data(chromatograms) submitted in the dossier could not be verified at the time of inspection. HPLC was available but no batch processing record /audit trial was provided as the firm did not have the software to trace the audit trail. Firm stated that all data got deleted from the system. Only pdf files were available and the selected chromatograms showed same AUC further questioning the authenticity of the submitted data. The system was not CFR compliant. The date and time of the system could also be changed. FTIR data submitted with registration application was altered, as admitted by QC representative. With reference to submitted documents in registration application, retained samples of both stability batches C-303 and C-304 were not available. Two packs/HDPE bottles of the product (with export only registration) were kept on stability, which were already opened. HVAC was not operational at the time of inspection of the firm. Temperature and humidity data logger along with pressure gauges were not operational. In the capsule filling area, plastic tubs were placed. Capsule filling and bottle filling was done in the same area. No bottle blowing area was present. Epoxy flooring was absent, rust observed on cabinets, open electrical switches. Washing and wet granulation area was in the same room and washing was done with tap water having plastic pipe attached to it with fungal growth. An opened hole in the wall was seen in the washing area used for suction. Stability chambers were not maintained under proper conditions: real-time 29.4°C / 42% RH; accelerated 38.4°C / 34.8% RH; a separate data logger for accelerated condition routed through chamber door

	was attached. The GMP certificate of API manufacturer was not provided; stability data of API was not as per Zone IVa condition and impurities were also not quantified in DP. There were discrepancies in batch records, as the BMRs indicated the use of excipients, whereas the product development formulation did not include any excipients. Additionally, no potency adjustment of the API was performed. Submitted for consideration by the Board.	
	Decision	
	Rejected The firm was granted the opportunity of personal hearing for clarification of the observations highlighted by the panel nominated by the Chairman, Registration Board for conducting product specific in inspection (PSI) but no representative from the firm appeared before the Board. The Board considering the observation of the panel decided to reject the case.	
99	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(1XM-8NG-G7N8, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-07,
	The proposed proprietary name / brand name	**Thalido 100mg Capsule**
	Label Claim	Each Capsule contains: Thalidomide.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x6's, 2x6's, 2x7's, 1x10's, 2x10's, 4x7's, 3x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Thalido (Thalidomide USP) 100mg Capsule of M/s Atco Laboratories
	Pharmacotherapeutic Group of (API)	Thalidomide is in a class of medications called immunomodulatory agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Changzhou Pharmaceutical Factory Address: No.518 Laodong East Road. Changzhou Jiangsu Province, 213018 .P.R. China
	Detail of stability batches of drug product	Batches: TC001, TC002, TCoo3 (Batch Size: 1500 tablets) 06 months real time and 06 months accelerated stability studies according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter dated 13-09-2024 for 800grams material is submitted from from Medpharm Research Lab. Clearance certificate dated 22-03-2024 is submitted (Medpharm Research Lab)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP tudies have been performed against the comparator's product i.e. Thalido (Thalidomide USP) 100mg Capsule of M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH (06 months) & Real Time at Temp:30±2˚C, Humidity:65±5% RH (12 months)
	The status in reference regulatory authorities	Thalidomid Capsule 100mg of M/s Celgene Corporation ADDRESS:7 Powder Horn Drive Warren, New Jersey 07059 (USFDA Approved)
	GMP status of the firm	N/A

	Evidence of approval of manufacturing facility	New DML No. 000971 issued on 18-09-2023 Capsule General Section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Subject to verification of loan letter.	
100	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(5BZ-UWL-SS12, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-25,
	The proposed proprietary name / brand name	**ZOLDREN 5mg/100ml Infusion**
	Label Claim	Each 100ml contains Zoledronic Acid monohydrate as Zoledronic Acid 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Zoleron (Zoledronic Acid) 5mg/100ml Solution for I.V. Infusion of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Biophosphonate
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synnat Pharma Pvt. Ltd. Address: Plot No.60A, Jawaharlal Nehru Pharma City, Parawada mandal, Anakapalli District- 531019, Andhra Pradesh, India
	Detail of stability batches of drug product	Batches: AZ001, Az002, AZ003 (Batch size: 600 vials) 06 months accelerated and 09 months real time stability data according to the conditions of zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan letter dated 05-02-2024 from M/s Medisave Pharmaceuticals for 50grams material is submitted. Clarance certificate dated 18-03-2022 is submitted (M/s Medisave Pharmaceuticals)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Zoleron (Zoledronic Acid) 5mg/100ml Solution for I.V. Infusion of M/s Genix Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH (06 months) & Real Time at Temp:30±2˚C, Humidity:65±5% RH (60 months)
	The status in reference regulatory authorities	Zoledronic Acid Injection 5mg per 100ml (0.05mg per ml) of M/s M/s Sagent Pharmaceuticals lnc. Address Sagent Pharmaceuticals Schaumburg Pharmaceutical, IL 60195 (USA) Made in Switzerland (USFDA Approved)

	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023 Liquid vial section (General) SVP is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Subject to verification of loan letter.	
101	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(DXS-HL8-DX7X, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	**Tadalox 5mg Tablet**
	Label Claim	Tadalox tablet 5mg Each film coated tablet contains: Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-De-Controlled,14-De-Controlled,20-De-Controlled,28-De-Controlled,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Fildil 5mg Tablet
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: RND/Tab25-1/T003/S1,(2)RND/Tab25-1/T003/S2 (3)RND/Tab25-1/T003/S3 (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-03-2025 is submitted for 1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against the comparator's product i.e. Fildil tablet by M/s Highnoon submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of IV-A is submitted.
	The status in reference regulatory authorities	Cialis tablet 5mg [USFDA approved]
	GMP status of the firm	Valid GMP and attached
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977] GMP certificate dated 01-12-2025 is submitted.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
102	Case Category	Any Other (Farooq Aslam)

	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(SHL-EXR-38SS, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-17,
	The proposed proprietary name / brand name	**Sigra**
	Label Claim	Each ml of reconstituted oral suspension contains: Sildenafil Citrate eq to Sildenefil.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's x 112ml 1's x 56ml 1's x 224ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30°C
	For generic drugs (me-too Status)	Silagro 10mg/ml by nabiqasim
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic GMP-specific phosphodiesterase (Type V)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals Limited by Plot number 68/A,Jawaharlal Nehru Pharma City,Parawada andal,Anakapalli district, Andhra Pradesh,India. 3102
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size: 78 bottles) 06 months accelerated and 09 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 16-07-2024 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against Silagro powder for suspension by M/s NabiQasim Industries.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Revatio 10mg/ml by VIATRIS (FDA Approved)
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	Approval layout is available dated : 27-Oct-2023
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
103	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi **(000333)**
	Application Form Dy. No / Tracking ID & date of submission	(U7T-XG7-7XZ3, 2025-08-19)
	Detail of Fee Submitted	37000.0, 2025-07-24,
	The proposed proprietary name / brand name	**VITAK 2mg/ml Injection**
	Label Claim	Each 1ml ampoule contains: Phytonadione (vitamin K1).....2mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x1's-As per SRO
	Shelf Life (Unit)	2 Year(s)protect from light store below 25 and avoid freezing
	For generic drugs (me-too Status)	K-lot 2mg/mL injection by M/s GT Pharma (Pvt) Ltd.,
	Pharmacotherapeutic Group of (API)	Hemostatic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Wanhe Pharmaceuticals
	Detail of stability batches of drug product	Batches: 202NS02-202NS03-202NS04 (Batch Size: 1000 ampoules) 06 months real time and 06 months accelerated stability data according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 01.01.2025 is submitted for 0.04Kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. K-lot 2mg/mL injection by M/s GT Pharma (pvt) Ltd.,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 months real time stability study data of batch no. v21801, 24 months data for batch no. v22801 and 12 months data of batch no. v23701according to the conditions of zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 16-02-2024.
	Evidence of approval of manufacturing facility	Injectable Ampoule-II section (General) is approved.
	Evaluation Remarks	
	1. The firm was asked to provide import documents. In reply the firm has stated that the material was received free of cost therefore the clearance certificate can not be provided. 2. The applied strength i.e 2mg/1mL ampoule is registered in Health Canada but the status of the the product appears as "Cancelled Post Marketing""	
	Decision	
	Deferred For: 1. Verification of import documents for drug substance. 2. Confirmation of approval status of the applied product in reference regulatory authorities as defined by Registration Board in its 275th meeting.	
104	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**
	Application Form Dy. No / Tracking ID & date of submission	(9RZ-ZZZ-TGT3, 2025-04-11)
	Detail of Fee Submitted	75000.0, 2025-02-04,
	The proposed proprietary name / brand name	**FAMTROL MT**

	Label Claim	Each actuation of the inhaler containing 69.6mcg of suspension delivers: Mometasone Furoate...115mcg Formoterol Fumarate Dihydrate....5.5mcg Each deliverable dose from actuator: Mometasone Furoate...100mcg Formoterol Fumarate dihydrate....5mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 actuation x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 15°C to 30°C
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI PHARMALABS LIMITED,,VAMSI LABS LTD
	Detail of stability batches of drug product	Batches: 24Sb-349-01, 24Sb-351-02, 24Sb-350-03 (Batch size: 60 cannisters) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Mometasone Furoate: Form 6 dated 12-12-2023 is submitted for 25grams material. Formoterol fumarate dihydrate: Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.15kg material is submitted along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Dulera Inhalational Aerosol by M/s 3M Healthcare ltd., UK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mometasone Furoate: 06 months accelerated and 12 months real time stability data according to the conditions of zone IV-A. Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	DULERA® inhalationa erosol by 3M Health Care Ltd.,Lough borough,United Kingdom (USFDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evidence of approval of manufacturing facility	MDI (Meter Dose Inhaler) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
105	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**
	Application Form Dy. No / Tracking ID & date of submission	(ZTP-W39-67PA, 2025-04-09)

	Detail of Fee Submitted	75000.0, 2025-02-04,
	The proposed proprietary name / brand name	**FAMTROL-MT**
	Label Claim	Each actuation of the inhaler containing 69.6mcg of suspension delivers: Mometasone Furoate...225mcg Formoterol Fumarate Dihydrate....5.5mcg Each deliverable dose from actuator is: Mometasone Furoate...200mcg Formoterol Fumarate dihydrate....5mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 Actuation x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature between 15°C to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocke
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI PHARMALABS LIMITED,,VAMSI LABS LTD
	Detail of stability batches of drug product	Batches: 24Sb-356-01, 24Sb-357-02, 24Sb-358-03 (Batch size: 60 cannisters) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Mometasone Furoate: Form 6 dated 12-12-2023 is submitted for 25grams material. Formoterol fumarate dihydrate: Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.15kg material is submitted along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Dulera Inhalational Aerosol by M/s 3M Healthcare ltd., UK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mometasone Furoate: 06 months accelerated and 12 months real time stability data according to the conditions of zone IV-A. Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	DULERA®inhalation aerosol by 3M Health Care Ltd.,Loughborough,United Kingdom
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evidence of approval of manufacturing facility	MDI (Meter Dose Inhaler) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
106	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**

Application Form Dy. No / Tracking ID & date of submission	(46L-8VR-LZD8, 2025-04-11)
Detail of Fee Submitted	37000.0, 2025-02-25,
The proposed proprietary name / brand name	**Famtrol BG**
Label Claim	Each metered dose (the dose leaving the valve) contains: Beclometasone dipropionate.....100mcg Formoterol fumarate dihydrate.....6mcg Glycopyrronium as bromide.....10mcg Each delivered dose (the dose leaving the mouthpiece) contains: Beclometasone dipropionate.....87mcg Formoterol fumarate dihydrate.....5mcg Glycopyrronium as bromide.....9mcg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	120 actuations in 1 -As per SRO
Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2°C-8°C
For generic drugs (me-too Status)	TRIMBOW,Beclomethasone (Dipropionate) /Formoterol Fumarate Dihydrate/Glycopyrronium Bromide,Chiesi Pharmaceuticals (Pvt) Limited,105579
Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocker/anticholinergic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	AARTI PHARMALABS LIMITED,AVIK PHARMACEUTICAL LTD,MELODY HEALTHCARE PVT.LTD
Detail of stability batches of drug product	Batches: 24Sb-387-01, 24Sb-388-02, 24Sb-389-03 (Batch size: 200 cannisters) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.15kg Formoterol fumarate Dihydrate. Form 6 dated 12-02-2024 for 0.3kg Beclomethasone Dipropionate. Form 6 dated 23-04-2024 for 0.025kg Glycopyrronium Bromide. Clearance certificates have not been submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Trimbow by M/s Chiesi.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Beclomethasone dipropionate: 06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A submitted. Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Glycopyrronium Bormide: 06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
The status in reference regulatory authorities	MHRA Approved.
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-06-2023.
Evidence of approval of manufacturing facility	MDI (Meter Dose Inhaler) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.

	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
107	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(VUY-848-XZ5V, 2025-02-21)
	Detail of Fee Submitted	75000.0, 2025-02-17,
	The proposed proprietary name / brand name	**Tadafold 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil (USP).....10mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: T04, T05, T06 (Batch size: 600 tablet)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Wnsfield Pharmaceuticals for 100 grams material is submitted. GD No. IPAF-2473-2024 dated 13-06-2024 is submitted for 1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Cialis 10mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (60 months) Stability data according to zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision DRAP Authority regarding ED drugs. The firm was asked to submit shortcomings of the case. In reply the firm has referred the minutes of 351st meeting wherein 03 (5mg, 10mg, 20mg) cases of M/s Welmark Pharma were approved manufactured by M/s Weatherfolds.	
	Decision	
	Approved Subject to verification of loan letter.	
108	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**

	Application Form Dy. No / Tracking ID & date of submission	(X1N-5QT-MHTQ, 2025-02-21)
	Detail of Fee Submitted	75000.0, 2025-02-17,
	The proposed proprietary name / brand name	**Tadafold 20mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil (USP).....20mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	fildil 20mg Tablet Hingnoon Laboratories
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T007, T008, T009 (Batch size: 600 tablet)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Wnsfield Pharmaceuticals for 100 grams material is submitted. GD No. IPAF-2473-2024 dated 13-06-2024 is submitted for 1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Cialis 20mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (60 months) Stability data according to zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision DRAP Authority regarding ED drugs. The firm was asked to submit shortcomings of the case. In reply the firm has referred the minutes of 351st meeting wherein 03 (5mg, 10mg, 20mg) cases of M/s Welmark Pharma were approved manufactured by M/s Weatherfolds.	
	Decision	
	Approved Subject to verification of loan letter.	
109	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(ZS4-WW2-369J, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-01-15,
	The proposed proprietary name / brand name	**Tadalox 2.5mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Fildil 2.5mg Tablet

	Pharmacotherapeutic Group of (API)	Urologicals: Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: RND/Tab25-1/T012/S1,(2)RND/Tab25-1/T012/S2 (3)RND/Tab25-1/T012/S3 (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-03-2025 is submitted for 1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against the comparator's product i.e. Fildil tabet by M/s Highnoon submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of IV-A is submitted.
	The status in reference regulatory authorities	Cialis tablet 2.5mg [USFDA approved]
	GMP status of the firm	Valid GMP is attached
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977] GMP certificate dated 01-12-2025 is submitted.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of Authority. The application fulfills the codal formalities.	
	Decision	
	Approved	
110	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(R2Z-UAJ-ELY1, 2024-03-07)
	Detail of Fee Submitted	30000.0, 2023-10-10,
	The proposed proprietary name / brand name	**Pancap**
	Label Claim	Each enteric coated tablet contains: Pantoprazole as sodium sesquihydrate.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's 10's 14's 21's 2-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Zentro tablet Bosch pharma
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Pharmaceuticals
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice dated 15-10-2020 vide dy.no. 2843.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e Zentro by M/s Bosch.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Last inspection report for renewal of DML is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved	
111	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi **(000838)**
	Application Form Dy. No / Tracking ID & date of submission	(4ZJ-XJ2-NZMR, 2024-04-18)
	Detail of Fee Submitted	75000.0, 2024-02-02,
	The proposed proprietary name / brand name	**Voxeto 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vortioxetine as Hydrobromide..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Vorbo 10mg Tablet by Weather FOlds Pharma
	Pharmacotherapeutic Group of (API)	Serotonin Modulators/Anti-Depressants
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
	Name & address of API manufacturer	PORTON PHARMA LIMITED SOLUTIONS LTD.
	Detail of stability batches of drug product	Batches: T01, T02, T03 (Batch size: 1200 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice dy.No. 2198 12-10-2021 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Brintellix 10mg tablet by Lundbeck Limited, UK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability studies conducted under the conditions of zone IV-A for 03 batches.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Last inspection report dated 17-10-2023.
	Evidence of approval of manufacturing facility	Tablet General Section in approved (M/s Weather Folds)
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved	
112	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**

	Application Form Dy. No / Tracking ID & date of submission	(EL1-TXQ-6HZX, 2024-10-24)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-03, 2024-10-22
	The proposed proprietary name / brand name	**Flucion 0.01% Topical oil**
	Label Claim	Each ml contain:- Fluocinolone Acetonide 0.11mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Derma Smooth Topical Gel Registration Number: 068638
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tianjin Tianyao Pharmaceuticals Co., Ltd. Address: No.19 Xin Ye 9th street, West Area of Tianjin Economic-Technological
	Detail of stability batches of drug product	Batches: T01, T02, T03 (Batch size: 120 bottles*120mL) 06 months real time and 06 months accelerated stability data according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 03-10-2023 for 2kg material (M/s Valor Pharma)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's poduct Derma Smooth topical Gel by M/s Valor Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 72 months real time stability data s submitted, Data is not according to zone IV-A.
	The status in reference regulatory authorities	Derma-Smoothe/FS® , USFDA Approved.
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Lotion General Section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities. Loan verification.	
	Decision	
	Approved Subject to verification of loan letter.	
113	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**
	Application Form Dy. No / Tracking ID & date of submission	(2U4-NV7-5G55, 2024-11-20)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Salmihale DPI Capsule**
	Label Claim	Each dry powder inhaler capsule contains: Fluticasone Propionate.....100mcg Salmeterol as Xinafoate.....50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,10's,20's,14's,2-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Seretide Disku 100mcg/50mcg DPI Capsule by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI PHARMALABS LIMITED ,JAYCO CHEMICAL INDUSTRIES
	Detail of stability batches of drug product	Batches: 24Sb-284-01, 24Sb-285-02, 24Sb-286-03 (Batch size: 3000 DPI capsules) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.25kg Fluticasone propionate is submitted along with unattested invoice. Form 6 dated 23-01-2024 for 200grams Salmeterol xinofoate submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Advair Disks 100/50 by M/s GSK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Fluticasone propionate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Salmeterol Xinofoate: 06 months accelerated stability data of 03 batches 24 month real time stability data of 01 batch according to zone IV-A 36 months stability data of 02 batches according to zone IV-A.
	The status in reference regulatory authorities	ADVAIR DISKUS 100mcg/50mcg by Glaxo Smith Kline
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evidence of approval of manufacturing facility	DPI Capsule (steroid) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evaluation Remarks	
	Form 6 along with unattested invoices has been submitted. New Section.	
	Decision	
	Approved	
114	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**
	Application Form Dy. No / Tracking ID & date of submission	(991-GP2-EQZS, 2024-11-20)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Salmihale DPI Capsule**
	Label Claim	Each dry powder inhaler capsule contains: Fluticasone Propionate.....500mcg Salmeterol as Xinafoate.....50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from heat, light & Moisture

	For generic drugs (me-too Status)	Seretide Disku 500mcg/50mcg DPI Capsule by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JAYCO CHEMICAL INDUSTRIES,AARTI PHARMALABS LIMITED
	Detail of stability batches of drug product	Batches: 24Sb-290-01, 24Sb-291-02, 24Sb-292-03 (Batch size: 3000 DPI capsules) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.25kg Fluticasone propionate is submitted along with unattested invoice. Form 6 dated 23-01-2024 for 200grams Salmeterol xinofoate submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Advair Disks 500/50 by M/s GSK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Fluticasone propionate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Salmeterol Xinofoate: 06 months accelerated stability data of 03 batches 24 month real time stability data of 01 batch according to zone IV-A 36 months stability data of 02 batches according to zone IV-A.
	The status in reference regulatory authorities	ADVAIR DISKUS 500mcg/50mcg by Glaxo Smith Kline
	GMP status of the firm	.GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evidence of approval of manufacturing facility	DPI Capsule (steroid) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evaluation Remarks	
	Form 6 along with unattested invoices has been submitted. New Section.	
	Decision	
	Approved	
115	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)**
	Application Form Dy. No / Tracking ID & date of submission	(B4D-2NJ-TPGD, 2024-11-29)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Salmihale DPI Capsule**
	Label Claim	Each dry powder inhaler capsule contains: Fluticasone Propionate.....250mcg Salmeterol as Xinafoate.....50mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30°C Protect from heat,light and moisture
	For generic drugs (me-too Status)	Seretide Disku 250mcg/50mcg by Glaxo Smith Kline (GSK)

	Pharmacotherapeutic Group of (API)	Corticosteroid/long acting B2 blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI PHARMALABS LIMITED
	Detail of stability batches of drug product	Batches: 24Sb-287-01, 24Sb-288-02, 24Sb-289-03 (Batch size: 3000 DPI capsules) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 No. DIL-C-0313AD dated 17-04-2024 for 0.25kg Fluticasone propionate is submitted along with unattested invoice. Form 6 dated 23-01-2024 for 200grams Salmeterol xinofoate submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Advair Disks 250/50 by M/s GSK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Fluticasone propionate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Salmeterol Xinofoate: 06 months accelerated stability data of 03 batches 24 month real time stability data of 01 batch according to zone IV-A 36 months stability data of 02 batches according to zone IV-A.
	The status in reference regulatory authorities	ADVAIR DISKUS 250mcg/50mcg by Glaxo Smith Kline
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	DPI Capsule (steroid) New Section is approved on 27-12-2023. GMP certificate issued on the basis of inspection conducted on 06-06-2023.
	Evaluation Remarks	
	The firm has submitted form 6 and unattested invoices. New Section,	
	Decision	
	Approved	
116	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(EHY-3VZ-7MMZ, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-10-17,
	The proposed proprietary name / brand name	**Coprex Tablet 150mg**
	Label Claim	Each film-coated tablet contains: Cenobamate.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ±

		2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted pharmaceutical equivalence of the applied product against the product Ontozry by (AngeliniPharma , Itlay Rome.) Submitted CDP results against the product Ontozry by (AngeliniPharma , Itlay Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 755%RH ± 5% for 12 months.
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
117	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(HHS-B6X-6Q64, 2025-11-06)
	Detail of Fee Submitted	75000, 2025-09-04,
	The proposed proprietary name / brand name	**Coprex Tablet 50mg**
	Label Claim	Each film-coated tablet contains: Cenobamate.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited

	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months. (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP Studies have been submittedt against the product Ontozry by (AngeliniPharma , Itlay Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 755%RH ± 5% for 12 months.
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
118	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(LWU-WNX-15GU, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-10-17,
	The proposed proprietary name / brand name	**Coprex Tablet 200mg**
	Label Claim	Each film-coated tablet contains: Cenobamate.....200mg (Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months. (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP Studies have been submittedt against the product Ontozry by (AngeliniPharma , Itlay Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 755%RH ± 5% for 12 months.
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
119	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(PLA-7WL-E4EV, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-09-04,
	The proposed proprietary name / brand name	**Coprex Tablet Initiation Pack 12.5mg & 25mg**
	Label Claim	Each initiation pack contains 12.5mg and 25mg tablet. Each tablet contains: Cenobamate..... 12.5mg Each film-coated tablet contains: Cenobamate.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's & 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA

	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Submitted stability study data of 3 batches for each strength at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months. (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence for each strength is submitted against the product Ontozry by (AngeliniPharma , Itlay Rome.) CDP studies for each strength have been submitted against the product Ontozry by (AngeliniPharma , Itlay Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 755%RH ± 5% for 12 months.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
120	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(Q4Y-XN5-UX9J, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-10-17,
	The proposed proprietary name / brand name	**Coprex Tablet 100mg**
	Label Claim	Each film-coated tablet contains: Cenobamate.....100m
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	14's, 28's & 84's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below at 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-Epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited
	Detail of stability batches of drug product	Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 06 months. (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-02-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP Studies have been submittedt against the product Ontozry by (AngeliniPharma , Itlay Rome.)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of Cenobamate at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C + 755%RH ± 5% for 12 months.
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-05-2025.
	Evidence of approval of manufacturing facility	Tablet (General) section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
121	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Oncogen Pharma (Pvt) Limited** WH-26 & 27-A3 , Korangi Creek Industrial Park (KCIP) **(000960)**
	Application Form Dy. No / Tracking ID & date of submission	(VPP-SEW-3DWY, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-10-31,
	The proposed proprietary name / brand name	**Onkivia (Ribociclib) Tablet 200mg**

	Label Claim	Each film-coated tablet contains: Ribociclib as Succinate 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x21's (63's) Alu/PVDC-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Do not refrigerate or freeze. Protect from heat & light
	For generic drugs (me-too Status)	Kisqali (Ribociclib) Tablet 200mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cdymax (India) Pharma Private Limited, No. 116/117, KIADB Industrial Area, Jigani 2nd Phase, Banglore, Karnataka
	Detail of stability batches of drug product	Batches: 013NS06-200, 013NS07-200 & 013NS08-200 (Batch size: 1700 tablets) 06 months accelerated and 06 months real time stability data for 03 stability batches according to the conditions of zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 31-01-2025 for 4kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against Kisqali tablet 200mg by M/s Novartis Pharma (Pakistan) Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 18 months real time stability data of 03 batches accoridng to the conditions of zone IV-B
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Last GMP Inspection was carried on 07th December 2023 and found good
	Evidence of approval of manufacturing facility	Tablet (Oncology) section was approved on 04-07-2022 GMP certificate issued on the basis of inspection conducted on 07-12-2023.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved	
122	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(ML7-2QW-LPT6, 2025-05-13)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Omacyn 150mg Tablet**
	Label Claim	Each film coated tablet contains: Omadacycline as Tosylate.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antibiotic (derivative of tetracycline)
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	BrightGene Bio-Medical Technology Co., Ltd.
	Detail of stability batches of drug product	Batches: OMD-001, OMD-002, OMD-003 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 30-09-2024 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Nuzyra 150mg tablet by M/s Paratek Pharmaceuticals Inc. USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated stability data of 03 batches at 5±2oC. 36 months real time stability data of 03 batches at -20oC±5oC.
	The status in reference regulatory authorities	Registered drug by Registered drug by US FDA as NYZURA (Omadacycline tosylate 150mg Tablets), for ORAL Use.
	GMP status of the firm	Last inspection report for renewal of DML dated 08-08-2025 is submitted.
	Evidence of approval of manufacturing facility	Tablet section (General Antibiotic) is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
123	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(UAS-UQG-78H3, 2025-10-10)
	Detail of Fee Submitted	75000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Repatic eye drops**
	Label Claim	Each mL contains: Ripasudil (as Hydrochloride hydrate) . .....4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Rho-kinase inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Flax Laboraotires

	Detail of stability batches of drug product	03 batches manufactured each having 03 liters batch size (576 bottles)
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate dated 02-10-2024 specifies 100gm import of RIPASUDIL HYDROCHLORIDE HYDRATE
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Glanatec Eye Drops (Batch No: YS4R), Exp date: 10/2027) of Teika Pharmaceutical Co., Ltd. Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 lots of Ripasudil were subjected to storage conditions as per Zone IV-A
	The status in reference regulatory authorities	Glanatec Eye Drop Teika Pharmaceutical Co., Ltd. Shinjo Factory Origin: Japan
	GMP status of the firm	GMP Compliant ; certificate issued on the basis of inspection dated 15-06-2023 i.e. valid till 15-06-2025
	Evidence of approval of manufacturing facility	Letter for issuance of DML dated 09-09-2021 specifies Opthalmic & Nasal Drop Section section
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
124	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(QHV-EEV-BSZ5, 2025-02-21)
	Detail of Fee Submitted	75000.0, 2025-02-17,
	The proposed proprietary name / brand name	**Tadafold 5mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil (USP).....5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	fildil 5mg Tablet Hingnoon Laboratories
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size: 600 tablet)

	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Wnsfield Pharmaceuticals for 100 grams material is submitted. GD No. IPAF-2473-2024 dated 13-06-2024 is submitted for 1kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Cialis 5mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (60 months) Stability data according to zone IV-A for 03 batches is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority. Shortcomings of the case were communicated to the firm but instead of submission of reply, the firm has referred case No. (7DE-LQZ-AEDD, 2025-08-22) of contract manufacturing wherein the manufacturer is M/s Weatherfolds Pharmaceuticals.	
	Decision	
	Approved Subject to verification of loan letter.	
125	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)**
	Application Form Dy. No / Tracking ID & date of submission	(4UE-7TJ-P8L9, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2023-11-24,
	The proposed proprietary name / brand name	**DOIN 8mg/4ml Injection**
	Label Claim	Each 4ml Ampoule Contains: Ondansetron as HCl....8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4mlx1s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30 degree centigrade
	For generic drugs (me-too Status)	ONSET 8mg/4ml Injection(Pharmedic Laboratories (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	serotonin type 3 receptor antagonist
	Name, address of Manufacturing site:	GT Pharma (PVT.) Ltd.-713-Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	ANUGRAHA CHEMICALS, Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District-561203. INDIA
	Detail of stability batches of drug product	Batches: GSD003 (06months accelerated and 12 months real time), GSD004 (06months accelerated and 12 months real time), GSD005 (06 months accelerated and 06 months real time) Batch size: 30,000 ampoules)
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice dy.no. 13466/DRAP dated 08-09-2021.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Onset Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according of zone IV-A is submitted.
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 17-11-2023 (GT Pharma)
	Evidence of approval of manufacturing facility	Liquid Injectable (General) for ampoules and vials (SVP) section is approved.(GT Pharma)
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved	
126	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(BQX-G1Y-R3RW, 2024-10-08)
	Detail of Fee Submitted	75000.0, 9000.0 2024-08-12, 2025-05-07
	The proposed proprietary name / brand name	**Cenova Tablets 12.5mg**
	Label Claim	Each tablet contains: Cenobamate ... 12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 11,765 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 12.5mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 12.5mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule	
	Decision	

	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
127	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(AR3-QV4-J6YM, 2024-09-24)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	**Cenova Tablets 50mg**
	Label Claim	Each film-coated tablet contains: Cenobamate ... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect form sunlight and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 6,666 Tablets each 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 50mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 50mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule	
	Decision	
	Approved	

	Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
128	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(QRX-HP3-45UY, 2024-10-08)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	**Cenova Tablets 200mg**
	Label Claim	Each film-coated tablet contains: Cenobamate ... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 1,666 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 200mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 200mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026.	

	ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
129	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(LM9-3VX-7SEG, 2024-09-10)
	Detail of Fee Submitted	75000.0, 9000.0 2024-09-02, 2025-05-07
	The proposed proprietary name / brand name	**Cenova Tablets 100mg**
	Label Claim	Each film-coated tablet contains: Cenobamate ... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from sunlight and moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N03AX, Antiepileptics.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 3,333 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate from DRAP (I&E) Karachi for import of 4000grams API has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 200mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry 100mg Tablets, EMA approved.
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (23-01-2023) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	

130	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(14J-94Y-Y39S, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Linzee 200mg**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix ..... 200mg (AS PER INNOVATORS SPECS)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	MEDIZAN LABORATORIES (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	GANSU HAOTIAN PHARMACEUTICAL CO., LTD. Corporate Office Address: No. 11 Chongqing road, Baiyin district, Baiyin city, Gansu province, China Phone No.: (86-755)23284190 Mobile No.: NA Email: sales@tianpharm.com Website: NA
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-Pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	351 ,Linza 200mg
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
131	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Albro Pharmaceuticals** 340/s Quiad-e-Azam Industrial Estate Kotlakhpat Lahore **(000175)**
	Application Form Dy. No / Tracking ID & date of submission	(196-WQT-NSV2, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**Primoday-N 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at Temperature below 25°C. Protect from sunlight, heat and moisture.

	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet OBS Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Synthetic progestational hormone
	Name, address of Manufacturing site:	M/s, SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	Primolut N Tablet 5mg of M/s Bayer plc (MHRA Approved)
	Detail of previous approval	Just-N 5mg Tablet Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
132	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(1T5-9LJ-LNAR, 2026-02-23)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Nepixo-500mg/20mg Tablets**
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydreate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's, 30's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Glomov Tablets. Manufacturer: Global Pharmaceuticals Address: Humak Islamabad, Islamabad Capital Territory
	Pharmacotherapeutic Group of (API)	Nonsteroidal Anti-inflammatory Drug (NSAID) and Proton Pump Inhibitor.
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: Registered in UK Brand Name: Vimovo modified release tablets Manufacturer: AstraZeneca Pharmaceutical industry company Address: AstraZeneca PLC 1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA UK
	Detail of previous approval	M-343, SNP 500mg/20mg Tablet

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
133	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(2UY-X6U-NTPX, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**PARAGEN 10mg/ml Infusion**
	Label Claim	Each Vial contains: Paracetamol 10mg/ml solution for infusion
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Brand Name: Provas (10mg/ml) Registration holder: M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi. Registration Number: 050650
	Pharmacotherapeutic Group of (API)	Anti-Pyretic
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Actogen 100ml Vial , Minutes of 330th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
134	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(39D-YSG-BXJL, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,

	The proposed proprietary name / brand name	**MOMATE LOTION**
	Label Claim	Each gram contains: Mometasone Furoate..... 1 mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Manufacturer Name Maxitech Pharma Brand Name Momate lotion Registration Number: 83744
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	ELOCON 0.1% w/w lotion 20ml by USFDA Approved
	Detail of previous approval	Mometrol 0.1% Lotion Approved in 347th Minutes of Meeting of DRAP.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
135	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(3XW-968-Z6LT, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**SBT 200mcg Rota Capsule**
	Label Claim	Each Rotacapsule contains: Salbutamol as Sulphate.....200mcg (Product Complies BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	For generic drugs (me-too Status)	Breavent 200mcg capsule Highnoon Laboratories Reg. No. 044593
	Pharmacotherapeutic Group of (API)	β2 adrenergic agonist, bronchodilator
	Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD

	Detail of previous approval	SBT Rota capsule | Minutes of 336th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
136	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(436-N3M-43H3, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Luzowl 1% Cream**
	Label Claim	Each gm Cream Contains: Luliconazole..... 10 mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Lunaz Cream by Winbrains Research Lab
	Pharmacotherapeutic Group of (API)	Imidazole & Triazole Derivatives (AntifungalU
	Name, address of Manufacturing site:	winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Usfda Approved
	Detail of previous approval	DRB 331, Lunaz Cream
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
137	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(4ES-QJV-ZDPT, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-14,

	The proposed proprietary name / brand name	**DEXCURE**
	Label Claim	Each capsule contains: Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole .....60 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3*10's-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Razodex capsules 30mg, Getz Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	M/S Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	USFDA Approved. Dexilant 30mg delayed release capsules , Takeda Pharmaceutical USA; Inc
	Detail of previous approval	Exilo 60mg, M344, Registration No. 126390
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
138	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(4QD-WBX-GBA9, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**Bio-Meth 125mg Injection**
	Label Claim	Each vial contains:Methylprednisolone Sodium Succinate 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	SOLU-MEDROL® by PFIZER
	Pharmacotherapeutic Group of (API)	Corticosteroids (used to treat relieve swelling, redness, itching, and allergic reactions)
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	SOLU-MEDROL® USFDA Approved
	Detail of previous approval	BIO-MEDROL 125 mg INJECTION, Minutes of 345th meeting of Registration Board (19th – 21st February, 2
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
139	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(4U6-J4R-EJR5, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Skydol 500mg Tablet**
	Label Claim	Each tablet contains: Paracetamol (B.P)..... 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Panadol 500mg Tablet of M/s Pharmatec Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Paracetamol belongs to a class of drugs called NSAID's
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Paracetamol 500mg Caplets /Paracetamol 500mg Tablets of M/s Max Remedies Ltd William Nadin Way Swadlincote Derbyshire DE11 0BB (MHRA Approved)
	Detail of previous approval	Peradol 500mg Tablet approved in 336th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
140	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**

	Application Form Dy. No / Tracking ID & date of submission	(53Z-9M9-UX4N, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amoclavin Suspension 250/62.5**
	Label Claim	Each 5ml contains: Amoxicillin Trihydrate (BP) eq. Amoxicillin.....250mg Potassium Clavulanate (BP) eq. Clavulanic Acid.....62.5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1-As per SRO,30ml-As per SRO,60ml-As per SRO,90ml-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Zamoclav suspension, Zafa Pharmaceutical, Reg. No. 035386.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Falamox Dry Powder Suspension 250mg/5ml, Minutes of 336th meeting of Registration Board (4th to 6th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
141	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(5DM-TP5-LMW6, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amoxicillin DS Suspension 250mg/5ml**
	Label Claim	Each 5ml contains: Amoxicillin as Trihydrate 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Amoxil forte 250mg/5ml dry suspension, GSK Karachi, Reg. No. 006814
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Name, address of Manufacturing site:	Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA approved

	Detail of previous approval	FAXCIL 250 mg/5ml suspension, Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
142	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(5HA-STX-7M1R, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**FEMVIT D INJECTION**
	Label Claim	Each ampoule Contains: Cholecalciferol.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Novel-D Injection by Danas Pharma (Reg #073183)
	Pharmacotherapeutic Group of (API)	Vitamin D3
	Name, address of Manufacturing site:	M/s Biogen Pharmaceuticals-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Cholecalciferol Injection (ANSM France Approved)
	Detail of previous approval	M-323rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
143	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**

	Application Form Dy. No / Tracking ID & date of submission	(67H-72B-2DJM, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Budeform 400mcg/12mcg DPI Capsule**
	Label Claim	Each capsule contains: Budesonide.....400mcg Formoterol fumarate dihydrate.....12mcg Each delivered dose contains: Budesonide.....320mcg Formoterol fumarate dihydrate.....9mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-Controlled,20's-Controlled,30's-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Formiget DPI by Getz Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Inhaled corticosteroids (ICS) in combination with longacting beta-2 agonists.
	Name, address of Manufacturing site:	Horizon Healthcare (Pvt) Ltd.-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	Symbicort Turbohaler (EMA Approved)
	Detail of previous approval	Budenox 400mcg/12mcg DPI Capsule , Meeting No. 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
144	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(69G-NDQ-HTUX, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Norsiq 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Primolut-N Tablet of M/s OBS Pharma Pvt. LTd.
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins.

	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Primolut N Tablet 5mg of M/s Bayer plc, 400 South Oak Way, Reading, Berkshire, RG2 6AD (MHRA Approved)
	Detail of previous approval	Just-N 5mg Tablet - 347th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
145	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(6DQ-7YB-TBDX, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**EMPLIMENT-XR**
	Label Claim	Each Film-coated extended-release Tablet Contains: Empagliflozin.....12.5mg Linagliptin.....2.5mg (as immediate release coating) Metformin HCl.....1000mg (as extended release coating) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearKeep in cool and dry place.protect from heat,sunlight and moisture.Store at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	complies
	Name, address of Manufacturing site:	Horizon healthcare (Pvt)Ltd. Sundar-plot no 33 sundar industrial estate Lahore-
	The status in reference regulatory authorities	complies
	Detail of previous approval	320
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
146	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(6TP-PMY-4WAN, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-29,
	The proposed proprietary name / brand name	**Clobeda Lotion**
	Label Claim	Each gram contains: Clobetasol propionate...0.5mg (0.05% w/w) (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 degree celsius
	For generic drugs (me-too Status)	Brand Name: Clobederm lotion Registration Number: 024516M/s Atco Laboratories Limited
	Pharmacotherapeutic Group of (API)	Corticosteroids, very potent (group IV) (D07AD0)
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	Clobetasol Propionate 0.05% Lotion Abbreviated New Drug Application (ANDA): 078223 Company: ACTAVIS MID ATLANTIC USFDA Approved
	Detail of previous approval	CLOBELLE LOTION meeting no .347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
147	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(71V-VU5-TNP3, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Linzee 100mg**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	MEDIZAN LABORATORIES (PVT.) LTD.

	Pharmacotherapeutic Group of (API)	GANSU HAOTIAN PHARMACEUTICAL CO., LTD. Corporate Office Address: No. 11 Chongqing road, Baiyin district, Baiyin city, Gansu province, China Phone No.: (86-755)23284190 Mobile No.: NA Email: sales@tianpharm.com Website: NA
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-Pakistan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	351 ,Linza 100mg
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
148	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(7LN-SZE-UHN3, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**KETOWIN LOTION 2% W/V**
	Label Claim	Each ml contains: Ketoconazole.....20 mg (w/v) (British Pharmacopeia)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Cleanazol shampoo 20mg by M/s Caraway.
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	Ketoconazole shampoo 2% by M/s Cosette, USFDA Approved
	Detail of previous approval	KETOCONIZ 2% Lotion approved in 351st minutes of meeting in DRAP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(7Q6-D35-NRVY, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Racego 10mg Sachet**
	Label Claim	Each Sachet Contains; Racecadotril ..... 10mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 16's-As per SRO
	Shelf Life (Unit)	2 Year Avoid exposure to heat, light and humidity. Store between 15 to 30°C
	For generic drugs (me-too Status)	Racedo 10mg sachet (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	Antidiarrheals
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Hidrasec sachet (By SOPHARTEX France)
	Detail of previous approval	Cadotril 10mg Sachet, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(7WR-74P-47S9, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**TAPENO TABLET**
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -------75mg (Innovator's Specifiocations)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Tapento IR 75mg Tablet by M/S Sami Pakistan
	Pharmacotherapeutic Group of (API)	Opiod analgesic

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Palexia IR 75mg Tablet by M/S Grünenthal GmbH, Germany By USFDA Approved
	Detail of previous approval	Tydol 75mg IR Tablet Approved in 347th meeting of DRAP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
151	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(876-XRU-L9P3, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Rinon 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Finerenone is a Nonsteroidal Mineralocorticoid-Receptor Antagonist
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	KERENDIA(finerenone) 10mg tablet of M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany (USFDA Approved)
	Detail of previous approval	Finren 10mg Tablet - 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

152	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)**
	Application Form Dy. No / Tracking ID & date of submission	(87Q-4S2-Q4HM, 2026-02-03)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**TAZOCENT-EF Injection**
	Label Claim	Each vial contains: Piperacillin as sodium.....2g Tazobactam as sodium 0.25g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	24 MonthDo not store above 25°C. Keep the vial in the outer carton to protect from light
	For generic drugs (me-too Status)	Pipraben 2.25g injection Reg.No 113270
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Name, address of Manufacturing site:	M/S Global Pharmaceuticals (Pvt) Ltd-Plot No. 22-23, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	VFEND 200mg lyophilized powder for injection, New Drug Application (NDA): 021464 Company: PFIZER USFDA approved
	Detail of previous approval	Already approved Minutes of 316th meeting of Registration Board (15-18 March, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
153	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(8HH-956-MDTH, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Nurofen DS 200mg/5ml Suspension**
	Label Claim	Each 5ml contains: Ibuprofen.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Brufen DS 200mg/5ml Suspension of M/s Abbott Laboratories Pakistan Ltd.

	Pharmacotherapeutic Group of (API)	Ibuprofen exerts its anti-inflammatory and analgesic effects through inhibition of both COX isoforms. (Reference
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Ibuprofen 200mg/5ml Pinewood Laboratories Ltd Ballymacarbry Clonmel Co. Tipperary Ireland (HPRA Approved)Oral Suspension of M/s
	Detail of previous approval	Ibuprofen DS 200mg/5ml Suspension approved in 348th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
154	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Albro Pharmaceuticals** 340/s Quiad-e-Azam Industrial Estate Kotlakhpat Lahore **(000175)**
	Application Form Dy. No / Tracking ID & date of submission	(8VW-Z3D-2D79, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**Alboston 10mg Tablet**
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE 10 MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at Temperature below 30°C. Protect from sunlight, heat and moisture.
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet OBS Pakistan (Pvt) Ltd., C-14 Mangopir Road SITE Karachi. , Karachi.
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES.
	Name, address of Manufacturing site:	M/s, SKYWIN PHARMACEUTICALS-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	TABLET D-GEST 10 MG Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
155	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(8X8-LVM-YXJ5, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Afebril 500/25mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol.....500mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	PANADOL NIGHT TABLET of M/s Haleon Pakistan Limited, Petro road, Jamshoro
	Pharmacotherapeutic Group of (API)	Paracetamol (central analgesic effect that is mediated through activation of descending serotonergic pathways) Diphenhydramine Hydrochloride (Antihistamines)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	PANADOL PM, Acetaminophen and diphenhydramine hydrochloride Film coated tablet of M/s GSK consumer Healthcare (USFDA Approved)
	Detail of previous approval	Peradol-D 500/25mg Tablet - 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
156	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(958-PSX-M1XX, 2026-02-11)

	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Beelive 400mg/100ml Infusion**
	Label Claim	Each 100ml of solution contains: Ibuprofen ..... 400 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Ubrof 400 mg/100ml Infusion of M/s SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Ibuoprofen B. Braun Infusion of M/s B. Braun Melsungen AG HPRA Approved
	Detail of previous approval	Nurofen Solution for Infusion 400mg/100ml - 339th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
157	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(9JY-DV6-PU87, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Nurofen 800/26.6mg Tablet**
	Label Claim	Each Film Coated tablet contains: Ibuprofen.....800mg Famotidine.....26.6mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Ibuprofen (analgesic & anti-inflammatory drug), Famotidine(Histamine-2 receptor antagonists (H2RAs))
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	DUEXIS (ibuprofen and famotidine 800mg/26.6mg) tablet of M/s Horizon Pharma

		USA, Inc. Lake Forest, IL 60045 (USFDA Approved)
	Detail of previous approval	Ibuprofen/Famotidine 800mg/26.6 Tablet approved in 343rd Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
158	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(9XX-G2J-R1J4, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Sartan-A 5mg/160mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/ 160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*14's-As per SRO
	Shelf Life (Unit)	3 YearDo not store above 30°C
	For generic drugs (me-too Status)	Covam 5mg/160mg film-coated tablets (Novartis Pharma (Pakistan) Limited)
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs) and Angiotensin II receptor blockers (ARBs)
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Exforge® 5mg/ 160mg film-coated tablets (Novartis Pharmaceuticals UK Ltd)
	Detail of previous approval	Cardi-AV 5/160mg Tablet, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
159	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(9Y7-MW3-ME4B, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**ETX 90mg**
	Label Claim	Each Film Coated Tablet Contains; Etoricoxib.....90mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20'S, 30'S-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Starcox 90mg Tablets , Getz Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	: Anti-inflammatory & Anti-rheumatic
	Name, address of Manufacturing site:	M/S Solaris Life Sciences Pvt. Ltd.-Plot#08, Street# S1, RCCI, Industrial Estate Rawat-
	The status in reference regulatory authorities	Arcoxia 90mg Tablets ,MERCK SHARP & DOHME (UK) LIMITED
	Detail of previous approval	Etoroxib 90mg, M336, Registration No. 121750
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
160	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(A11-3RN-B14G, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	**Bempex**
	Label Claim	Each Film Coated Tablet Contains: Bempedoic Acid.....180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Metrochem API Pvt. Ltd. Bhanu Enclave, No 302, above Hero Showroom, Sundar Nagar, Erragadda, Hyderabad, Telangana 500038, India Tel:+91-40-23700421/23812317
	Name, address of Manufacturing site:	Horizon healthcare (Pvt)Ltd. Sundar-plot no 33 sundar industrial estate Lahore-
	The status in reference regulatory authorities	complies

	Detail of previous approval	322
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
161	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(ARU-DED-GTPW, 2026-02-23)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Nepixo-375mg/20mg Tablets**
	Label Claim	Each modified release tablet contains: Naproxen.....375mg (Enteric coated Core) Esomeprazole as Magnesium Trihydreate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, 28's, 30's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Glomov Tablets. Manufacturer: Global Pharmaceuticals Address: Humak Islamabad, Islamabad Capital Territory
	Pharmacotherapeutic Group of (API)	Nonsteroidal Anti-inflammatory Drug (NSAID) and Proton Pump Inhibitor.
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: Registered in UK Brand Name: Vimovo modified release tablets Manufacturer: AstraZeneca Pharmaceutical industry companyAddress: AstraZeneca PLC 1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA UK
	Detail of previous approval	M-343, SNP 375mg/20mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
162	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(AS1-B3Z-2H1A, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Etroxin 90mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Etoricoxib.....90mg (Manufacturer Spec's)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Centigrade
	For generic drugs (me-too Status)	Starcox 90mg Tablets (Getz Pharma (Pvt) Limited)
	Pharmacotherapeutic Group of (API)	Anti-inflammatory & Anti-rheumatic Products Non- Steroids.
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Arcoxia 90mg Tablet (MERCK SHARP & DOHME (UK) LIMITED)
	Detail of previous approval	Etoroxib 90mg tablets, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
163	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**KARSONS PHARMACEUTICALS** PLOT NO 1 STREET NO SS-3, NATIONAL INDUSTRIAL ZONE RAWAT **(000854)**
	Application Form Dy. No / Tracking ID & date of submission	(B1D-3RX-6PZL, 2026-02-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	**C-KOLIN 250MG/2ML Injection**
	Label Claim	Each Ampoule (2mL) Contains: Citicoline as Sodium Salt (USP).....250Mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C

	For generic drugs (me-too Status)	Coli wan Injection 250mg
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals,-PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	CITICOLINE PANPHARMA 250 mg/2 ml,
	Detail of previous approval	Zykolin Injection 250mg/2ml (M-347)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
164	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Himedic Pharmaceuticals Pvt Ltd** 19 KM link Multan Road Lahore **(000824)**
	Application Form Dy. No / Tracking ID & date of submission	(B72-QX3-HHWU, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	**Zoliget Dry Oral Suspension**
	Label Claim	Each 5ml reconstituted suspension contains: Linezolid 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	Barizold Dry powder suspension 100 mg/5 ml
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Shrooq Pharmaceuticals Pvt.Ltd-21-KM, Ferozepur Road, Lahore.-
	The status in reference regulatory authorities	Provided
	Detail of previous approval	Inzox Oral Dry Suspension, M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
165	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Semos Pharmaceuticals PVT LTD** Plot No.11, Sector 12-A North Karachi, Industrial Area,

		Karachi, Pakistan **(000335)**
	Application Form Dy. No / Tracking ID & date of submission	(BD3-RWL-L8MB, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Semfer Injection 500mg/10ml**
	Label Claim	Each 10ml contains: Iron as Ferric Carboxymaltose.....500mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml x 1's, 10ml x2's, 10ml x 3's, 10ml x 4's, 10ml x 5's and 10ml x 1-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Boferin Injection 500mg/10ml (Manufactured by: Bosch Pharmaceuticals Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	API Name: Ferric Carboxymaltose (Manufacturer name: Bright Gene Bio-Medical Technology Co., Ltd. China)
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-Plot No 208-C Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA Approved, Brand name: Ferinject Injection (Ferric Carboxymaltose)
	Detail of previous approval	Meeting No: Minutes of 352th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
166	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(BJB-VYP-A2UG, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Ampnex Capsules 500mg**
	Label Claim	Each Capsule Contains: Ampicillin as Trihydrate 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10-As per SRO,100-As per SRO,20-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Penbritin 500mg Capsule, GSK Pakistan, Reg. No. 000189

	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	MHRA approved
	Detail of previous approval	Ampiwell 500mg Capsule, Minutes of 343rd meeting of Registration Board (3rd-5th December, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
167	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(BTN-DYR-X7TD, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Clava-T 375mg Tablet**
	Label Claim	Each film coated tablet contains: Ammoxicillin trihydrate eq. to Amoxicillin.....250mg Potassium clavulanate eq. to Clavulanic acid....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmention 375mg Tablet of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Augmentin 375mg Tablet of M/s AUGMENTIN is a registered trademark of GlaxoSmithKline and is licensed to Dr. Reddy's Laboratories Inc, Distributed by: Dr. Reddy's Laboratories Inc. Bridgewater, NJ 08807
	Detail of previous approval	Amoxi 375mg Tablet - 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
168	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Health care pharmaceuticals** 40 km lahore Road multan **(000905)**
	Application Form Dy. No / Tracking ID & date of submission	(DHB-1T9-B2UG, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Keto 30mg/ml Injection**
	Label Claim	Each 1ml ampoule contains Ketorolac Tromethamine ..... 30mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	M/s Martin Dow Marker Ltd. Toradol 30mg /1ml Reg. NO.108584
	Pharmacotherapeutic Group of (API)	ANTI-INFLAMMATORY, NON-STEROID
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
169	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Health care pharmaceuticals** 40 km lahore Road multan **(000905)**
	Application Form Dy. No / Tracking ID & date of submission	(DS6-N4P-HMVQ, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**NBP Injection**
	Label Claim	Each ml contains Nalbuphine Hydrochloride ..... 10mg/ml (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Kinz inj . Reg No 018686 By Sami Pharmaceuticals (Pvt) Ltd.

	Pharmacotherapeutic Group of (API)	Opioid agonist-antagonist..
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Minutes of 326th meeting of Registration Board (14th to 16th March, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
170	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(E9P-96W-HALS, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**BETAWIN-G CREAM**
	Label Claim	Each gram contains: Betamethasone as dipropionate .....0.5mg (0.05% w/w) Gentamicin as Sulphate .....1mg (0.1% w/w) (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Brand Name: Gentanix-B Cream Company Nmae: Biogen Pharma Reg No.: 070201
	Pharmacotherapeutic Group of (API)	Betamethasone dipropionate (Corticosteroids) Gentamicin Sulphate (Antibiotic)
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM chekbeli Road Rawat Rawalpindi.-
	The status in reference regulatory authorities	Mibetin 1 mg/g + 0.5 mg/g Cream, MHRA approved. One gram of cream contains 1 mg gentamicin (as 1.67 mg gentamicin sulfate) and 0.5 mg betamethasone (as 0.64 mg betamethasone dipropionate).
	Detail of previous approval	Fusigen-G Cream. approved Minutes of 333rd meeting of Registration Board (19th To 20th December, 202
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
171	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(EHH-987-EP84, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**IndaGly Plus 150mcg+50mcg+160mcg DPI Capsule.**
	Label Claim	Each capsule contains: Indacaterol(as acetate).....150 mcg Glycopyrronium (as bromide) .....50 mcg Mometasone Furoate.....160 mcg Each delivered dose contains: Indacaterol(as acetate).....114 mcg Glycopyrronium (as bromide) .....46 mcg Mometasone Furoate.....136 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Glydale DPI capsule by Horizon Healthcare Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Indacaterol Acetate: Indacaterol is an inhaled long-acting beta-2 adrenergic agonist. Glycopyrronium Bromide: Glycopyrronium bromide is a medication of the muscarinic anticholinergic group. Mometasone Furoate: Mometasone furoate is a corticosteroid
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	EMA Approved detailed provided in Module 1 Section 1.5.9
	Detail of previous approval	Glydale DPI capsule, 339 DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
172	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(EM8-GZB-TEDM, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Paratom Duo Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....200mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg M/s SAMI Pharmaceuticals Pvt. Ltd. Registration # 108579
	Pharmacotherapeutic Group of (API)	Paracetamol (Analgesic and Antipyretics) Ibuprofen (Non-steroidal Anti-inflammatory Drug)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets M/S Reckitt Benckiser Healthcare International
	Detail of previous approval	Ibuprofen-P 500mg+200mg Tablet Approved in Minutes of 348th Meeting of DRAP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
173	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**FESTEL LABORATORIES** THOKAR NIAZ BAIG , MULTAN ROAD, LAHORE. **(000556)**
	Application Form Dy. No / Tracking ID & date of submission	(EWW-VTR-8DSB, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**MEROFEST 500mg INJECTION**
	Label Claim	Each Vial contains: Meropenem (as trihydrate) .....500mg (Blended with sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30c
	For generic drugs (me-too Status)	Cili-Penem Injection 500mg byM/s Ipram Pharma

	Pharmacotherapeutic Group of (API)	Data Already Approved in 307 MoM, Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Meronem IV 500mg Powder for solution for injection or infusion MHRA UK.
	Detail of previous approval	Ronem 500mg Injection in 307 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
174	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(GAW-REE-7R4X, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Timus 1mg Capsule**
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus.....1mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	Tacgraf 1mg Capsules (CCL Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Immunosupressants
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Tacrolimus Capsules 1mg, USP (Mylan Pharmaceuticals Inc)
	Detail of previous approval	Tacor Capsules 1mg, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
175	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(GQ3-G8S-D1R3, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Didiges 10mg Tablet**
	Label Claim	Each film coated tablet contains 10 mg of Dydrogesterone.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets of M/s Mylan IRE Healthcare Limited, Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	D-Gest 10mg Tablet - 336th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
176	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(GYZ-VX3-X154, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Aspadol 75mg IR Tablet**
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -------75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tapento IR 75mg Tablet of M/s SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Palexia IR 75mg Tablet of M/s Grünenthal GmBH, Germany (MHRA Approved)
	Detail of previous approval	Tydol 75mg IR Tablet approved in 347th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
177	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)**
	Application Form Dy. No / Tracking ID & date of submission	(H4B-6YS-53WY, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-20,
	The proposed proprietary name / brand name	**FASTAID MOUTHWASH**
	Label Claim	100ml of the solution contains: Active substance: 0.074% w/v diclofenac free acid
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-As per SRO,200ml-As per SRO,250ml-As per SRO,300ml-As per SRO
	Shelf Life (Unit)	2 YearStore in the original package below 30 °C
	For generic drugs (me-too Status)	Declodent Mouthwash, Kaizen Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs)
	Name, address of Manufacturing site:	Kaizen Pharmaceuticals (Pvt) Ltd.-E-127, E128, E129, North Western Industrial Zone, Bin-Qasim, Karachi, Pakistan-
	The status in reference regulatory authorities	Diclodent 0.74 mg/ml Mouthwash , Medicines and Healthcare Products Regulatory Agency (MHRA)
	Detail of previous approval	Declodent Mouthwash, 352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
178	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(HJ5-Q3A-JDHA, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**SVL**
	Label Claim	Each Film Coated Tablet Contains; Sevelamer HCL.....800mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3*10's-As per SRO
	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Renavel Tablets 800mg , Registration No: 075510,AMP Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti hyperphosphatemia
	Name, address of Manufacturing site:	M/S Solaris Life Sciences Pvt. Ltd.-Plot# 08, Street# S-1, RCCI Industrial Estate, Rawat-
	The status in reference regulatory authorities	Renagel 800mg Tablets, Genzyme Pharmaceuticals UK Ltd.
	Detail of previous approval	Sevelmer 800mg, M344, Registration No. 126392
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
179	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)**
	Application Form Dy. No / Tracking ID & date of submission	(HSV-8UP-RZGZ, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**MECOFER**
	Label Claim	Each 10ml Contains: IRON AS Ferric Carboxymaltose.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 X 1'S-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperature
	For generic drugs (me-too Status)	B

	Pharmacotherapeutic Group of (API)	IRON REPLACMENT PRODUCT
	Name, address of Manufacturing site:	HI-MED PHARMACEUTICALS-208-C SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	FERINJECT
	Detail of previous approval	FBM-500 INJECTION/10 ML (352 DRB)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
180	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(HTP-ZMN-PGVU, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**RUSO 20mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Rosuvastatin Calcium (equivalent to Rosuvastatin) ..... 20mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 25□C. Store in the original blister packaging in order to protect from light and moisture.
	For generic drugs (me-too Status)	Rovista 20mg Tablets (Getz Pharmaceuticals (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors (statins)
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Crestor 20mg Tablet (Astra Zeneca Pharmaceuticals)
	Detail of previous approval	Suvasta 20mg Tablets, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
181	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(J8D-7XG-NJ9Y, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Pipta 4.5gm Injection**
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) : 4.0 g Tazobactam (as Tazobactam Sodium) : 0.5 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tanzo 4.5gm Injection of M/s Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Zosyn Injection of M/s Wyeth Pharmaceuticals (USFDA Approved)
	Detail of previous approval	Tazopip 4.5gm Injection - 335th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
182	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)**
	Application Form Dy. No / Tracking ID & date of submission	(JG7-DGJ-5PLX, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Noren 5 mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO

	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Primolut N 5mg Tablet
	Pharmacotherapeutic Group of (API)	synthetic Progestational hormone
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 1, Al Badar Industrial Estate, Phase-II, Sheikhupura, Road, Lahore-
	The status in reference regulatory authorities	Primolut N Tablet 5mg
	Detail of previous approval	Just-N 5mg Tablet, M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
183	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(JQ9-U63-S172, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Sartan-A 10mg/160mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine).....10mg Valsartan.....160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*14's-As per SRO
	Shelf Life (Unit)	3 YearDo not store above 30°C.
	For generic drugs (me-too Status)	Exforge 10mg/160mg film coated tablets (Novartis Pharma (Pakistan) Limited)
	Pharmacotherapeutic Group of (API)	fixed-dose combination (FDC) antihypertensive agent
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Exforge® 10mg/ 160 mg film-coated tablets (by Novartis Pharmaceuticals UK Ltd.)
	Detail of previous approval	Cardi-AV 10/160mg Tablet, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
184	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(JVA-RNX-6T4N, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	**HYDROWIN INJECTION 100mg**
	Label Claim	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone..... 100 mg (USP Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Cortizone injection by Global pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	Cortizone injection by Global pharma
	Detail of previous approval	BIOCORT 100mg Injection Approved in 307th minutes of meeting in DRAP
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
185	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(L3U-3MW-E8GW, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**TYBRO 18MCG Rota Capsule**
	Label Claim	Each RotaCapsule contains: Tiotropium as Bromide Monohydrate.....18 Mcg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated:

		40°C ± 2°C / 75% ± 5%RH for 6 months
	For generic drugs (me-too Status)	Apollo-F Capsule Nexus Pharma Karachi. (Reg# 076149)
	Pharmacotherapeutic Group of (API)	Anticholinergic
	Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	Spiriva 18mcg inhalation powder MHRA approved
	Detail of previous approval	Tybro 18mcg Rota capsule | Minutes of 336th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
186	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(L71-E6N-51RV, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**BETAWIN LOTION 0.1%**
	Label Claim	Each ml of lotion Contains: Betamethasone as valerate.....0.1% w/v (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15°C to 25°C
	For generic drugs (me-too Status)	Betnovate lotion by GSK
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	ENVEE Drugs Pvt. Ltd. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujrat India. By USFDA Approved.
	Detail of previous approval	VALBE 60ml Lotion Approved in
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
187	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(L88-HM5-1E36, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	**osmogen sachet**
	Label Claim	Each sachet contains: Sodium chloride.....2.6g Potassium chloride.....1.5g Glucose anhydrous.....13.5g Trisodium citrate dihydrate.....2.9g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 20's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Weirsol Sachet Manufactured by: Werrick Pharma
	Pharmacotherapeutic Group of (API)	Oral Rehydrate Salt
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	WHIO approved
	Detail of previous approval	BIOTRAL Sachet, Minutes of 312th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
188	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(L9E-B4D-WRY2, 2026-02-13)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Clava-T 625mg Tablet**
	Label Claim	Each film coated tablet contains: Ammoxicillin trihydrate eq. to Amoxicillin.....500mg Potassium clavulanate eq. to Clavulanic acid....125mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmention 625mg Tablet of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Augmentin 625mg Tablet of M/s AUGMENTIN is a registered trademark of GlaxoSmithKline and is licensed to Dr. Reddy's Laboratories Inc, Distributed by: Dr. Reddy's Laboratories Inc. Bridgewater, NJ 08807
	Detail of previous approval	Amoxi 625mg Tablet - 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
189	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(LL9-8DJ-NVYU, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Fluvanta 200mcg+62.5mcg+25mcg DPI Capsule**
	Label Claim	Each capsule contains: Fluticasone furoate.....200 mcg Umeclidinium (as bromide) .....62.5 mcg Vilanterol (as trifenatate) .....25 mcg Each delivered dose contains: Fluticasone furoate.....184 mcg Umeclidinium (as bromide) .....55 mcg Vilanterol (as trifenatate) .....22 mcg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Tresorol 200mcg/62.5mcg/25mcg DPI CAPSULE.(Horizon Healthcare Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Fluticasone Furoate: Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD)

		depending on the product. Umeclidinium: Umeclidinium is a long-acting muscarinic antagonist. Vilanterol: Vilanterol is a selective long-acting β2-agonist.
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	USFDA Approved detailed provided in Module 1 Section 1.5.9
	Detail of previous approval	Tresorol 200mcg/62.5mcg/25mcg, 336 DRB Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
190	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(LPP-G6U-3L4Z, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Fero-C 500mg/10ml Injection**
	Label Claim	Each ml contains: Ferric carboxymaltose Equivalent to Elemental Iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection of M/s Pharmasol Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Ferric carboxymaltose injection is in a class of medications called iron replacement products. It works by replenishing iron stores so that the body can make more red blood cells.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	Name & address of API manufacturer	Nanjing Hancer Pharmaceutical Co.,Ltd. Address: No. 18, Jichang Road, Lishui Economic & TechnologicalTechnological Development Zone, Jiangsu, China
	Detail of stability batches of drug product	Refer to product approved in 347th Meeting of DRB
	Documents for the procurement of API with approval from DRAP (in case of Import)	Refer to product approved in 347th Meeting of DRB

	Pharmaceutical Equivalence and Comparative Dissolution Profile	IZER (Ferric carboxymaltose) 500mg/10ml Injection of M/s Pharmasol Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the stability studies on Zone-IVa.
	The status in reference regulatory authorities	Ferinject 50mg/ml Injection of M/s Vifor Pharma (MHRA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	See attached DML of Manufacturer No. 000971
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
191	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(M2Q-EAH-2BPA, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Estra Plus 2mg/0.5mg Tablet**
	Label Claim	Each of the 11 white tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown tablets contains: Estradiol Valerate.....2mg Norgestrel.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet of M/s Bayer Pakistan (Pvt.) Limited, Plot No. 23, Sector No. 22, Korangi industrial Area, 74900, Karachi-Pakistan.
	Pharmacotherapeutic Group of (API)	Estradiol is in a class of medications called estrogen hormones. It works by replacing estrogen that is normally produced by the body. Norgestrel is a progestin, or a synthetic progestogen, and hence is an agonist of the progesterone receptor, the biological target of progestogens like progesterone.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Bayer Weimar GmbH und Co. KG, Weimar, Germany. (National Drug Registry of the Ministry of Health)
	Detail of previous approval	Estragest 2/0.5mg Tablet - 347th Meeting

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
192	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(NL9-8YV-32ZY, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**PEPSER INSTA20mg+1680mg Sachet**
	Label Claim	Each Sachet contains: Omeprazole .....20mg Sodium bicarbonate .....1680mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Risec Insta Manufacturer: Getz Pharma Address: 29-30/27, Korangi Industrial Area, Karachi 74900, Pakistan. 29-30/27, Korangi Industrial Area, Karachi
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors (PPIs),Alkalinizing agents
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	SRA Registration Status: Registered in USA. Brand Name: Zegerid 20mg/1680mg sachet Manufacturer: Salix Pharmaceuticals Address:400 Somerset Corporate Blvd. Bridgewater, NJ 08807 USA
	Detail of previous approval	M-344, omesol plus 20mg/1680mg sachet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
193	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(NPG-ZPN-1MYP, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Naproflex 500/20mg Tablet**
	Label Claim	Each Modified release tablet contains: Naproxen.....500mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg(Immediate released coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Glomov 500mg/20mg Tablet of M/s Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Naproxen belongs to a class of drugs NSAIDS. Esomeprazole belongs to a class of drugs Proton Pump Inhibitor.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Vimovo 500/20mg modified-release tablet of M/s Grunenthal Ltd (USFDA Approved)
	Detail of previous approval	Napsom 20/500mg Tablet approved in 331st Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
194	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(PB1-8YJ-GA3D, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Clava 1.2gm Injection**
	Label Claim	Each vial contains: Ammoxicillin Sodium eq. to Amoxicillin.....1000mg Potassium clavulanate eq. to Clavulanic acid....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Calamox 1.2gm Injection of M/s Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Co-amoxiclav 1000 mg/200 mg powder for solution for injection/infusion of M/s Instituto Biochimico Italiano G. Lorenzini S.p.A. Via Fossignano, 2 Italy, (HPRA Approved)
	Detail of previous approval	Amoxi 1.2gm Injection - 349th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
195	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(PL7-XQB-S9GZ, 2026-02-13)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Solofer Capsules 30mg**
	Label Claim	Each capsule contains: Iron (as Ferric Maltol).....30mg (Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year25° C
	For generic drugs (me-too Status)	Me To Registration Status: Registered in Pakistan Brand Name: Ferric Maltol 20mg Capsule Manufacturer: AGP Limited Adress: Plot no,F/46 ,S.I.T.E-II,Phase-II, Super Highway, Karachi, Pakistan . Refe
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Iron Supplement WHO ATC Code: B03AB10
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: USFDA Approved. Brand Name: Accrufer 30 mg Capsules New Drug Application (NDA): 212320 Manufacturer: Shield Tx. Adress: 9901 Broadway St, Ste 113, San Antonio, Texas 78217

		https://www.accessdata.fda.gov/scripts/cder/daf/index.event=BasicSearch.process
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
196	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**KARSONS PHARMACEUTICALS** PLOT NO 1 STREET NO SS-3, NATIONAL INDUSTRIAL ZONE RAWAT **(000854)**
	Application Form Dy. No / Tracking ID & date of submission	(PX5-M6Q-11MP, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	**ROZIMIBE 5mg + 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Rosuvastatin as Calcium Salt (USP).....5MG Ezetimibe (USP) 10MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Rovista EZ 5mg+10mg Tablet
	Pharmacotherapeutic Group of (API)	Anti-Hyperlipidimic
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals,-PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	ROSZET TABLET
	Detail of previous approval	Reebo-Ez Tablet 5mg+10mg (352)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
197	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**

	Application Form Dy. No / Tracking ID & date of submission	(QDE-3M3-SLBV, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**EMPLIMENT-XR**
	Label Claim	Each Film-coated extended-release Tablet Contains: Empagliflozin.....10mg Linagliptin.....5mg (AS IMMEDIATE RELEASE COATING) Metformin HCl.....1000mg (AS EXTENDED RELEASE CORE) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearKeep in cool and dry place.protect from heat,sunlight and moisture.Store at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD. No, 15 Shuangfeng Road, Fotang, Yiwu, Zhejiang..AND AARTI DRUGS LIMITED Mahendra Industrial Estate, Ground floor plot no. 109-D, Road No. 29, Sion (East),BAKUL PHARMA PRIVATE LIMITED Plot 6202, GIDC Estate, Ankleshwar- 393002, Gujarat, India., China. E-mail: zhp@zhp.com.cn
	Name, address of Manufacturing site:	Horizon healthcare (Pvt)Ltd. Sundar-plot no 33 sundar industrial estate Lahore-
	The status in reference regulatory authorities	complies
	Detail of previous approval	320M
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
198	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(QGJ-6M2-UMQX, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	**C-KOLIN 1000mg/4ml Injection**
	Label Claim	Each Ampoule (4ML) Contains: Citicoline as Sodium Salt (USP).....1000mg (Product complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Brand Name of Approved Medicines NEUROTEC INJECTION Manufacturer SCHAZOO LABORATORIES Strength 1000mg/4ml Composition Each 4ML contains:- Citicoline……..1000mg Registration Number 045995
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	M/S Wnsfeild Pharmaceuticals, -Plot No. 122, Block - A, Phase - V, Industrial Estate, Hattar, KPK, Pakistan-
	The status in reference regulatory authorities	agenceprd. ansm.sante.fr/php/ecodex/frames.php?specid=63283120&typedoc=N&ref=N0198593.ht
	Detail of previous approval	C-Kolin 250mg/2ml Injection | Minutes of 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
199	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**KARSONS PHARMACEUTICALS** PLOT NO 1 STREET NO SS-3, NATIONAL INDUSTRIAL ZONE RAWAT **(000854)**
	Application Form Dy. No / Tracking ID & date of submission	(QPV-9X7-4VM9, 2026-02-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	**C-KOLIN 1000mg/4ml Injection**
	Label Claim	Each Ampoule (4ml) Contains: Citicoline as Sodium Salt (USP).....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Neurotec 1000mg/4ml injection
	Pharmacotherapeutic Group of (API)	Anti-Parkinson
	Name, address of Manufacturing site:	WNSFEILD Pharmaceuticals,-PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN-
	The status in reference regulatory authorities	Somazina 1000mg/4ml Injection
	Detail of previous approval	Zykolin Injection 1000mg/4ml (M-343)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
200	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(QU2-L82-4VGH, 2026-02-13)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Sepol 10mg/ml Infusion**
	Label Claim	Each Vial contains: Paracetamol 10mg/ml solution for infusion
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Provas (10mg/ml) by Sami Pharma
	Pharmacotherapeutic Group of (API)	Anti-pyretic
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	Actogen, Meeting No. 330th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
201	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**FESTEL LABORATORIES** THOKAR NIAZ BAIG , MULTAN ROAD, LAHORE. **(000556)**
	Application Form Dy. No / Tracking ID & date of submission	(QVL-U9Q-5S62, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**MEROFEST 1g INJECTION**
	Label Claim	Each Vial contains: Meropenem (as trihydrate) .....1g (Blended with sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30c
	For generic drugs (me-too Status)	Cili-Penem Injection 1g byM/s Ipram Pharma
	Pharmacotherapeutic Group of (API)	Data Already Approved in 307 MoM, Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Meronem IV 1g Powder for solution for injection or infusion MHRA UK.
	Detail of previous approval	Ronem 1g Injection in 307 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
202	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(R8R-R3L-7BMV, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Fluvanta 100mcg+62.5mcg+25mcg DPI Capsule**
	Label Claim	Each capsule contains: Fluticasone furoate.....100 mcg Umeclidinium (as bromide) .....62.5 mcg Vilanterol (as trifenatate) .....25 mcg Each delivered dose contains: Fluticasone furoate.....92 mcg Umeclidinium (as bromide) .....55 mcg Vilanterol (as trifenatate) .....22 mcg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Tresorol 100mcg/62.5mcg/25mcg by Horizon Healthcare Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Fluticasone Furoate: Fluticasone furoate is an inhaled corticosteroid that can be used as maintenance treatment of asthma and/or chronic obstructive pulmonary disease (COPD) depending on the product. Umeclidinium: Umeclidinium is a long-acting muscarinic

		antagonist. Vilanterol: Vilanterol is a selective long-acting β2-agonist.
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	USFDA Approved detailed provided in Module 1 Section 1.5.9
	Detail of previous approval	Tresorol 100mcg/62.5mcg/25mcg, 336 DRB Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
203	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**linear pharma** plot # 18 street # s-4 national industrial zone (rcci) rawat islamabad **(000670)**
	Application Form Dy. No / Tracking ID & date of submission	(RBE-6NP-SZVJ, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-10-29,
	The proposed proprietary name / brand name	**GLOW-ON INJECTION 600MG INJECTION**
	Label Claim	Each Vial Contains : Glutathion as Sodium (Lyophillized Powder) .....600mg As per Innovator specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 10's ,20'S . 50'S, 100'S-As per SRO
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	347TH DRB meeting Siti-Gluta 600mg injection
	Pharmacotherapeutic Group of (API)	DIETRY SUPPLEMENT ANTIOXIDANT
	Name, address of Manufacturing site:	BIO-LABS PVT LTD ISLAMABAD-Plot No 145 Industrial Triangle Kahuta road Islamabad-2500,Pakistan-
	The status in reference regulatory authorities	BIOMEDICA FOSCAMA INDUSTRIA ,ITALY
	Detail of previous approval	Siti-Gluta 600mg Inj ection by MS Biolabs Pvt Ltd 347TH DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
204	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(RGX-QMR-VWZ2, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Cefrasky 500mg Capsule**
	Label Claim	Each Capsule contains: Cephradine.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Velosef 500mg Capsule of M/s GSK
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	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)
	Detail of previous approval	Ceframit 500mg Capsule approved in 344th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
205	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(RXT-5VD-4VZ2, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-27,
	The proposed proprietary name / brand name	**Mimate lotion 0.1%**
	Label Claim	Each gram contains: Mometasone Furoate..... 1 mg (USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 degree
	For generic drugs (me-too Status)	Maxitech Pharma MIMATE lotion Registration Number: 83744

	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	ELOCON 0.1% w/w lotion 20ml Manufacturer Name: Merck & Co. Inc White house station, NJ 08889, FDA Approved
	Detail of previous approval	Mometrol 0.1% Lotion meeting 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
206	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(S81-7NU-23JP, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Rinon 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Finerenone is a Nonsteroidal Mineralocorticoid-Receptor Antagonist
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	KERENDIA(finerenone) 20mg tablet of M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany (USFDA Approved)
	Detail of previous approval	Finren 20mg Tablet - 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
207	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)**
	Application Form Dy. No / Tracking ID & date of submission	(SGS-5PU-DAD4, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-04,
	The proposed proprietary name / brand name	**RELXO INJECTION**
	Label Claim	EACH 2 ML CONTAINS: THIOCOLCHICOSIDE .....4 MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ML X 5'S-As per SRO
	Shelf Life (Unit)	2 Yearstore at BELOW 25 C
	For generic drugs (me-too Status)	THIOLAX INJECTION
	Pharmacotherapeutic Group of (API)	NERVOUS SYSTEM MUSCLE RELAXANT
	Name, address of Manufacturing site:	HI-MED PHARMACEUTICALS-208-C SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	RELIEF 4 MG/2 ML INJECTION (IASIS PHARMA HELLAS S.A (137 FILIS AVE,134 51 ATHENS, GREECE)
	Detail of previous approval	THC 4MG/2ML INJECTION 351 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
208	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(SJ2-D93-SV3Q, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**Esoson 20mg Capsule**
	Label Claim	Each capsule contains: - Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole .....20mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-De-Controlled,1x10's-De-Controlled,2x7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade
	For generic drugs (me-too Status)	Nexum capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 033890

	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd.-Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura. -
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Eso-Rose 20mg Capsule, 326th meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
209	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**ANEEB PHARMACEUTICAL PVT LIMITED** 24 KM BEDIAN ROAD LAHORE **(000555)**
	Application Form Dy. No / Tracking ID & date of submission	(SRD-PJ6-E3E2, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-20,
	The proposed proprietary name / brand name	**Amoclavin Suspension 125mg/5ml**
	Label Claim	Each 5ml contains: Amoxicillin Trihydrate (BP) eq. Amoxicillin.....125mg Potassium Clavulanate (BP) eq. Clavulanic Acid.....31.25mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1-As per SRO,30ml-As per SRO,60ml-As per SRO,90ml-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30 oC
	For generic drugs (me-too Status)	Augmentin 125 mg/31.25mg, GSK Pakistan, Reg. No. 009264.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin
	Name, address of Manufacturing site:	M/s. Fynk Pharmaceuticals-19-km G.T.Road, kala Shah Kaku, Lahore, Pakistan-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Falamox Dry Powder Suspension 125mg/5ml, Minutes of 336th meeting of Registration Board (4th to 6th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
210	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(STL-WM4-VH6Q, 2026-02-11)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Pentadol IR 75mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -------75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tapento IR 75mg Tablet of M/s SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Palexia IR 75mg Tablet of M/s Grünenthal GmbH, Germany (MHRA Approved).
	Detail of previous approval	Tydol 75mg IR Tablet approved in 347th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
211	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(TB5-7Z4-GJED, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Revevent Inhalation Solution 175mcg/3ml**
	Label Claim	Each single 3 ml unit-dose vial contains: Revefenacin.....175 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,30's-De-Controlled,5's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C in a dry place away from direct heat or sunlight.

	For generic drugs (me-too Status)	Refcin Inhalation Solution 175mcg/3ml by M/s Horizon Healthcare (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Anticholinergic agent used to treat COPD
	Name, address of Manufacturing site:	Horizon Healthcare (Pvt) Ltd.-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	YUPELRI Inhalation solution (USFDA Approved)
	Detail of previous approval	Refcin Inhalation Solution 175mcg/3ml, Meeting No. 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
212	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**HONIG PHARMACEUTICALS LABORATORIES** Rawalpindi **(000550)**
	Application Form Dy. No / Tracking ID & date of submission	(TW8-SJ4-SX38, 2026-02-10)
	Detail of Fee Submitted	97200, 2026-01-29,
	The proposed proprietary name / brand name	**HONEM 1g Injection**
	Label Claim	Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	MOPEN M/s Hilton Pharma 036427
	Pharmacotherapeutic Group of (API)	Carbapenem antibacterial
	Name, address of Manufacturing site:	Dew-max Pharmaceuticals (Pvt) Ltd.-Plot No. 6 Street SS-4 Main Industrial area Rawat, Islamabad-
	The status in reference regulatory authorities	Approved in FDA
	Detail of previous approval	M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

213	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(TZH-18L-BWM5, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**CLOBEDIN LOTION 0.05%W/W**
	Label Claim	Each gram contains: Clobetasol propionate.....0.5mg (0.05% w/w) (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Manufacturer Name Atco Laboratories Limited Brand Name Clobederm lotion Registration Number: 024516
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	Brand Name: CLOBEX lotion 60ml Manufacturer Name: DPT Laboratories, Ltd. San Antonio, Texas 78215 USA GALDERMA is a registered trademark FDA Approved
	Detail of previous approval	Clobetasol Lotion 0.05 % w/w
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
214	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(UJ9-S5Z-Z9LS, 2026-02-12)
	Detail of Fee Submitted	97200, 2026-01-08,
	The proposed proprietary name / brand name	**Esoson 40mg Capsule**
	Label Claim	Each capsule contains: - Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole .....40mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-De-Controlled,1x10's-De-Controlled,2x7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade
	For generic drugs (me-too Status)	Nexum capsule 40mg by Getz Pharma Pakistan

	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	ICU Pharmaceuticals SMC Pvt. Ltd. -Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	Eso-Rose 40mg Capsule, 326th meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
215	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(V5D-76Y-DPRS, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Sartan-A 5mg/160mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*14's-As per SRO
	Shelf Life (Unit)	3 YearStore below 30C
	For generic drugs (me-too Status)	Exforge 5 mg/80 mg film-coated tablets (Novartis Pharma (Pakistan) Limited)
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers (CCBs) and Angiotensin II receptor blockers (ARBs)
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Exforge® 5 mg/80 mg film-coated tablets (Novartis Pharmaceuticals UK Ltd)
	Detail of previous approval	Cardi-AV 5mg/ 80mg Tablets, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
216	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(V9L-LE6-NJW8, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Timus 0.5mg Capsule**
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	Tacgraf 0.5mg Capsules (CCL Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Immunosupressants
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Tacrolimus Capsules 0.5mg, USP (Mylan Pharmaceuticals Inc)
	Detail of previous approval	Tacor Capsules 0.5mg, DRB 344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
217	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(W62-MT3-5GMW, 2026-02-16)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**PEPSER INSTA4 0mg+1680mg Sachet**
	Label Claim	Each Sachet contains: Omeprazole .....40mg Sodium bicarbonate .....1680mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 14's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Me too Status: Registered in Pakistan Brand Name: Risec Insta Manufacturer: Getz Pharma

		Address: 29-30/27, Korangi Industrial Area, Karachi 74900, Pakistan. 29-30/27, Korangi Industrial Area, Karachi
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors (PPIs),Alkalinizing agents
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	M-344, omesol plus 40mg/1680mg sachet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
218	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(W7M-PL4-BAT2, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**PERMIWIN LOTION**
	Label Claim	Each ml contains: Permethrin.....50 mg (5% w/v) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	<> Manufacturer Name Biogen phrama Brand Name Scabizim 50mg Lotion Composition Each ml contains: Permethrin…….50 mg (5% w/v) Dosage Form Lotion
	Pharmacotherapeutic Group of (API)	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Name, address of Manufacturing site:	Biogen Life Sciences-8-Km, Chkbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Permethrin 5% w/v Cream MHRA approved Manufactured by Bristol-Myers Squibb Company Buffalo, NY USA 14213 U.S.Patent Nos.: 5,648,394 and 4,720,489
	Detail of previous approval	Applied product is approved for Biogen Life Sciences in Minutes of M-339th Meeting of Registration B
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
219	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(WAJ-P4J-QJRQ, 2026-02-13)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Napowin Tablet**
	Label Claim	Each Film Coated tablet contains: Naproxen Sodium.....220mg Diphenhydramine Hydrochloride.....25mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree C
	For generic drugs (me-too Status)	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet M/s Bayer HealthCare LLC
	Pharmacotherapeutic Group of (API)	NSAID / Antihistamine
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet M/s Bayer HealthCare
	Detail of previous approval	Naprox-D 220mg/25mg Tablet Approved in Minutes of 348th Meeting of Registration Board (01st – 02nd J
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
220	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)**
	Application Form Dy. No / Tracking ID & date of submission	(WDT-965-7GVY, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-08,

	The proposed proprietary name / brand name	**TAZOCENT-DS Injection**
	Label Claim	Each vial contains: Piperacillin as sodium.....4g Tazobactam as sodium 0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	24 MonthDo not store above 25°C. Keep the vial in the outer carton to protect from light
	For generic drugs (me-too Status)	Pipraben 4.5g injection Reg.No 113269
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Name, address of Manufacturing site:	M/S Global Pharmaceuticals (Pvt) Ltd-Plot No. 22-23, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Piperacillin and Tazobactam Company Sandoz (ANDA 065363)
	Detail of previous approval	Already approved Minutes of 316th meeting of Registration Board (15-18 March, 2022)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
221	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**FESTEL LABORATORIES** THOKAR NIAZ BAIG , MULTAN ROAD, LAHORE. **(000556)**
	Application Form Dy. No / Tracking ID & date of submission	(WGE-NU4-3G6E, 2026-02-03)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**FEBACT 2G INJECTION**
	Label Claim	Each Vial Contains: Cefoperazone as Sodium...1g Sulbactam as Sodium...1g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30c
	For generic drugs (me-too Status)	Cebac Injection by Bosch Pharma
	Pharmacotherapeutic Group of (API)	Data Already Approved in 333 MoM, Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 2g PDMA Approved Japan
	Detail of previous approval	Wincef 2gm Injection in 333 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
222	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(WRT-JHN-SJWL, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-27,
	The proposed proprietary name / brand name	**Aprotan 12.5mg tablet**
	Label Claim	Each Film-coated tablet contains Aprocitentan ....12.5mg (As per Innovators specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Neutan Pharma (Anhui) Co., Ltd, China. Address: No.1018, Jin'an Road, Economic& Technology Development District, Suzhou, Anhui, 234001 China Tel: +021 58003086
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
223	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(WS4-JG4-EZY1, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Pipta 2.25gm Injection**
	Label Claim	Each Vial contains: Piperacillin (as Piperacillin Sodium) : 2.0 g Tazobactam (as Tazobactam

		Sodium) : 0.25 g (as lyophilized powder for IV injection)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Tanzo 2.25gm Injection of M/s Bosch Pharmaceuticals
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Zosyn Injection of M/s Wyeth Pharmaceuticals (USFDA Approved)
	Detail of previous approval	Tazopip 2.25gm Injection - 335th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
224	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(WS6-MRZ-BJTP, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	**HYDROWIN INJECTION 250mg**
	Label Claim	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone..... 250 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Cortizone injection by Global pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	Cortizone injection by Global pharma USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
225	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(WTV-QZD-AMX2, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-27,
	The proposed proprietary name / brand name	**Lotvix 5% Lotion**
	Label Claim	Each ml contains: Permethrin.....50 mg (5% w/v)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 Degree Celsisu
	For generic drugs (me-too Status)	Biogen phrama Scabizim 50mg Lotion
	Pharmacotherapeutic Group of (API)	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Name, address of Manufacturing site:	Biogen life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	Permethrin 5% w/v Cream MHRA approved
	Detail of previous approval	Permgen 5% Lotion Meeting 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
226	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(WVX-L2R-6RDX, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**Racego 30mg Sachet**
	Label Claim	Each Sachet Contains: Racecadotril ..... 30mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 16's Aluminium foil sachet-As per SRO
	Shelf Life (Unit)	2 Year Avoid exposure to heat, light and humidity. Store between 15 to 30°C.

	For generic drugs (me-too Status)	Racedo 30mg sachet (Highnoon laboratories ltd)
	Pharmacotherapeutic Group of (API)	Antidiarrheals
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Hidrasec sachet (By SOPHARTEX France)
	Detail of previous approval	Cadotril 30mg Sachet, DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
227	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(X72-6TH-8EQ9, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**IndaGly 110mcg/50mcg DPI Capsule**
	Label Claim	Each capsule contains: Indacaterol maleate 143mcg eq. to Indacaterol ..... 110mcg Glycopyrronium bromide 63mcg eq. to Glycopyrronium ..... 50mcg Each delivered dose contains: Indacaterol maleate 110mcg eq. to Indacaterol .....85mcg Glycopyrronium bromide 54mcg eq. to Glycopyrronium ..... 43mcg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Glyderol 110mcg/50mcg.(Horizon Healthcare Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	Indacaterol Maleate:'ultra' long-acting beta 2-adrenergic agonist . Glycopyrronium Bromide: Anticholinergic group.
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #35-A, Small Industrial Estate, Taxila-
	The status in reference regulatory authorities	TGA Approved detailed provided in Module 1 Section 1.5.9
	Detail of previous approval	Glyderol 110mcg/50mcg. 339 DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
228	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(Y6G-WD5-TLV7, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Skydol 160mg/5ml Suspension**
	Label Claim	Each 5ml contains: Paracetamol (B.P)..... 160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Panadol 160mg/5ml Suspension of M/s GSK
	Pharmacotherapeutic Group of (API)	Paracetamolbelongs to a class of drugs called NSAID's
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Children's TYLENOL Acetaminophen Suspension USP 160 mg/5 mL of M/s McNeil Consumer Healthcare division of Johnson & Johnson Inc. 88 McNabb Street Markham, Ontario L3R 5L2 (Health Canada Approved)
	Detail of previous approval	Peradol 160mg/5ml Suspension approved in 336th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
229	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(YA4-XBJ-SZ8R, 2026-02-16)
	Detail of Fee Submitted	38700, 58500 2025-12-24, 2026-02-03

	The proposed proprietary name / brand name	**METHISOL 40mg Injection**
	Label Claim	Each vial contains: Methylprednisolone sodium succinate equivalent to Methylprednisolone 40 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Solu Medrol Injection (Pfizer)
	Pharmacotherapeutic Group of (API)	glucocorticoid)
	Name, address of Manufacturing site:	M/s WENOVO PHARMACEUTICALS, -PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI, PUNJAB -
	The status in reference regulatory authorities	EMC/FDA Approved
	Detail of previous approval	DRAP 339th Meeting 1535-1536
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
230	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(YAE-GJY-9GUE, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**Clava-S 312.5mg/5ml Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....250mg Potassium clavulanate eq. to Clavulanic acid....62.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmention 312.5mg/5ml Suspension of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Augmention 312.5mg/5ml Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (FDA Approved)
	Detail of previous approval	Amoxi 312.5mg/5ml Suspension - 344th Meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
231	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(YMH-VNH-431G, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Aleve-PM 220/25mg Tablet**
	Label Claim	Each Film Coated tablet contains: Naproxen Sodium.....220mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet of M/s Bayer HealthCare LLC
	Pharmacotherapeutic Group of (API)	Naproxen Sodium (is a non-steroidal anti-inflammatory drug (NSAID)) & Diphenhydramine Hydrochloride (Antihistamines)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	ALEVE PM 25mg/220mg tablet of M/s Bayer HealthCare LLC, (USFDA Approved)
	Detail of previous approval	Naprox-D 220/25mg Tablet approved in 348th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
232	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(YPL-4ER-PQES, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-23,
	The proposed proprietary name / brand name	**RUSO 10mg Tablet**
	Label Claim	Each Film Coated Tablet Contains; Rosuvastatin Calcium USP equivalent to Rosovastatin.....10mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 25□C. Store in the original blister packaging in order to protect from light and moisture.
	For generic drugs (me-too Status)	Rovista 10mg Tablets (Getz Pharmaceuticals (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors (statins)
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Crestor 10mg Tablet (Astra Zeneca Pharmaceuticals)
	Detail of previous approval	Suvasta 10mg Tablets, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
233	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(YX6-6RS-11XE, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**Tacpro 1mg Capsule**
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus.....1mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Tacgraf 1mg Capsule by CCl Pharmaceuticals

	Pharmacotherapeutic Group of (API)	immunosupressants
	Name, address of Manufacturing site:	Solaris Life Sciences -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-Pakistan-
	The status in reference regulatory authorities	USFDA APPROVED (Tacrolimus 1mg Capsule) Mylan Pharmaceuticals
	Detail of previous approval	344 Meetings of Registration Board held on 31th Dec,2024 to 2nd Jan 2025.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
234	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(Z32-PHV-W8GD, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Nurofen 400mg Tablet**
	Label Claim	Each Film Coated Tablet contains Ibuprofen.....400mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Brufen 400mg Tablet of M/s Abbott Laboratories Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	Ibuprofen exerts its anti-inflammatory and analgesic effects through inhibition of both COX isoforms. (Reference
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Ibuprofen Bril 400mg Tablet of M/s Brillpharma (Ireland) Limited Inniscarra, Main Street, Rathcoole, Co. Dublin, Ireland (HPRA Approved)
	Detail of previous approval	Ibuprofen 400mg Tablet approved in 351st Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
235	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(Z74-4N5-PUVL, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**Tacpro 0.5mg Capsule**
	Label Claim	Each Capsule contains: Tacrolimus Monohydrate equivalent to Tacrolimus 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Tacgraf 0.5mg Capsule by CCl Pharmaceuticals
	Pharmacotherapeutic Group of (API)	immunosupressants
	Name, address of Manufacturing site:	Solaris Life Sciences -Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	USFDA approved by Mylan Pharmaceuticlas Inc.
	Detail of previous approval	344 Meetings of Registration Board held on 31th Dec,2024 to 2nd Jan 2025.(Tacor 0.5mg Capsule)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
236	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(ZBV-SUQ-PUV1, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**Esmart 75mg/200mcg Tablet**
	Label Claim	Each Film Coated Modified Release Tablet contains: Diclofenac sodium----------75mg (Enteric coated core) Misoprostol ----------200mcg (immediate release coat)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Rotec 75mg/200mcg Tablet of M/s Searle Pakistan
	Pharmacotherapeutic Group of (API)	Diclofenac Sodium----------NSAIDs Misoprostol ----------Prostaglandin analogue
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Arthrotec 75mg/200mcg Tablet of M/s Pfizer (USFDA Approved)
	Detail of previous approval	Artec 75mg/200mcg Tablet approved in 343rd Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
237	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Winthrox Laboratories Pvt. Ltd** K-219-A, SITE, Super Highway Phase II, Karachi **(000807)**
	Application Form Dy. No / Tracking ID & date of submission	(ZHE-3JN-6MGJ, 2026-01-27)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	**BETAWIN-N CREAM**
	Label Claim	Each gram contains: Betamethasone (as Valerate) ... 1mg Neomycin Sulfate ..... 5mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 degree Centigrade
	For generic drugs (me-too Status)	Betnovate-N Cream
	Pharmacotherapeutic Group of (API)	Corticosteroids and Antibiotics
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES -8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan.-
	The status in reference regulatory authorities	Betnovate-N cream MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
238	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(ZJ5-NHJ-YQ1W, 2026-02-13)
	Detail of Fee Submitted	97200, 2026-01-14,
	The proposed proprietary name / brand name	**Clava-T 1000mg Tablet**
	Label Claim	Each film coated tablet contains: Ammoxicillin trihydrate eq. to Amoxicillin.....875mg Potassium clavulanate eq. to Clavulanic acid....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmention BD 1000mg Tablet of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Augmentin 1000mg Tablet of M/s AUGMENTIN is a registered trademark of GlaxoSmithKline and is licensed to Dr. Reddy's Laboratories Inc, Distributed by: Dr. Reddy's Laboratories Inc. Bridgewater, NJ 08807
	Detail of previous approval	Amoxi 1000mg Tablet - 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
239	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aurik Pharmaceuticals Pvt Ltd** PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI **(000802)**
	Application Form Dy. No / Tracking ID & date of submission	(ZYS-MZV-YNPX, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Healom 40mg Inj**
	Label Claim	Each vial contains: Omeprazole as Sodium.....40mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Risek 40mg Inj
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	BIOGEN LIFE SCIENCES-8Km,Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	DRAP
	Detail of previous approval	OMJENT INJECTION 40MG I.V. Minutes of 3l2th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
240	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**LIVEN PHARMACEUTICALS** 49-KM MULTAN ROAD, PHOOL NAGAR, DISTRICT, KASUR PAKISTAN **(000881)**
	Application Form Dy. No / Tracking ID & date of submission	(ZYU-1N3-S4R7, 2026-02-04)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Clava-S 156.25mg/5ml Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....125mg Potassium clavulanate eq. to Clavulanic acid....31.25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Augmention 156.25mg/5ml Suspension of M/s GSK Pakistan
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic,
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al-Badar Industrial Estate, 18-KM Sheikhupura Road, Lahore - Pakistan-
	The status in reference regulatory authorities	Augmention 156.25mg/5ml Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (FDA Approved)
	Detail of previous approval	Amoxi 156mg/5ml Suspension - 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
241	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(B6X-XJU-2M4M, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	**Keto-Dew Tablet**
	Label Claim	Each film coated tablet contains: α-Ketoanalogue to isoleucine (Calcium-salt)... 67 mg α-Ketoanalogue to leucine (Calcium-salt)... 101 mg α-Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α-Ketoanalogue to valine (Calcium-Salt) 86 mg α-hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet 1.25mmol = 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
242	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**

	Application Form Dy. No / Tracking ID & date of submission	(EWM-WGQ-UP34, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	**Rosotec 20mg Tablet**
	Label Claim	Each film coated tablet contains: Rosuvastatin Calcium (equivalent to Rosuvastatin) 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
243	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)**
	Application Form Dy. No / Tracking ID & date of submission	(TTP-UV9-NVG9, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-27,
	The proposed proprietary name / brand name	**Gabfit 75mg capsule**
	Label Claim	Each Capsule Contains; Pregabalin ..... 75mg (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 º C
	For generic drugs (me-too Status)	Gabica 75mg capsules,Getz Pharma (pvt) Limited 29-30/27 Korangi Industrial Area, Karachi, Sindh 74900, PK ;
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot No. 8, Street No. S-1, RCCI, Industrial Estate, Rawat-PAKISTAN-
	The status in reference regulatory authorities	Lyrica® 75 mg hard capsules, Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium,Hoge Wei 10 1930, Zaventem, Vlaams Brabant Belgium
	Detail of previous approval	

	Evaluation Remarks	
	The firm initially selected NO in data already approved. However, later it has informed vide General Request TID: QVQ-US3-PU8Y that cross referred product has been approved in 352nd Meeting of the Registration Board. Accordingly, in light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
244	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)**
	Application Form Dy. No / Tracking ID & date of submission	(DEZ-LB5-N6HU, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-27,
	The proposed proprietary name / brand name	**Linzopin 600mg tablet**
	Label Claim	Each film coated tablet contains; Linezolid ..... 600mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 º C
	For generic drugs (me-too Status)	Zoldap 600mg tablets,M/s Getz Pharma Private Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot No. 8, Street No. S-1, RCCI, Industrial Estate, Rawat-PAKISTAN-
	The status in reference regulatory authorities	Zyvox 600mg tablets,Pfizer Service Company,,BVBA, Hoge Wei 10, 1930 Zaventem, Belgium
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in data already approved. However, later it has informed vide General Request TID: QVQ-US3-PU8Y that cross referred product has been approved in 352nd Meeting of the Registration Board. Accordingly, in light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
245	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)**

	Application Form Dy. No / Tracking ID & date of submission	(7JQ-Z28-616B, 2025-10-22)
	Detail of Fee Submitted	93000.0, 2025-06-19,
	The proposed proprietary name / brand name	**Spaspin 40mg/0.04mg Injection**
	Label Claim	Each 4ml ampoule contains: Hydrated Phloroglucinol .....40mg Trimethyl Phloroglucinol .....0.04mg (Innovators Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	ANAFORTAN PLUS AGP Pakistan
	Pharmacotherapeutic Group of (API)	Spasmolytic agent
	Name, address of Manufacturing site:	M/s Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Spasfon Injection, Teva Sante, ANSM FRANCE APPROVED DRUG
	Detail of previous approval	
	Evaluation Remarks	
	The firm has applied in light of decision of 350th meeting of Registration Board and shared PRV approval of cross-referred product vide letter no. F-119-PRVC/2024 (PR-II) dated 16 May 2024.	
	Decision	
	Approved	
246	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**Merixil Pharma** Office 28, 2nd Floor, Rose Plaza , I-8 Markaz **(DHO-ISB-1745)**
	Application Form Dy. No / Tracking ID & date of submission	(35E-AG5-GN3D, 2025-09-29)
	Detail of Fee Submitted	300000.0, 2025-06-24,
	The proposed proprietary name / brand name	**INJECTION ZOLEDRONIC ACID NORMON 4 MG/100ML**
	Label Claim	100 ml infusion bags contains 4.264 mg Zoledronic acid monohydrate, corresponding to 4 mg Zoledronic acid on an anhydrous basis
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1`s-Controlled
	Shelf Life (Unit)	24 Month(s)BELOW 30 C
	For generic drugs (me-too Status)	Zolinic 4mg/100ml Infusion
	Pharmacotherapeutic Group of (API)	M05BA08; bisphosphonates
	Name, address of Manufacturing site:	LABORATORIOS NORMON, S.A.-Ronda de Valdecarrizo, 6, Tres Cantos, 28760 Madrid-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product Aclasta 5 mg solution for infusion of Sandoz, EMA/ MHRA approved
	Name, address of Marketing Authorization Holder:	MERIXIL PHARMA, FLAT NO.28 2ND FLOOR, PLOT NO.13, ROSE-1 PLAZA I-8 MARKAZ, ISLAMABAD, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Certificate NoES077HV/23a dated 03.10.2024 issued by agencia esponola de medicamentos COPP from Sweeden certificate No 5.8.1-2025-042301 dated 19.05.2025

	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03n batches on accelerated and long term stability
	The status in reference regulatory authorities	US FDA/MHRA/EMEA-ZOMETA Injection
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Registration Board.	
	Decision	
	Approved Approved as per import policy	
247	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**Merixil Pharma** Office 28, 2nd Floor, Rose Plaza , I-8 Markaz **(DHO-ISB-1745)**
	Application Form Dy. No / Tracking ID & date of submission	(EBJ-BSP-UM6W, 2025-10-01)
	Detail of Fee Submitted	313500, 2025-09-19,
	The proposed proprietary name / brand name	**OCTREOTIDE 100 MICROGRAM/1ML SOLUTION**
	Label Claim	Each Vial contain Octreotide 100 microgram/1ml solution for injection / infusion) as Acetate
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5`s & 1`s-De-Controlled
	Shelf Life (Unit)	36 Year(s)2 TO 8 c
	For generic drugs (me-too Status)	Asterotide Acetate Injection 0.1Mg/Ml
	Pharmacotherapeutic Group of (API)	ATC code : H01CB02, (SOMATOSTATIN AND ANALOGUES)
	Name, address of Manufacturing site:	Sichuan Huiyu Pharmaceutical Co., Ltd-Building 3, No333 Hanyang Road, Shizhang District, Neijiang, Sichuan, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sandostatin Novartis
	Name, address of Marketing Authorization Holder:	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY,, United Kingdom
	Details of Certificates (CoPP/FSC/cGMP):	EUDRA GMP
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated conditions
	The status in reference regulatory authorities	US FDA/MHRA/EMEA-SANDOSTATIN Injection
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board	
	Decision	
	Approved Approved as per import policy	
248	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(8GV-9NJ-T42G, 2025-09-22)
	Detail of Fee Submitted	93000.0, 2025-07-29,
	The proposed proprietary name / brand name	**Edalis 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Tadalafil 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Procial 10mg (Wimits pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/s ULTRATECH INDIA LTD.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd.-129-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 10mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	Detail of previous approval	Procial 10mg tablet 345th (19-02-2025)
	Evaluation Remarks	
	The firm initially provided reference of wrong meeting. Later on, they provided Registration letter for cross-referred product issued after M-351.	
	Decision	
	Approved	
249	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(L7M-2QR-PSBT, 2025-10-01)
	Detail of Fee Submitted	93000.0, 4200 2025-07-29, 2025-09-12
	The proposed proprietary name / brand name	**Edalis 5mg**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Procial 5mg (Wimits pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/s ULTRATECH INDIA LTD.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd.-129-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Tadalafil Tablets 5mg (Ajanta Pharma USA Inc., Bridgewater)
	Detail of previous approval	Procial 5mg tablet 345th (19-02-2025)
	Evaluation Remarks	

	Initially the firm applied with wrong reference. Now they have provided Registration Letter for their corss-reference product from M-351.	
	Decision	
	Approved	
250	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welmed Pharmaceutical Industries (Pvt) Ltd.** Plot No. 108/1 Road No. R-2 I.E. Gadoon. **(000546)**
	Application Form Dy. No / Tracking ID & date of submission	(LAE-HZN-6N4S, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-05-09,
	The proposed proprietary name / brand name	**Vela 20mg Tablet**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 20mg of M/s Ajanta Pharma USA Inc., Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Procial 20mg Tablet approved in 345th Meeting
	Evaluation Remarks	
	Initially the firm provided wrong reference. Now they have provided Registration letter from M-351.	
	Decision	
	Approved	
251	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore **(000845)**
	Application Form Dy. No / Tracking ID & date of submission	(W93-AVS-8M2G, 2025-10-01)
	Detail of Fee Submitted	93000.0, 4200 2025-07-29, 2025-09-12
	The proposed proprietary name / brand name	**Edalis 20mg**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Procial 20mg (Wimits pharmaceuticals)
	Pharmacotherapeutic Group of (API)	M/s ULTRATECH INDIA LTD.

	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd.-129-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Tadalafil Tablets 20mg (Ajanta Pharma USA Inc., Bridgewater)
	Detail of previous approval	Procial 20mg tablet 345th (19-02-2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
252	Case Category	Priority As Per 257-M of RB (Iqra Aftab)
	Name, address of Applicant.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore **(000872)**
	Application Form Dy. No / Tracking ID & date of submission	(X14-1RL-TZY2, 2025-10-08)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Glynib 100mg Tablet**
	Label Claim	Each film coated tablet contains: Imatinib mesilate equivalent to Imatinib.... 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	IM-Tab Tablet 100mg (087792) Werrick Pharmaceuticals
	Pharmacotherapeutic Group of (API)	L01EA01 (BCR-ABL tyrosine kinase inhibitors)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Anxin Pharmaceutical Co., Ltd., ,Laoling site: Circular Economy Demonstration Park, Laoling County, Dezhou City 253600, Shandong Province,
	Detail of stability batches of drug product	Stability data of 3 batches according to Zone IV-A till 6 months accelerated and real time with batch size of 2500 tablets E091, E092, E093
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 5, Clearence certifiacte dated 06-11-2023 Batch No. VZ3003P.,Qty. 10kg, DOM 24-07-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been performed against Glivec 100mg Tablets manufacturer Novartis Pharma Produktions GmbH, Wehr, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches according to Zone IV-A till 24 months (BJ020316001, BJ020316002 and BJ020316003)
	The status in reference regulatory authorities	Glivec® 100 mg film-coated tablets (MHRA Approved)

	GMP status of the firm	GMP certificate dated 05-11-2024 issued on the basis of panel inspection for renewal of DML and grant of new section: Steroid Tablet section conducted on 24-09-2024 and 25-09-2024.
	Evidence of approval of manufacturing facility	Tablet (Anti-cancer) Section
	Evaluation Remarks	
	Decision	
	Approved	
253	Case Category	New Molecule/Formulation (Iqra Aftab)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(Y8S-YBR-14X4, 2025-09-29)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**Penviro Cream 5g (1% w/w)**
	Label Claim	Each gram of cream contains. Penciclovir.....10mg (1% w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature (20°C to 25ºC).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	D06BB06 Antivirals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Charioteer Pharmaceutical Co., Ltd. ,Tongyuan Creek, War Township, Xianju County, Taizhou City, Zhejiang Province, 317321
	Detail of stability batches of drug product	PEC-001, PEC-002, PEC-003 Each of 500packs
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached with invoice number CH210180-WWF ADC attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Denavir Cream 1% w/w, M/s Mylan Pharaceuticals, US.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
	The status in reference regulatory authorities	DENAVIR, USFDA
	GMP status of the firm	w.e.f 16-08-2022 applied for renewal 21-12-2023
	Evidence of approval of manufacturing facility	DML# 000856 w.e.f 24-04-2017 Letter of renewal of DML 8-11-2023 mentioning cream, ointment and gel section.
	Evaluation Remarks	
	Inclusion of Polymorphism test in API and DP specification is required.Firm has submitted their reply vide tracking ID PWE-L3R-HNHV dated 02-03-2026 wherein, firm has revised its DS specification (Addition of polymorphic form).	
	Decision	
	Approved Approved subject to the submission of:-	

	i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
254	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(GHA-7PX-YS64, 2025-10-07)
	Detail of Fee Submitted	313500, 2025-08-27,
	The proposed proprietary name / brand name	**Everose 5mg Tablet**
	Label Claim	Each film-coated tablet contains ..... Everolimus 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C.
	For generic drugs (me-too Status)	Afinitor 5mg Tablet (Novartis Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Biocon Limited, India
	Name, address of Manufacturing site:	CTCbio -228-16, Gangchon-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea-North Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Samyang Holding Corporation , 79, Sinildong-ro, Daedeok-gu, Daejeon, , Republic of Korea , North Korea
	Details of Certificates (CoPP/FSC/cGMP):	06.02.2027 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
	The status in reference regulatory authorities	Afinitor 5mg Tablet (Novartis Pharmaceuticals, Korea)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
255	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**

	Application Form Dy. No / Tracking ID & date of submission	(PX6-XVX-QGRV, 2025-10-31)
	Detail of Fee Submitted	313500, 2025-09-29,
	The proposed proprietary name / brand name	**Everose 10mg Tablet**
	Label Claim	Each film-coated tablet contains.....10mg Everolimus
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's (1x30)-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C.
	For generic drugs (me-too Status)	Afinitor 10mg Tablet (Novartis)
	Pharmacotherapeutic Group of (API)	Biocon Limited, India
	Name, address of Manufacturing site:	CTCbio INC.,-228-16, Gangchon-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea-North Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Samyang Holding Corporation , 79, Sinildong-ro, Daedeok-gu, Daejeon, , Republic of Korea , North Korea
	Details of Certificates (CoPP/FSC/cGMP):	December 2025
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
	The status in reference regulatory authorities	Afinitor 10mg Tablet (Novartis Pharmaceuticals, Korea)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
256	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(J8T-S6W-GPBR, 2025-10-10)
	Detail of Fee Submitted	313500, 2025-09-16,
	The proposed proprietary name / brand name	**Bendamustine AqVida 150mg/1.5ml (100mg/ml) Concentrate for Solution for Infusion (Bendamustine)**
	Label Claim	Each Vial contains..... Bendamustine 150 mg (100mg/ml)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's & 5's (Vials)-As per SRO
	Shelf Life (Unit)	24 MonthStore between 2-8°C.

	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Biophore India Pharmaceuticals Pvt. Ltd.
	Name, address of Manufacturing site:	AqVida GmbH -Werkstr.21 23942 Dassow-Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	AqVida GmbH , Kaiser-Wilhelm-Str.89, 20355 Humburg, Germany
	Details of Certificates (CoPP/FSC/cGMP):	December 2025
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 Months
	The status in reference regulatory authorities	LEVACT® (Bendamustine hydrochloride 100 mg/mL powder for concentrate for solution for infusion); Novartis UK
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
257	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(NTL-539-VU5Q, 2025-10-14)
	Detail of Fee Submitted	313500, 2025-10-09,
	The proposed proprietary name / brand name	**Bendamustine AqVida 200mg/2ml Concentrate for Solution for Infusion**
	Label Claim	Each 2ml contains..... Bendamustine 200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	(1x1's) & (1x5's)-As per SRO
	Shelf Life (Unit)	24 MonthStore in a refrigerator (2°C – 8°C)
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Biophore India Pharmaceuticals Pvt. Ltd.
	Name, address of Manufacturing site:	AqVida GmbH -Werkstr. 21 23942 Dassow-Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in relevant section
	Name, address of Marketing Authorization Holder:	AqVida GmbH , Kaiser- Wilhelm-Str. 89 20355 Hamburg, Germany
	Details of Certificates (CoPP/FSC/cGMP):	Dec 2025
	Details of Authorization Letter :	Not applicable for Importer
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months

	The status in reference regulatory authorities	TRENDA (bendamustine hydrochloride) for injection, for Intravenous Infusion (Netherlands)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
258	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(5EN-T6S-R3Z4, 2026-02-04)
	Detail of Fee Submitted	313500, 2025-10-20,
	The proposed proprietary name / brand name	**Trabectedin EVER Pharma 1 mg powder for concentrate for solution for infusion**
	Label Claim	Each vial of powder contains 1 mg of trabectedin One ml of reconstituted solution contains 0.05 mg of trabectedin
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-As per SRO
	Shelf Life (Unit)	48 MonthStore in a refrigerator (2°C - 8°C).
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	antineoplatic
	Name, address of Manufacturing site:	• Secondary packaging &Batch release EVER Pharma-Brüsseler Strasse 18 07747 Jena Germany-Germany ,Bulk product: BSP Pharmaceuticals S.P.A., -Via Appia Km.65,561, Loc, Latina Scalo (LT), 04013 Latina (LT) Italy -Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Enclosed
	Name, address of Marketing Authorization Holder:	EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria, Austria
	Details of Certificates (CoPP/FSC/cGMP):	Enclosed
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Enclosed
	The status in reference regulatory authorities	YONDELIS (trabectedin) powder, lyophilized, for solution for injection,Baxter Oncology GmbH Halle/Westfalen, Germany
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to the submission of:-	

i. The original legalized CoPP/GMP and FSC, and in accordance with the current import policy.

ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026.

ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.

259	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(1U1-2DN-LGE6, 2025-12-01)
	Detail of Fee Submitted	313500, 2025-11-24,
	The proposed proprietary name / brand name	**Ivosenib 250mg Tablet**
	Label Claim	Each film-coated tablet contains 250 mg of Ivosidenib.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x60's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Henan Jin Huaitang Biological Engineering Co.,Ltd China
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhala-1208, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	01.10.2026 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Tibsovo 250 mg film-coated tablets (France)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of:- i The original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	

260	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(2YW-7X7-BGDM, 2026-02-03)
	Detail of Fee Submitted	313500, 2025-12-15,
	The proposed proprietary name / brand name	**Selcaxen 40mg Capsule**
	Label Claim	Each hard capsule contains..... Selpercatinib 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x30's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	KAIFENG PHARMACEUTICAL(GROUP) COMPANY LIMITED.
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Rahman's Regnum Centre (11th) Floor) 191/1, Tejgaon C/A, Dhaka-1208,-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	01.10.2026 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Retsevmo 40mg Hard Capsules (Lilly S.A., Spain)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of:- i The original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
261	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**

	Application Form Dy. No / Tracking ID & date of submission	(BDR-BZB-ZEBZ, 2026-02-04)
	Detail of Fee Submitted	313500, 2025-11-17,
	The proposed proprietary name / brand name	**Capixet 500mg Tablet**
	Label Claim	Each film coated tablet contains Capecitabine 500mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Xelobig 500mg Tablet (Searle Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Capecitabine
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhala-1208, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	01.10.2026 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
	The status in reference regulatory authorities	Xeloda 500 mg film-coated Tablets. (Germany)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
262	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(RQ1-W1N-2E27, 2025-09-23)
	Detail of Fee Submitted	300000.0, 2025-06-05,
	The proposed proprietary name / brand name	**Osimert Tablet**
	Label Claim	Each Film Coated Tablet Contains..... Osimertinib Mesylate INN Equivalent to 80 mg Osimertinib.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Tagrix Tablet 80mg (Himmel Pharmaceuticals)

	Pharmacotherapeutic Group of (API)	Kaifeng Pharmaceutical(Group)Company Limited.
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Factory: Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, Bangladesh. | Head office Address: Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	19.07.2023 to 19.07.2025 (For Manufacturing Facility)
	Details of Authorization Letter :	Not Applicable for Finished drug Product Importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	Tagrisso 80mg Tablets (Sudan)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
263	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(SVH-9GG-E9G1, 2026-02-04)
	Detail of Fee Submitted	313500, 2025-12-05,
	The proposed proprietary name / brand name	**Enasinib 50mg Tablet**
	Label Claim	Each film coated tablet contains Enasidenib Mesylate INN equivalent to Enasjdenib 50 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x30's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Kaifeng Pharmaceutical (Group) Company Limited.
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, Bangladesh

	Details of Certificates (CoPP/FSC/cGMP):	01.10.2026 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product Importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	IDHIFA 50mg Tablet (Bristol Mayers Squibb, USA)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of:- i The original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
264	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(E6R-MTV-JTTX, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**Amaryl**
	Label Claim	Each tablet contains: Glimepiride 3mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's -De-Controlled,10's-De-Controlled,30's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	Diabryl tablet 3mg
	Pharmacotherapeutic Group of (API)	sulfonylurea oral antidiabetic medication
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PRUDENCE PHARMACHEM
	Detail of stability batches of drug product	3000 tablets each of RND/Tab25-1/T007/S1, RND/Tab25-1/T007/S2 ,RND/Tab25-1/T007/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from Ms Novamed without timely intimation to DRAP.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP data against Diabryl tablet 3mg B#21247 of Ms Novamed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
	The status in reference regulatory authorities	Amaryl 3mg sanofi-aventis U.S. LLC Bridgewater, NJ 08807 A SANOFI COMPANY
	GMP status of the firm	valid

	Evidence of approval of manufacturing facility	DML#000977(Attached)
	Evaluation Remarks	
	API loan may be verified accordingly.	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
265	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(GP7-86Y-DBUD, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**Amaryl**
	Label Claim	Each tablet contains: Glimepiride 1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,20's -De-Controlled,30's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	ORINASE tablet 1mg
	Pharmacotherapeutic Group of (API)	ANti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PRUDENCE PHARMACHEM
	Detail of stability batches of drug product	three batches 3000 each RND/Tab25-1/T005/S1, RND/Tab25-1/T005/S2, RND/Tab25-1/T005/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Novamed without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against Orinase tablet 1mg B#F0177
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
	The status in reference regulatory authorities	Amaryl 1mg sanofi-aventis U.S. LLC Bridgewater, NJ 08807 A SANOFI COMPANY
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	DML#000977(Attached)
	Evaluation Remarks	
	API loan may be verified, accordingly.	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
266	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(MSR-HE9-LWEQ, 2025-09-12)

	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**Amaryl**
	Label Claim	Each tablet contains : Glimepiride.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,20's -De-Controlled,30's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	Diabryl tablet 4mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PRUDENCE PHARMACHEM
	Detail of stability batches of drug product	Three batches of 3000 tablets each, RND/Tab25-1/T008/S1, RND/Tab25-1/T008/S2, RND/Tab25-1/T008/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Novamed without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against Diabryl tablet 4mg B#21081
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
	The status in reference regulatory authorities	Amaryl 4mg sanofi-aventis U.S. LLC Bridgewater, NJ 08807 A SANOFI COMPANY
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	DML#000977(Attached)
	Evaluation Remarks	
	API loan may be verified accordingly.	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
267	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(VB2-JHT-Z8QD, 2025-09-11)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**Amaryl**
	Label Claim	Each tablet contains: Glimepiride.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's & 30's -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place and protect from direct sunlight
	For generic drugs (me-too Status)	Diabryl tablet 2mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PRUDENCE PHARMACHEM

	Detail of stability batches of drug product	three batches of 3000 tablets each RND/Tab25-1/T006/S1 RND/Tab25-1/T006/S2 RND/Tab25-1/T006/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from Ms Novamed without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP against Diabryl tablet 2mg B#21145
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data till shelf life attached
	The status in reference regulatory authorities	Amaryl 2mg sanofi-aventis U.S. LLC Bridgewater, NJ 08807 A SANOFI COMPANY
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	DML#000977(Attached)
	Evaluation Remarks	
	Loan may be verified accordingly.	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
268	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. **(000978)**
	Application Form Dy. No / Tracking ID & date of submission	(53G-WVS-D1VU, 2026-01-02)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-05, 2024-11-08
	The proposed proprietary name / brand name	**Qioxime 400mg capsule**
	Label Claim	Each hard gelatin Capsule contains Cefixime as trihydrate.....400mg (Manufacturer Specs)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x5s-Controlled
	Shelf Life (Unit)	2 Year(s)below 30C
	For generic drugs (me-too Status)	Cepspan 400mg capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Pharmagen Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	three batches of 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	--
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Cefspan 400 capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	

	The firm has not submitted audit trail report and informed that their HPLC systems are not 21CFR compliant.	
	Decision	
	Rejected The Registration Board rejected the product since the HPLC software is not 21 CFR compliant and audit trial could not be verified.	
269	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(6DN-4WM-PXRU, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**O-Zole 40mg Capsule**
	Label Claim	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	TEpH 40mg Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd.
	Detail of stability batches of drug product	(1)RND/Cap25-1/T004/S1,(2)RND/Cap25-1/T004/S1 (3)RND/Cap25-1/T004/S1 2000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against TEpH 40 capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life as per zone IV-A conditions
	The status in reference regulatory authorities	Omeprazole 40mg capsule MHRA Approved
	GMP status of the firm	Valid GMP is attached
	Evidence of approval of manufacturing facility	Capsule section[General] against DML No. [000977]
	Evaluation Remarks	
	Decision	
	Approved	
270	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(8RG-T7A-E1BQ, 2026-02-06)
	Detail of Fee Submitted	38700, 2026-01-07,
	The proposed proprietary name / brand name	**O-Zole 20mg Capsule**

	Label Claim	Each capsule contains. Omeprazole coated pellets eq to Omeprazole 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	TEpH 20mg Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd.
	Detail of stability batches of drug product	(1)RND/Cap25-1/T003/S1,(2)RND/Cap25-1/T003/S1 (3)RND/Cap25-1/T003/S1 (2000 capsules each)
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against TEpH 20 capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life as per zone IV-A conditions
	The status in reference regulatory authorities	Omeprazole 20mg capsule MHRA Approved
	GMP status of the firm	Valid GMP and attached
	Evidence of approval of manufacturing facility	Capsule section[General] against DML No. [000977]
	Evaluation Remarks	
	Decision	
	Approved	
271	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(5QT-M23-BWA3, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	**Tems 0.4mg Capsule**
	Label Claim	Each Capsule contains: Tamsulosin hydrochloride (as modified released pellets) 0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Tamsolin 0.4mg Capsule
	Pharmacotherapeutic Group of (API)	Alpha-adrenergic blockers: Urologic agent (used in benign prostatic hyperplasia)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt) Ltd
	Detail of stability batches of drug product	(1)RND/RND/CAP25-1/T005/S001, (2) RND/CAP25-1/T005/S002 (3) RND/CAP25-1/T005/S003 (2000 capsules each)
	Documents for the procurement of API with approval from DRAP	N/A

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against Tamsolin 0.4mg Capsule B# 214C45
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid GMP and attached
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977]
	Evaluation Remarks	
	Decision	
	Approved	

272	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(1H5-338-STXM, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**EYEPAT 0.2% Ophthalmic Solution**
	Label Claim	Each ml contains: Olopatadine Hydrochloride equivalent to Olopatadine ..... 2.0mg (USP Specs).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Olopharm Forte Ophthalmic Solution by Epharm Laboratories
	Pharmacotherapeutic Group of (API)	Selective H1-receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CURIA SPAIN S.AU. Parque Technologico, Parcela 105-A 47151 Boecillo, Valladolid, Spain. Spain
	Detail of stability batches of drug product	3 batches;600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Hansel without timely intimation to DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data against Eyepat 0.2% of Ms Hansel
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	

Sr. No.	Observation	Firm's response

1	Justification shall be submitted for trial batch manufacturing prior to issuance of DML.	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

273		
	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(SMP-9LT-HZHW, 2026-01-28)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Q-MOX 0.5% Ophthalmic Solution**
	Label Claim	Each ml contains: Moxifloxacin HCl equivalent to Moxifloxacin.....5mg (USP Specs).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Ocumox Eye Drops by Macquin's International
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enaltec Labs Pvt.Ltd, Plot No 825-827 Sector -3 Industrial Area, Pithampur, Dist- Dhar -454774, M.P India
	Detail of stability batches of drug product	600 bottles each of 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan API from Ms Hansel without timely approval from DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data against Q-Mox 0.5% Ophthalmic Solution of Ms Hansel Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	FDA approved
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No	Observation	Firm's reply
1	Justification shall be submitted for trial batch manufacturing prior to issuance of DML	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

274	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(E96-JYJ-823G, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**EYEPAT 0.7% Ophthalmic Solution**
	Label Claim	Each ml contains: Olopatadine Hydrochloride equivalent to Olopatadine ..... 7.0mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Xepat-OD Opthalmic Solution 0.7%
	Pharmacotherapeutic Group of (API)	Selective H1-receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	CURIA SPAIN S.AU. Parque Technologico, Parcela 105-A 47151 Boecillo, Valladolid, Spain. Spain
	Detail of stability batches of drug product	600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from Ms Hansel without timely intimation to DRAP.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data against Xepat-OD Opthalmic Solution 0.7%
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	Health Canada approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observation	Firm's response
1	Justification shall be submitted for trial batch manufacturing prior to issuance of DML	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

275	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**

	Application Form Dy. No / Tracking ID & date of submission	(B8A-Q6E-UPML, 2025-11-03)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**Moxiair 400mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Moxifloxacin hydrochloride (equivalent to moxifloxacin 400mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Moxiget 400mg Tablet
	Pharmacotherapeutic Group of (API)	Zenith Chemical Industries (PVT) Ltd
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical Industries (PVT) Ltd
	Detail of stability batches of drug product	(1)RND/Tab25-1/T017/S1,(2)RND/Tab25-1/T017/S2 (3)RND/Tab25-1/T017/S3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local procurement from Zenith Chemical Industries (PVT) Ltd (007/2025)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile against Moxiget
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life attached
	The status in reference regulatory authorities	Avelox 400mg Tablet by Bayer
	GMP status of the firm	Valid GMP
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977]
	Evaluation Remarks	
	Decision	
	Approved	
276	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road **(000455)**
	Application Form Dy. No / Tracking ID & date of submission	(27R-3RL-256S, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Gablite 300mg Capsule**
	Label Claim	Gablite 300mg Capsule Each Capsule Contains: Pregabalin.....300mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Gabica 300mg Capsule by M/s Getz Pharma, Karachi
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Almelo Pvt. Ltd Unit-II, Survey No: 227, 228 & 136, 137, Shabashpally Village, Shivampet Mandal, Medak, Telangana, India
	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 Import)	API loan from Ms Genesis without timely intimation to DRAP, hence may be verified accordingly
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data against Gabica 300mg capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Lyrica 300mg Capsule By Upjohn UK Limited MHRA Approved.
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
277	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road **(000455)**
	Application Form Dy. No / Tracking ID & date of submission	(Y4W-BDL-W5Z6, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-06-28,
	The proposed proprietary name / brand name	**GABLITE CAPSULE 75MG**
	Label Claim	Each Capsule Contains: Pregabalin.....75mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)	Gabica 75mg Capsule by M/s Getz Pharma, Karachi
	Pharmacotherapeutic Group of (API)	Anti convulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ALMELO PRIVATE LIMITED SURVEY NOS. 227, 228 & 137, 136, SHABASHPALLY VILLAGE, SHIVAMPET MANDAL, MEDAK DISTRICT, PINCODE 502334,TELANGANA STATE,INDIA
	Detail of stability batches of drug product	1500 Capsules is for each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Genesis without timely approval from DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Gabica 75mg Capsule by M/s Getz Pharma, Karachi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.

	The status in reference regulatory authorities	Amarox 75mg Capsule By UK Limited MHRA Approved.
	GMP status of the firm	Attached.
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
278	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road **(000455)**
	Application Form Dy. No / Tracking ID & date of submission	(TYA-1R7-XR31, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Gablite 150mg Capsule**
	Label Claim	Gablite 150mg Capsule Each Capsule Contains: Pregabalin.....150mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Gabica 150mg Capsule by M/s Getz Pharma, Karachi
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Almelo Pvt. Ltd Unit-II, Survey No: 227, 228 & 136, 137, Shabashpally Village, Shivampet Mandal, Medak, Telangana, India
	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 Import)	API loan from Ms Genesis without timely intimation to DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data against Gabica 150mg capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Lyrica 150mg Capsule By Upjohn UK Limited MHRA Approved.
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
279	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road **(000455)**

	Application Form Dy. No / Tracking ID & date of submission	(6AJ-SN7-61Y2, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Doxylite 100mg Capsule**
	Label Claim	Each Capsule contains: Doxycycline(as Hyclate).....100mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's 100's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Doxycycline capsule 100mg (Zafa Pharmaceuticals) Reg. No. 031290
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Three batches of 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Obsons Pharma without timely intimation to DRAP, hence may be verified accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies data submitted against Vibramycin
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Doxycycline capsule 100mg (USFDA) Manufactured by: Chartwell Pharmaceuticals, LLC. Congers, NY 10920
	GMP status of the firm	Additional section granted on 08-11-2022
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
280	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(X94-SUA-ZXXV, 2026-01-30)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Opticon-A Ophthalmic Solution**
	Label Claim	Each mL Contains: Naphazoline HCl .....0.25mg Pheniramine Meleate....3mg (USP Specs).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	OPTICON-A by Winthrox (Pvt.) Ltd.

Pharmacotherapeutic Group of (API)	Naphazoline Hydrochloride: direct-acting alpha adrenergic agonist Pheniramine Maleate: First-generation H1 antihistamine
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	M/S HARIKA DRUGS PRIVATE LIMITED SY. NO. 165/A & 165/E, GUMMADIDALA (VILLLAGE), GUMMADIDALA (MANDAL), SANGAREDDY (DIST.), TELANGANA, INDIA. ,PRECISE BIOPHARMA PVT LTD PLOT NO. C-384, T.T.C. INDUSTRIALAREA, M.I.D.C.,PAWANE VILLAGE, VANIMUMBAI-400703 (INDIA)India.
Detail of stability batches of drug product	600 bottles of each batch.
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from Ms Winthrox without timely intimation to DRAP hence may be verified accordingly
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Opticon-A Ophthalmic Solution of Ms Winthrox
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
The status in reference regulatory authorities	USFDA approved
GMP status of the firm	New DML
Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observation	Firm's response
	Justification shall be submitted for trial batch manufacturing prior to issuance of DML	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
281	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(8SG-EE7-VR1D, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**EYEPAT 0.1% Ophthalmic Solution**
	Label Claim	Each ml contains: Olopatadine HCl eq. to Olopatadine ..... 0.1% w/v (USP Specs).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Olopharm Ophthalmic Solution by Epharm Laboratories
	Pharmacotherapeutic Group of (API)	Selective H1-receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CURIA SPAIN S.AU. Parque Technologico, Parcela 105-A 47151 Boecillo, Valladolid, Spain. Spain
	Detail of stability batches of drug product	600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Hansel pharmaceuticals without timely intimation to DRAP, hence loan verification may be confirmed accordingly.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Olopat 0.1% ophthalmic solution of Ms Vega Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	Attached.
	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observation	Firm's response
	Justification shall be submitted for trial batch manufacturing prior to issuance of DML	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure

			process validation, preparedness, and continuity of operations while awaiting the official documentation.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

282	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(8UM-M96-1PYS, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-12-12,
	The proposed proprietary name / brand name	**LOTINOL 0.5% Ophthalmic Suspension**
	Label Claim	Each ml contains: Loteprednol Etabonate ....5.0mg (Innovator's Specs.).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Tobol Ophthalmic Suspension by MEDICAIDS PAKISTAN PVT LTD
	Pharmacotherapeutic Group of (API)	Ophthalmic Anti-inflammatory Agent (Corticosteroid)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shanghai Orgpharma Chemical Co., Ltd, 3rd Floor, Middle B, No.88, Beijing East Road, Taicang City,Suzhou City Jiangsu P.R.China(China)
	Detail of stability batches of drug product	600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Winthrox Laboratories without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Lotinol 0.5% Ophthalmic Suspension of Ms Winthrox
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observations	Firm's response
	Justification shall be submitted for trial batch manufacturing prior to issuance of DML	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial

			batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

	Decision	
	Approved Registration letter will be issued after verification of loan letter of API.	
283	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(XQP-US7-ZWRP, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Lintal 11 % Oral Powder**
	Label Claim	Each 1000 gm. Contains: Lincomycin HCl.....11 %
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000 gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,15 kg-De-Controlled,2.5 kg-De-Controlled,20 kg-De-Controlled,20gm-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,5 kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 25°C.
	For generic drugs (me-too Status)	ACLINCO 11 %
	Pharmacotherapeutic Group of (API)	Antimicrobial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
284	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(UNY-95E-EU6G, 2025-07-09)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Lintal 40 % Oral Powder**
	Label Claim	Each 1000 gm. Contains: Lincomycin HCl.....40 %
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place below 25°C.
	For generic drugs (me-too Status)	ACLINCO 40 % Reg# 116957
	Pharmacotherapeutic Group of (API)	Antimicrobial/Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
285	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(RGU-HXX-7HML, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Click-6 Oral Powder**
	Label Claim	Each Kg powder contains: Sodium benzoate (B.P) .....500gm, Ethanol B Aminophosphoric acid (M.S) ...100gm, Vitamin A (B.P) .....10000000 i.u, Vitamin E (B.P) .....2500mg, Vitamin K3 (B.P) .....1000mg, Vitamin C (B.P).....2500mg.
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,15 kg-De-Controlled,20 kg-De-Controlled,25 kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25□c - 30□c)
	For generic drugs (me-too Status)	Diurizone Water Soluble Powder (Reg. # 073908)
	Pharmacotherapeutic Group of (API)	vitamins and mineral supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
286	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(THE-Z2B-N1RG, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**NOVA SIGN INJECTION 250ML**
	Label Claim	Each ml contains: - Novaminsulfon.....40mgEtilefrin .....0.2mgCalcium gluconate .....100mgMagnesium gluconate .....10mgSodium salicylate .....7mgNicotinamide ..... 0.3mgCaffeine .....10mgBoric acid .....10mg(As Per Innovator‟s specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	NEVIT FORTE INJECTION REG. # 058987 (NAWAN LABORTORIES (PVT.)LTD. KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

287	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(TGL-MMM-4R75, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	**ETER DIMIZINE INJECTION(50ML),**
	Label Claim	Each ml contains:- Diminazine aceturate .....105mg Antipyrine.....131mg (As Per Innovator‟s specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRONIFAS INJECTION REG. NO. 080724 M/S. INTERVAC (PVT) LTD.,SHEIKHUPURA
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
288	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(RBG-158-87V5, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	**ETER CALCIO INJECTION(500ML)**
	Label Claim	Each 250ml Contains: - Calcium Gluconate .....50gm Sodium Dimethyl Aminomethyl Phenylphosphinite .....1gm Magnesium Camphosulphonate..... 2gm Boric Acid .....6gm Sorbitol 12.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CALCIO PH INJECTABLE SOLUTION REG. NO. 018843 PRIX PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
289	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(QWA-YPZ-GEDJ, 2025-05-17)
	Detail of Fee Submitted	37000.0, 2025-05-16,
	The proposed proprietary name / brand name	**ETER FLOR-30 INJECTION**
	Label Claim	Each ml contain Florfenicol.....300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	Elkoflor Injection Reg. No. 082491 (M/S ELKO ORGANIZATION (PVT.) LTD.KARACHI)
	Pharmacotherapeutic Group of (API)	ANtibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
290	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(77R-9NW-NH5U, 2024-10-26)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	**KETONOL INJECTION**
	Label Claim	Each ml contains:- Ketoprofen 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CATOPROFEN INJECTION REG. # 101472 (HILTON PHARMACEUTICALS KARACHI)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
291	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(38Z-BV9-157A, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	**: ETER NOR 20 ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Norfloxacin HCL.....20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled,100ml-De-Controlled,2.5 Liter -De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	NOR-OXIME ORAL LIQUID REG. NO. 080137 (BIO-OXIME PHARMACEUTICALS FAISALABAD)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
292	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(1G8-BZR-ZH4U, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	**ETER DIMIZINE INJECTION(100ML)**
	Label Claim	Each ml contains:- Diminazine aceturate .....105mg Antipyrine.....131mg (As Per Innovator‟s specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRONIFAS INJECTION REG. NO. 080724 M/S. INTERVAC (PVT) LTD.,SHEIKHUPURA
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
293	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(EUA-AJD-1V4B, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-26,
	The proposed proprietary name / brand name	**Neurocobal Injection 50ml**
	Label Claim	Each 3ml contains: - Thiamine HCl (Vitamin B1) .....100mg Pyridoxine HCl (Vitamin B6).....100mg Cyanocobalamine (Vitamin B12) 500mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	NEUROFOS INJECTION. REG. # 063582 (ZAKFAS PHARMACEUTICALS (PVT.) LTD, MULTAN)
	Pharmacotherapeutic Group of (API)	Multivitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
294	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(L3G-4RB-W7HX, 2025-07-07)

	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	**ETER DIMIZINE INJECTION(10ML),**
	Label Claim	Each ml contains Diminazine aceturate .....105mg Antipyrine.....131mg (As Per Innovator‟s specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRONIFAS INJECTION REG. NO. 080724 M/S. INTERVAC (PVT) LTD.,SHEIKHUPURA
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
295	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(39J-NW5-HV8P, 2024-10-24)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**ANTIAL INJECTION**
	Label Claim	Each ml contains:- Pheniramine maleate.....11.35mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	ANTIL INJECTION REG. # 074750 (IZFAAR PHARMACEUTICAL INDUSTRIES (PVT.)LTD.ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
296	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)**
	Application Form Dy. No / Tracking ID & date of submission	(T1E-PEE-49YQ, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Am Nix Oral Powder**
	Label Claim	Each 100gm contains: Amantadine HCl 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25°c - 30°c)
	For generic drugs (me-too Status)	Metadine Powder (Reg. No: 088040, Farm Aid Group)
	Pharmacotherapeutic Group of (API)	Antiparkinson
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel based on the available equipment / machinery required in production and quality control such as availability of FTIR, HPLC, UV-Visible Spectrophotometer, stability chambers etc., technical staff, SOPs, documents and commitment of the management
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Formulation contains AMANTADINE.Target specs are dog,cats and poultry.	
	Decision	
	Approved Approved upto 100g pack size	
297	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(WSQ-94W-SQ8N, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	**ETER CALCIO INJECTION (250ml)**
	Label Claim	Each 250ml Contains: - Calcium Gluconate .....50gm Sodium Dimethyl Aminomethyl Phenylphosphinite .....1gm Magnesium Camphosulphonate 2gm Boric Acid .....6gm Sorbitol 12.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CALCIO PH INJECTABLE SOLUTION REG. NO. 018843 (M/S PRIX PHARMACEUTICALS(PVT.)LTD. LAHORE)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
298	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(WR3-XJP-SXGD, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	**ETER NOR 25 ORAL LIQUID**
	Label Claim	Each 100ml contains:- Norfloxacin HCL.....25gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled,100ml-De-Controlled,2.5 Liter -De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled,50ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	NORMAK LIQUID REG. NO. 058943 (M/S A & K PHARMACEUTICAL FAISALABAD)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
299	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(S5X-238-QE92, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	**TILCO 30 INJECTION (500ML)**
	Label Claim	Each ml contains:Tilmycosin 300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500 ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	Tilcolina Injection Reg. No. 049674 Alina Combine Pharmaceuticals (Pvt.)Ltd.Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
300	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(77Y-LX6-RGYY, 2024-10-24)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**ETER COOL ORAL SOLUTION.**
	Label Claim	Each 1000ml contains:- Ascorbic acid ..... 60gm Potassium Chloride ..... 1.5gm Sodium Chloride ..... 9.5gm Sodium Citrate..... 3.9gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Litre-De-Controlled,100ml-De-Controlled,500ml -De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	EC-COOL ORAL SOLUTION. Reg. No. 034544 (ATTABAK PHARMACEUTICAL INDUSTRIES ISLAMABAD)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
301	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(4AH-BZ4-8TEU, 2025-08-10)

	Detail of Fee Submitted	93000.0, 4200.0 2025-07-21, 2025-08-16
	The proposed proprietary name / brand name	**Bromithol 20-40 Oral Liquid**
	Label Claim	Each ml contains: Bromhexine HCl (BP)..... 20 mg Menthol (usp).....40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	BROMITHOL Oral Liquid 20/40 (Registration No. 118387)
	Pharmacotherapeutic Group of (API)	Mucolytic (Antiviral)
	Name, address of Manufacturing site:	ACME Pharmaceuticals-Plot No 29, Street No SS_2, RCCI, Industrial Estate Rawat-
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
302	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(BQM-HXQ-ZD9R, 2025-08-10)
	Detail of Fee Submitted	93000.0, 4200 2025-07-21, 2026-02-18
	The proposed proprietary name / brand name	**HIGH DOX Oral Liquid**
	Label Claim	Each 1 L Contains: Colistin Sulphate.....500 MIU Tylosin Tartrate.....100 g Doxycycline HCl .....200 g Bromohexine HCl.....10 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	High Dox Oral Liquid (Reg # 088041) Farm Aid Group Haripur
	Pharmacotherapeutic Group of (API)	ANTIBACTERIAL
	Name, address of Manufacturing site:	Farm AID Group-Plot No 3/2, Phase-I&II Hattar Industrial Estate Haripur-
	GMP status of the firm	Grant of Section

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
303	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(BQR-HLW-HUHH, 2025-08-10)
	Detail of Fee Submitted	93000.0, 4200 2025-07-21, 2026-02-18
	The proposed proprietary name / brand name	**SPIROX ORAL POWDER**
	Label Claim	Each gm. Contains: Lincomycin as HCl.....50 mg Spectinomycin HCl.....75 mg Spiramycin Adipate.....25 mg Bromohexine HCl.....5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Spirox Powder (Reg # 118635) Farm Aid Group Haripur
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Farm AID Group-Plot No 3/2, Phase-I&II Hattar Industrial Estate Haripur-
	GMP status of the firm	Grant of Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size.	
304	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(VRB-HPM-DJQX, 2025-08-10)
	Detail of Fee Submitted	93000.0, 4200 2025-07-21, 2026-02-18
	The proposed proprietary name / brand name	**FAGOBAN POWDER**

	Label Claim	Each 12 gm. Contains: Neomycin Sulphate.....400 mg. Streptomycin Sulphate.....400 mg. Sulphaguanidine.....4 gm. Kaolin.....4 gm. Pectin.....400 mg. Bismuth Subnitrate.....2 gm. Vitamin A Acetate.....80000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,12gm-De-Controlled,15gm-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,30gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Fagoban Powder (Reg # 114866) Farm Aid Group Haripur
	Pharmacotherapeutic Group of (API)	Antibacterial, Antibiotic, Antidiarrheal.
	Name, address of Manufacturing site:	Farm AID Group-Plot No 3/2, Phase-I&II Hattar Industrial Estate Haripur-
	GMP status of the firm	Grant of Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
305	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(WBQ-SL3-H9GL, 2025-08-10)
	Detail of Fee Submitted	93000.0, 4200.0 2025-07-21, 2025-08-16
	The proposed proprietary name / brand name	**Bromithol 10-20 Oral Liquid**
	Label Claim	Each ml contains Bromhexine HCl (BP)..... 10 mg Menthol (usp)..... 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	BROMITHOL Oral Liquid 10/20 (Registration No. 117031)
	Pharmacotherapeutic Group of (API)	Mucolytic (Antiviral)
	Name, address of Manufacturing site:	ACME Pharmaceuticals-Plot No 29, Street No SS_2, RCCI, Industrial Estate Rawat-
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved Approved upto 1 litre pack size.	
306	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(TD7-67D-NLBV, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	**QUINADOX POWDER**
	Label Claim	Each kg contains: - Olaquindox..... 100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm,-De-Controlled,10gm-De-Controlled,10kg -De-Controlled,1Kg,-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	OLANDOX POWDER REG.NO. 101443 M/S STAR LABORTORIES LAHORE
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size	
307	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(PUY-LT8-PPME, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	**NOVA-VIT INJECTION (100ML)**
	Label Claim	Each ml contains: Each ml contains:- Novaminsulfon (USP) .....40mg Etilefrin (as HCL) (BP) .....0.2mg Calcium Gluconate USP.....100mg Magnesium Gluconate USP.....10mg Sodium Salicylate BP .....7mg Nicotinamide BP.....0.3mg Caffeine.....10mg Boric acid.....10mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRI-SEDAXVIT INJECTION REG. # 079256 M/S. PRIX PHARMACEUUTICAL (PVT.)LTD. KARACHI.
	Pharmacotherapeutic Group of (API)	Electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
308	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(2JU-VUM-TXQ7, 2024-10-23)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**Eter Enzyme Powder**
	Label Claim	Each 1000gm contains:- Proteases .....100,000IU Lipases ..... 23000IU Amylases ..... 125000IU Mannases .....20000IU Bacillus subtilis ..... 1000mg Vitamin E ..... 20gm Vitamin C 40gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,100gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ENERGINE ORAL POWDER. Reg.# 033236(MEDI EXCEL PHARMACEUTICALS (PVT.) LTD)
	Pharmacotherapeutic Group of (API)	Enzymes/Vitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size	

309	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)**
	Application Form Dy. No / Tracking ID & date of submission	(4DG-N1G-6WV8, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	**ETER OLAVIT POWDER.**
	Label Claim	Each 1000gm contains:- Olanquindox.....100gm Vitamin A.....0.6miu Vitamin D3.....0.4miu Vitamin E.....0.05miu
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,200gm-De-Controlled,25 Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	OLADOX ORAL POWDER REG.NO. 063810 (M/S BIOGEN PHARMA (PVT.)LTD. ISLAMABAD.)
	Pharmacotherapeutic Group of (API)	Antibiotics & Multivitamins.
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size	
310	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)**
	Application Form Dy. No / Tracking ID & date of submission	(S4T-7AE-SZVW, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-05,
	The proposed proprietary name / brand name	**Niclozone Oral Suspension**
	Label Claim	Niclozone Oral Suspension contains : Niclosamide 250 gm/1 Liter Oxfendazole 10 gm/1 Liter
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml, 20ml, 50ml, 100ml, 250ml, 500ml, 1liter, 5li-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room Temperature. Protect from direct sunlight.
	For generic drugs (me-too Status)	Niczole suspension Reg#063865

	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has valid DML but GMP inspection has not been done yet.	
	Decision	
	Approved Approved upto 1 litre pack size	
311	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(2G9-HYZ-ZTZX, 2025-04-05)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 1000MCG INJECTION**
	Label Claim	Each ml contains: Cyanocobalamin.....1000mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Cyancob 1000 Injection (Reg. # 074021) Prix Pharmaceuticals Pvt Ltd, Pakistan
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
312	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(AT1-SR5-G58G, 2025-04-11)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 500MCG INJECTION**
	Label Claim	Cyanocobalamin 500mcg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	CYANOCO Injection (Reg. # 041241) International Pharma Labs
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
313	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(E7Q-NDJ-VMMV, 2025-04-05)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 1000MCG INJECTION**
	Label Claim	Each ml contains: Cyanocobalamin.....1000mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Cyancob 1000 Injection (Reg. # 074021) Prix Pharmaceuticals Pvt Ltd, Pakistan
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
314	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(HYY-E2Q-JBBM, 2025-04-11)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 500MCG INJECTION**
	Label Claim	Cyanocobalamin 500mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	CYANOCO Injection (Reg. # 041241) International Pharma Labs
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
315	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(VT1-ZT4-A2VD, 2025-04-05)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 250MCG INJECTION**
	Label Claim	Each ml contains: Cyanocobalamin.....250mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat
	For generic drugs (me-too Status)	Cynosel Injection (Reg. # 094483) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Vitamin B 12

	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
316	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(PY8-3WS-NAX8, 2025-04-05)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**CYANOXON 250MCG INJECTION**
	Label Claim	Each ml contains: Cyanocobalamin.....250mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat
	For generic drugs (me-too Status)	Cynosel Injection (Reg. # 094483) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
317	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(JAJ-TZS-GV32, 2025-04-05)

	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**BUPEXON INJECTION**
	Label Claim	Each ml contains: bupervaquone.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Parvon Injection (Reg. # 034580) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiprotozoal agent, Antitheilerial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
318	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(P18-2UT-3RYG, 2025-04-05)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**BUPEXON INJECTION**
	Label Claim	Each ml contains: Bupervaquone ..... 50mg (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Parvon Injection (Reg. # 034580) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiprotozoal agent, Antitheilerial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
319	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(PUZ-TXB-S1TL, 2025-04-03)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**Axomec 1.2% Injection**
	Label Claim	Each ml contains: Ivermectin .....12mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c)
	For generic drugs (me-too Status)	MECTOGEN INJECTION (REG # 075623) BIO GEN PHARMACEUTICALS RAWAT
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
320	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(UYV-P83-NUAN, 2025-04-04)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**Axomec 1.2% Injection**
	Label Claim	Each ml contains: Ivermectin .....12mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.

	For generic drugs (me-too Status)	Mectogen Injection (Reg. # 075623), Bio Gen Pharmaceuticals Rawat
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
321	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(WDJ-V6H-X4XD, 2025-04-03)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**KETOFARM INJECTION**
	Label Claim	Each ml contains: Ketoprofen 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C.
	For generic drugs (me-too Status)	Ketoject Injection (Reg. # 043141) Selomore Pharmaceuticals Lahore
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
322	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(ZY3-EVW-7TSD, 2025-04-04)

	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**Axomec 1.2% Injection**
	Label Claim	Each ml contains: Ivermectin .....12mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c) Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Mectogen Injection (Reg. # 075623), Bio Gen Pharmaceuticals Rawat
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
323	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)**
	Application Form Dy. No / Tracking ID & date of submission	(T9T-TGR-6J2W, 2025-04-03)
	Detail of Fee Submitted	37000.0, 2025-03-26,
	The proposed proprietary name / brand name	**KETOFARM INJECTION**
	Label Claim	Each ml contains: Ketoprofen 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at refrigeration (15□c - 25□c)
	For generic drugs (me-too Status)	Ketoject Injection (Reg. # 043141) Selomore Pharmaceuticals Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
324	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(6Z5-Q1N-L8QQ, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**BRONCHIS INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Amoxicillin As Trihydrate.....150mg Gentamycin Sulphat 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	LEWISTO 190 INJECTION (109197) ARCHARD PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
325	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(VXG-MJ3-81YJ, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**BRONCHIS INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Amoxicillin As Trihydrate.....150mg Gentamycin Sulphate 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	LEWISTO 190 INJECTION (109196) ARCHARD PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--

	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
326	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(5QU-H6G-127J, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**TOPSTONE 450 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin (BP) .....200mg Streptomycin Sulphate (BP) 250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	I-PRO-STREP INJECTION (080524) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
327	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(S3S-XJ2-NMLP, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**TOPSTONE 360 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin (BP).....200mg Streptomycin Sulphate (BP).....160mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled

	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	I-PRO-STREP INJECTION (080525) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
328	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(B2T-PJ3-G5D2, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**PROTHIN INJECTION**
	Label Claim	: Each ml contains: (As Per Innovator Spec.) Benzathine Penicillin G (BP) .....100,000 IU Procaine Penicillin G (USP) .....150,000 IU Dihydrostreptomycin Sulphate EQ To Dihydrostreptomycin(BP Vet) 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	BPS-LA INJECTION (080951) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
329	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(7LN-MXU-ET68, 2025-11-13)

	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MEGPEN 450 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin G (USP).....200mg Dihydrostreptomycin Sulphate (BP Vet).....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	STREP-PRO INJECTION (080955) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
330	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(2PH-33S-ABEZ, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MEGPEN 360 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin G (USP).....200mg Dihydrostreptomycin Sulphate (BP Vet).....160mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	STREPTOCAINE INJECTION (106742) GRAND PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
331	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(SD8-HXQ-HBNH, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**PROTHIN INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Benzathine Penicillin G (BP) .....100,000 IU Procaine Penicillin G (USP) .....150,000 IU Dihydrostreptomycin Sulphate EQ To Dihydrostreptomycin(BP Vet) 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30 °C
	For generic drugs (me-too Status)	BPS-LA INJECTION (080951) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
332	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(251-RRY-SSG6, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**MOXCOL 12% INJECTION**
	Label Claim	: Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....120mg Colistine Sulphate.....3,00,000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	COLICILLIN L.A 12% INJECTION (50ml) (087152) BAARIK PHARMA

	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
333	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(V7W-GB4-GEX3, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOXLI MOX 50% POWDER**
	Label Claim	Each 1000gm powder contains Amoxicillin as Trihydrate BP..... 500g (BP Spec.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100G-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	RYMOX-50% W/S POWDER (069665) ZUMRAS PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
334	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(N6E-P83-SWP5, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**DM-PSB PREMIX POWDER**

	Label Claim	Each Kg powder contains (Innovator's Spec.) Procaine Penicillin BP..... 12g Streptomycin Sulphate BP..... 36g Zinc Bacitracin BP..... 52g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,100G-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	PSB-100 W/S POWDER (013257) ELPA LABORATORIES
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
335	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(JRE-HRH-JWED, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**PECLIN MOX 1000 POWDER**
	Label Claim	Each 1000gm powder contains (Innovator's Spec.) Lincomycin HCl BP..... 8.8g Spectinomycin 2HCL BP..... 8.8g Amoxicillin As Trihydrate BP.....,. 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	LINCOSAC-200 W/S POWDER (081696) SANNA LABORATORIES
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved Approved upto 1 kg pack size	
336	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(JA5-54B-UDX7, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MEGPEN 400 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin G (USP).....200,000IU Dihydrostreptomycin Sulphate (BP Vet).....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	STREPTOMET INJECTION (080954) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
337	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(E95-VMA-222Q, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**PECLIN MOX 20 POWDER**
	Label Claim	: Each 100gm powder contains (Innovator's Spec.) Lincomycin HCl BP..... 8.8g Spectinomycin HCL BP..... 8.8g Amoxicillin Trihydrate BP.....,. 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10Kg-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,500G-De-Controlled,5Kg-De-Controlled,KG-De-Controlled

	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AMOXPECLIN W/S POWDER (102086) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
338	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(1ZS-29U-H88B, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**BERVIS INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Amoxicillin(As Amoxicillin Trihydrate).....140mg Clavulanic Acid as Potasium Clavulanate.....35mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	MOXI-CLAV INJECTION (103816) GRAND PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
339	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(2N4-1DY-3Q31, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,

	The proposed proprietary name / brand name	**ICONIC 150 INJECTION**
	Label Claim	Each ml contains: (As PerInnovator Spec.) Amoxicillin(as Trihydrate).....100mg Cloxacillin(As Sodium).....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	I MOCLOX INJECTION (074762) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
340	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(2S9-6UR-22MU, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**BROTIN POWDER**
	Label Claim	Each 1000g powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate B.P ..... 100g Lincomycin HCl ..... 50g Colistin Sulphate B.P..... 500MIU Bromhexine HCl 5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000g-De-Controlled,100g-De-Controlled,10kg-De-Controlled,250g-De-Controlled,25kg-De-Controlled,500g-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	COLAB W/S POWDER (079839 DECENT PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends renewal of DML and grants additional sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

	Approved upto 1 kg pack size	
341	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(4RB-8GS-HRW8, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**MOXCOL 12% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....120mg Colistine Sulphate.....3,00,000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	COLICILLIN L.A 12% INJECTION (100ml) (087153) BAARIK PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
342	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(8V9-ZXA-7X33, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**ICONIC 250 1INJECTION**
	Label Claim	Each ml contains: (As PerInnovator Spec.) Amoxicillin(as Trihydrate)..... 125mg Cloxacillin(As Sodium)..... 125mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	MOX INJECTION (074761) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
343	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(63N-GAM-AJGY, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**D MOX LA 15% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	AMOCILLIN 15% INJECTION (50ml) (113595) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
344	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(E84-G21-J62E, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOX MAARSON 15% POWDER**
	Label Claim	Each 1000gm powder contains (Innovator's Spec.) Amoxicillin As Trihydrate BP.....,,,,,.... 15% Colistin sulphate BP..... 550MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100g-De-Controlled,10KG-De-Controlled,250g-De-Controlled,25KG-De-Controlled,500g-De-Controlled,5KG-De-Controlled

	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	FULL MOSK W/S POWDER (087192) FARM AID GROUP
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
345	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(E81-VV3-N577, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**SPECBRO POWDER**
	Label Claim	Each 100g powder contains (As Per Innovator Spec.) Amoxicillin as Trihydrate B.P ..... 10g Spectinomycin As HCl ..... . 5.0g Colistin Sulphate B.P..... 50MIU Bromhexine HCl 0.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AS-PLUS W/S POWDER (071063) ATTABAK PHARMA
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
346	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**

	Application Form Dy. No / Tracking ID & date of submission	(W58-ZTS-NRUT, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**D MOX LA 20% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AMOCILLIN 20% LA INJECTION (100ml) (113598) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
347	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(WUL-S42-TJ8E, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOX MAARSON 23% POWDER**
	Label Claim	: Each 100gm powder contains (Innovator's Spec.) Amoxicillin As Trihydrate BP.....,,,,,.... 23G Colistin sulphate BP..... 100MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100G-De-Controlled,25 Kg-De-Controlled,250G-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	ATC-PLUS W/S POWDER (088113) SANNA LABOTERIES FSD
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved Approved upto 1 kg pack size.	
348	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(R7G-Q7X-U82H, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**VENROMOX E POWDER**
	Label Claim	Each gm powder contains (Innovator's Spec.) Amoxicillin Trihydrate BP EQ TO BASE..... 200mg Lincomycin HCL BP EQ TO BASE..... . 88mg Spectinomycin Sulphate BP EQ TO BASE ..... 88mg Vitamin E Acetate USP..... 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,100g-De-Controlled,25 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	LINCOMOXEL PLUS W/S POWDER (080960) SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	Antibacterials, Vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
349	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(S47-7LH-6D32, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**DEXOTIN 50 POWDER**
	Label Claim	Each 100gm powder contains (INNOVATOR'S Spec.) Amoxicillin Trihydrate BP ..... 50g Colistin sulphate BP ..... 50MIU Dextrose Anhydrous BP qs..... 100g

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	EUROMOX-50 W/S POWDER (080156) DECENT PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
350	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(S6P-S1M-GTVJ, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**ICONIC 150 INJECTION**
	Label Claim	: Each ml contains: (As PerInnovator Spec.) Amoxicillin(as Trihydrate).....100mg Cloxacillin(As Sodium).....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	I MOCLOX INJECTION (074762) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
351	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**

	Application Form Dy. No / Tracking ID & date of submission	(SML-ZJ6-ULR5, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOX MAARSON 50% POWDER**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Amoxicillin As Trihydrate BP.....,,,,.... 50g Colistin sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100G-De-Controlled,10kg-De-Controlled,250g-De-Controlled,25kg-De-Controlled,500g-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	AMOX-C MAARSON W/S POWDER (071054) ATTABAK PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant the addition section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
352	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(AQP-BLU-TUZS, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**DM STEPEN 2.5G DRY POWDER INJECTION**
	Label Claim	Each dry powder vial contains: (As per Innovator spec.) Benzyl Penicillin .....500,000 IU Penicillin G Procaine.....15, 00,000 IU Streptomycin Sulphate.....2.5 GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4.3G -De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	Strellin 20/2.5 Injection (113467) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
353	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(VA8-URU-2YVR, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**PECLIN MOX 10 POWDER**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Lincomycin As HCl BP..... 5g Spectinomycin As HCL BP..... 5g Amoxicillin As Trihydrate BP.....,. 10g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10Kg-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,500G-De-Controlled,5Kg-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	MOXI LINE W/S POWDER (087197) FARM AID GROUP
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
354	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(BT8-PUG-HZYA, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**STOP PEN DRY POWDER INJECTION**
	Label Claim	Each dry powder vial contains: (As per Innovator spec.) Penicillin G Procaine.....3, 000,000 IU Penicillin G Sodium .....1,000,000 IU Dihydrostreptomycin Sulphate.....5 GM

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	DG Strept Injection (113469) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Penicillin Aminoglycoside antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
355	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(U14-VMJ-2YXD, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**MOXCOL 20% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....20mg Colistine Sulphate..... . 0.5MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	COLISTIN-MOX 20/.5 INJECTION (100ml) (113602) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
356	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(MPP-HS9-VJR8, 2025-11-12)

	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**ICONIC 250 INJECTION**
	Label Claim	Each ml contains: (As PerInnovator Spec.) Amoxicillin(as Trihydrate)..... 125mg Cloxacillin(As Sodium)..... 125mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	MOX INJECTION (074761) INTERNATIONAL PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
357	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(Q4Z-65W-7UPS, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MOXCOL 10% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....100mg Colistine Sulphate.....2,50,000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	COLIMOXIN INJECTION (100ml) (034576) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

358	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(W13-5DU-LEBZ, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**D MOX LA 15% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AMOCILLIN 15% INJECTION (100ml) (113596) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
359	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(UUB-A2A-76ZP, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**BENSEN P DRY POWDER INJECTION**
	Label Claim	Each dry powder vial contains: (As per Innovator spec.) Procaine Penicillin .....3,000,000 IU Benzyl Penicillin .....1000,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3G-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	B-Penicillin Injection (112313) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Penicillin antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
360	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(QH9-NLN-SRPE, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**DEXOTIN 23 POWDER**
	Label Claim	Each 1000gm powder contains (INNOVATOR'S Spec.) Amoxicillin Trihydrate BP ..... 230GM Colistin sulphate BP ..... 1000MIU Dextrose Anhydrous BP qs..... 1000g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	SENACILIN W/S POWDER (079845) DECENT PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
361	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(JZA-TX3-2RV4, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**DM STEPEN 5G DRY POWDER INJECTION**
	Label Claim	: Each dry powder vial contains: (As per Innovator spec.) Benzyl Penicillin ..... 500,000 IU Penicillin G

		Procaine..... 15, 00,000 IU Streptomycin Sulphate..... 5 GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	6.8G/Vails-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	BIOPEN 5G Injection (081718) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Penicillin Aminoglycoside antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
362	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(NUS-TUZ-5XNH, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOXLI MOX 80% POWDER**
	Label Claim	Each gm powder contains Amoxicillin Trihydrate BP 918.23mg Eq to 800mg Amoxicillin Base (BP Spec.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 Kg-De-Controlled,100G-De-Controlled,25 Kg-De-Controlled,250G-De-Controlled,500G-De-Controlled,5Kg-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	DOKAMOX-80% W/S POWDER (082505) ORIENT ANIMAL HEALTH
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
363	Case Category	New Section (Sabahat Zehra)

	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(THZ-L7U-JH4G, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**M COTIN 10 POWDER**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Lincomycin HCl BP..... 5g Spectinomycin Sulphate BP..... 5g Amoxicillin As Trihydrate BP.....,. 10g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	SPECTOCILLIN W/S POWDER (088641) BAARIK PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
364	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(UUM-4VR-82P6, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOX MAARSON 20% POWDER**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Amoxicillin As Trihydrate BP.....,,,,.... 20G Colistin sulphate BP..... 80MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100G-De-Controlled,10Kg-De-Controlled,25 Kg-De-Controlled,250G-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AMOXITIN C W/S POWDER (071062) ATTABAK PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterial

	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
365	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(3GV-9D2-81W2, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**PECLIN MOX 9 POWDER**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Lincomycin HCl BP..... 9g Spectinomycin 2HCL BP..... 8.8g Amoxicillin As Trihydrate BP.....,. 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,100G-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,500G-De-Controlled,5Kg-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	LINCO SPEC-A W/S POWDER (073942) INSHAL PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
366	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(3JW-VWM-QXBP, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOX MAARSON 15/50 POWDER**

	Label Claim	: Each 100gm powder contains (Innovator's Spec.) Amoxicillin As Trihydrate BP.....,,,,,.... 15g Colistin sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100G-De-Controlled,10kg-De-Controlled,250G-De-Controlled,25kg-De-Controlled,500G-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30 °C
	For generic drugs (me-too Status)	MOXIBAK C W/S POWDER (062175) ATTABAK PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
367	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(6QL-LHN-YDU7, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**M COTIN 20 POWDER**
	Label Claim	: Each 100gm powder contains (Innovator's Spec.) Lincomycin As HCl BP..... 8.8g Spectinomycin As Sulphate BP..... 8.8g Amoxicillin As Trihydrate BP.....,. 20g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,100G-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled,Kg-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	AMICOSIN E W/S POWDER (085482) VETZ PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved Approved upto 1 kg pack size	
368	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(8DN-NYX-2JE3, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MYCLIN MOX POWDER**
	Label Claim	Each Kg powder contains (Innovator's Spec.) Amoxicillin as Trihydrate BP..... 100g Colistin sulphate BP..... 50g Neomycin Sulphate BP..... 200g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	NEO AC W/S POWDER (079844) DECENT PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterials
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
369	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(954-RQZ-9GRZ, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOXLI MOX 60% POWDER**
	Label Claim	Each 1000gm powder contains (BP) Amoxicillin as Trihydrate BP..... 600g (BP Spec.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100G-De-Controlled,250G-De-Controlled,25Kg-De-Controlled,5 Kg-De-Controlled,500G-De-Controlled

	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	TRIGER W/S POWDER (080958) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
370	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(99Q-UDA-H314, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MOXCOL 10% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....100mg Colistine Sulphate.....2,50,000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	COLIMOXIN INJECTION (50ml) (034576) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
371	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(9DU-6ZL-5EJ4, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,

	The proposed proprietary name / brand name	**BRONCHIS 40 INJECTION**
	Label Claim	: Each ml contains: (As Per Innovator Spec.) Amoxicillin AS Trihydrate.....150mg Gentamycin Sulphate.....40,000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	LEWISTO 109194 ARCHARD PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
372	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(AT3-NAV-SESE, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-10-28,
	The proposed proprietary name / brand name	**MOXLI MOX 70% POWDER**
	Label Claim	Each 100gm powder contains (BP) Amoxicillin Trihydrate BP Eq to 70g Amoxicillin Base..... (BP Spec.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100G-De-Controlled,10KG-De-Controlled,250G-De-Controlled,25KG-De-Controlled,500G-De-Controlled,5KG-De-Controlled,KG-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	PRIMOX W/S POWDER (074032) PRIX PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	

373	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(DM1-LLX-PLDY, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**TOPSTONE 400 INJECTION**
	Label Claim	Each ml contains: (As Per Innovatror Spec.) Procaine Penicillin (BP).....200,000IU Streptomycin Sulphate (BP).....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	STREP-STREP INJECTION (057047) LEADS PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
374	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(DR3-PPD-EH3X, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**PENZYL DRY POWDER INJECTION**
	Label Claim	: Each dry powder vial contains: (As per Innovator spec.) Benzyl Penicillin ..... 500,000 IU Streptomycin Sulphate..... 5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	G-BENZ Injection (106731) GRAND PHARMA
	Pharmacotherapeutic Group of (API)	Penicillin Aminoglycoside antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
375	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(DRG-X11-U2UE, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**MOXCOL 20% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin As Trihydrate.....20mg Colistine Sulphate..... . 0.5MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	COLISTIN-MOX 20/.5 INJECTION (50ml) (113601) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
376	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(R64-3X3-DQYD, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**BERVIS INJECTION**
	Label Claim	: Each ml contains: (As Per Innovator Spec.) Amoxicillin(As Amoxicillin Trihydrate) .....140mg Clavulanic Acid as Potasium Clavulanate 35mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C

	For generic drugs (me-too Status)	MOXI-CLAV INJECTION (103816) Grand Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
377	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(P1Q-P2V-3E6N, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MEGPEN 400 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin G (USP).....200,000IU Dihydrostreptomycin Sulphate (BP Vet).....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	STREPTOMET INJECTION (080954) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	Broad-spectrum antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
378	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(H3L-7ZW-MLYU, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-10,

	The proposed proprietary name / brand name	**MAARSON 40 DRY POWDER INJECTION**
	Label Claim	Each dry powder vial contains: (As per Innovator spec.) Penicillin G Procaine.....4, 000,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	PP Cillin 4-M Injection (112338) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
379	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(MBA-3R8-Y2RN, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**MEGPEN 450 INJECTION**
	Label Claim	Each ml contains: (As Per Innovator Spec.) Procaine Penicillin G (USP).....200MG Dihydrostreptomycin Sulphate (BP Vet).....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	STREP-PRO INJECTION (080955) SELMORE PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

380	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(TQ4-1JA-U1E7, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-05,
	The proposed proprietary name / brand name	**D MOX LA 20% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	AMOCILLIN 20% LA INJECTION (50ml) (113597) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
381	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(RQ6-NL6-VLEN, 2025-07-09)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**Neotal 70% Oral Powder**
	Label Claim	Each 1 kg Contains: NEOMYCIN SULPHATE 70% w/w.....700 gm. /1000gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25 c - 30 c)
	For generic drugs (me-too Status)	HIGHNEO 70% Oral Powder (Reg. # 116971)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size	
382	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(S2T-STU-LVP4, 2025-06-26)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**C-TAL Oral Liquid**
	Label Claim	Each ml Contains: Enrofloxacin .....75 mg Sulfametoxypyridazine.....75 mg Sulphmethazine.....50 mg Trimethoprim.....25 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Litter-De-Controlled,100ml-De-Controlled,2.5 Litter-De-Controlled,20 Litter-De-Controlled,20ml-De-Controlled,25 Litter-De-Controlled,250ml-De-Controlled,5 Litter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. Store at room temperature (25 c - 30 c)
	For generic drugs (me-too Status)	Cina T.S
	Pharmacotherapeutic Group of (API)	Antibacterial Agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size	
383	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(SL6-NZ6-PP7B, 2025-07-09)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**Neotal100% Oral Powder**
	Label Claim	Each 1 kg Contains: NEOMYCIN SULPHATE 100% w/w.....1000 gm. /1000gm

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25 c - 30 c)
	For generic drugs (me-too Status)	NEOROX 100 Oral Powder Reg# 111294
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
384	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(U3M-MAW-393H, 2025-07-10)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**Pivo-Dek Oral Powder**
	Label Claim	Each 1 kg Contains: Vitamin A.....2, 00, 00,000 IU Vitamin D3.....20, 00,000 IU Vitamin E.....6,000 mg Vitamin K3.....5,000 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place below 30□c
	For generic drugs (me-too Status)	Symodek Oral Powder Reg#013679
	Pharmacotherapeutic Group of (API)	Vitamin supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	

385	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(VV2-8TZ-URGV, 2025-06-27)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**Cure Fort Oral Powder**
	Label Claim	Each 1 Kg Contains: Vitamin A.....15, 000, 000 IU Calcium Pentothenate.....10,000 mg Vitamin D3.....300, 0000 IU Nicotinic Acid.....25,000 mg Vitamin E.....6000 mg Folic Acid.....750 mg Vitamin K3.....4000 mg Vitamin C.....15,000 mg Vitamin B1.....5000 mg Vitamin B12.....9000 mcg Vitamin B2.....6000 mg Vitamin B6.....4000 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20gm-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place below 30□c
	For generic drugs (me-too Status)	SYMOSTRESS Oral Powder
	Pharmacotherapeutic Group of (API)	Vitamin Supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size	
386	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(995-1ZM-J31T, 2025-06-26)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	**Leva Q Oral Liquid**
	Label Claim	Each 1 L Contains: LEVAMISOLE 15 mg/ml
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100ml-De-Controlled,120ml-De-Controlled,2.5 Littre-De-Controlled,20 Litter-De-Controlled,25 Litter-De-Controlled,30ml-De-Controlled,5 Litter-De-Controlled,60ml-De-Controlled

	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	LEVACOL 1.5 %
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size	
387	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(T1A-416-9A63, 2025-07-09)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26
	The proposed proprietary name / brand name	**DANOTAL Oral Powder**
	Label Claim	Each 1 gm powder contains Danofloxacin....100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10kg-De-Controlled,15kg-De-Controlled,1kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25□c - 30□c)
	For generic drugs (me-too Status)	Danocin 10% Powder (Reg. # 063697)
	Pharmacotherapeutic Group of (API)	Antibiotic / Antibacterial.
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size	
388	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(WU5-QJS-71T8, 2025-06-27)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-26

	The proposed proprietary name / brand name	**Vigo Fast Oral Powder**
	Label Claim	Each 100 g Contains: Vitamin D3.....2 gm. L-Lysine.....25 gm. Vitamin E.....9 gm. DL-Methionine.....50 gm. Choline Chloride.....100 gm. Virginiamycin.....12 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm -De-Controlled,25kg-De-Controlled,500gm -De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place below 30□c Protect from light and keep away from the reach of children.
	For generic drugs (me-too Status)	Supercine TM
	Pharmacotherapeutic Group of (API)	ANTIBACTERIAL + MULTI VITAMINS
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
389	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(QVJ-GQU-XSXZ, 2025-07-29)
	Detail of Fee Submitted	37000.0, 2025-07-18,
	The proposed proprietary name / brand name	**PRIMISOL 300 BOLUS**
	Label Claim	Each bolus contains: Levamisole HCl .....300 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x5's & 10x10's boli in Blister Pack/Box (Each bl-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Leva 300 Bolus Regd. No. 073987
	Pharmacotherapeutic Group of (API)	anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has applied for the renewal of DML vide Tracking ID # NA4-EM1-WLXB. However firm has valid GMP certificate.	
	Decision	

	Approved	
390	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	**ATCO LIFE SCIENCES (PRIVATE) LIMITED** B-18 S.I.T.E. Karachi **(051)**
	Application Form Dy. No / Tracking ID & date of submission	(5B8-AUV-6GBS, 2025-09-16)
	Detail of Fee Submitted	313500.0, 2025-08-07,
	The proposed proprietary name / brand name	**OLATAB 100mg Tablet**
	Label Claim	Each film coated tablet contains: Olaparib 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3×10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile are Attached and performed against the Lynparza ®l 00 Film Coat ed Tablet , AstraZenec a AB, Sweden
	Name, address of Marketing Authorization Holder:	Atco Life Sciences (Private) Limited., B-18 S.I.T.E., Karachi-75700., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted CoPP ,Certificate no. DGDA/6-214/15317 dated 28-08-2024 issued by Directorate General of Drug Administration, Bangladesh. Product specific Letter of Authorization dated May 31,2025 is submitted by the applicant.
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 12 Months Data of Long-Term Stability is attached in Module 3.
	The status in reference regulatory authorities	Lynparza 100 mg film-coated tablets manufactured by AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge, CB2 0AA, U.K.
	Evaluation Remarks	
	Submit filled batch manufacturing record of all three stability batches. Firm in their reply informed that, in accordance with the Finished Product Release SOP of the manufacturer, M/s Eskayef Pharmaceuticals Ltd. (SOP No. R/06/009), all batch-related manufacturing documents are retained for a period of one year after the expiry of the respective batch. Accordingly, as the stability batches (Mfg date: Feb,2022) under reference have completed their defined document retention period, the filled Batch Manufacturing Records are no longer available in the manufacturer's archive.	
	Decision	
	Deferred	

	Deferred for submission of complete stability data of three commercial batches of the drug product performed as per zone-IV conditions. All batch-related manufacturing documents for these stability batches should be maintained and available. The stability data should be submitted along with the corresponding Batch Manufacturing Records (BMRs).	
391	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(9R5-SJY-9WSV, 2025-10-07)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Vastat 150mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....150mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	hypoxia-inducible factor prolyl-hydroxylase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm submitted six month stability data conducted at 40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from M/s. Horizon Healthcare
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the innovator product Vafseo 150mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%
	The status in reference regulatory authorities	Registered drug by US FDA (VAFSEO (vadadustat) tablets, for oral use)
	GMP status of the firm	GMP Issuance date: 07-04-2025 Valid Date: 06-04-2028
	Evidence of approval of manufacturing facility	Firm submitted the renewal of DML Letter mentioned that firm has tablet (general section).
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	

392	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(ESH-LDL-9GHH, 2025-10-08)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Vastat 450mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....450mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	hypoxia-inducible factor prolyl-hydroxylase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm submitted six month stability data conducted at 40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from M/s. Horizon Healthcare.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the innovator product Vafseo 450mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted stability data of drug substance performed at 40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%.
	The status in reference regulatory authorities	Registered drug by US FDA (VAFSEO (vadadustat) tablets, for oral use)
	GMP status of the firm	GMP Issuance date: 07-04-2025 Valid Date: 06-04-2028
	Evidence of approval of manufacturing facility	Firm submitted the renewal of DML Letter mentioned that firm has tablet (general section).
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
393	Case Category	New Molecule/Formulation (Saima Hussain)

	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(T5B-UJ9-SYWJ, 2025-10-08)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Vastat 300mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....300mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	hypoxia-inducible factor prolyl-hydroxylase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm submitted six month stability data conducted at 40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from M/s. Horizon Healthcare.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the innovator product Vafseo 300mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted stability data of drug substance performed at 40°C ± 2°C / NMT 75% RH, 30°C ± 2°C / 65% RH ± 5%.
	The status in reference regulatory authorities	Registered drug by US FDA (VAFSEO (vadadustat) tablets, for oral use)
	GMP status of the firm	Issuance date: 07-04-2025 Valid Date: 06-04-2028
	Evidence of approval of manufacturing facility	Firm submitted the renewal of DML Letter mentioned that firm has tablet (general section).
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
394	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **(01-**

	374-0006-118530D)
Application Form Dy. No / Tracking ID & date of submission	(AL3-PGL-8PZL, 2025-12-30)
Detail of Fee Submitted	313500.0, 2025-08-13,
The proposed proprietary name / brand name	**ZUVIDOX-L**
Label Claim	Doxorubicin Hydrochloride BP: 2 mg/vial, Each ml contains: Doxorubicin Hydrochloride BP..... 2 mg (As Pegylated Liposome) Water for Injection BP..... q. s.
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 MonthStore at 2-8°C, protecting from light.
For generic drugs (me-too Status)	DOXULIP Manufacturer: United Biotech Strength & Concentration: 20 mg / 10 mL (2 mg/mL) liposomal doxorubicin HCl Composition: PEG-coated (stealth) liposomal formulation with DSPC/MPEG-DSPE etc. Dosa
Pharmacotherapeutic Group of (API)	Anti-Cancer
Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEH. NURPUR, DISTT. KANGRA-176201 (H.P.)-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	The test product (Doxorubicin Hydrochloride Liposome Injection, 20 mg/10 mL) and the reference product (PEGADRIA 20®) are pharmaceutically equivalent, as both are parenteral liposomal formulations containing the same active ingredient (Doxorubicin Hydrochloride, 2 mg/mL) in the same dosage form, strength, and route of administration. Both formulations employ identical key excipients (HSPC, Cholesterol, MPEG-DSPE, Ammonium Sulfate, L-Histidine, Sucrose, Ethanol, and Water for Injection) in comparable quantitative composition, ensuring equivalence in quality, safety, and intended use.
Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., 1-A, INDUSTRIAL AREA, RAJA KA BAGH, TEH. NURPUR, DISTT. KANGRA-176201 (H.P.), India
Details of Certificates (CoPP/FSC/cGMP):	Valid
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability data reports of doxorubicin HCl Ph. Eur. for Accelerated and long term conditions for the batch No. 061213003, 061213004, 061213005 are provided
The status in reference regulatory authorities	DOXIL, Manufacturer: Baxter Healthcare Corp. (Janssen) Strength: 20mg/10ml (2mg/ml), Composition PEG-coated (stealth) liposomal formulation with DSPC/MPEG-DSPE etc. , Dosage Form Single-dose vial, IV infusion,Pack Size 10 mL vial USFDA Approved
Evaluation Remarks	

	The GMP certificate submitted in module-I, issued by the Health and Family Welfare Department, Himachal Pradesh, identifies the manufacturing site as: M/s Zuvius Lifesciences Pvt. Ltd. c/o M/s Kwality Pharmaceuticals Ltd., Plot No. 1-A, Industrial Area, Raja Ka Bagh, District Kangra, Himachal Pradesh (India) – 176201. Further, the Certificate of Pharmaceutical Product (COPP) states the manufacturer as M/s Zuvius Lifesciences Pvt. Ltd. and does not disclose that the product is manufactured at the facility of M/s Kwality Pharmaceuticals Limited. This discrepancy indicates that the submitted COPP does not accurately reflect the actual manufacturing site and, therefore, does not provide correct and complete information. Additionally, Module III, particularly the sections relating to pharmaceutical development and stability data of the drug product, indicates that the product is manufactured at the facility of M/s Kwality Pharmaceuticals Limited not at M/s Zuvius Lifesciences Pvt. Ltd as claimed in the submitted CoPP. In the light of above given facts, the instant case has been placed before the Registration Board for consideration on the same analogy as adopted in its 353rd meeting, wherein the Board decided to reject the registration applications received under the category of a loan-license arrangement.	
	Decision	
	Rejected Rejected in light of decision taken bin its 353rd meeting wherein the Board decided to reject the registration applications received under the category of a loan-license arrangement as the same is not practiced in Pakistan as per existing legislative permissions.	
395	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(J56-GEX-3E3P, 2025-07-25)
	Detail of Fee Submitted	37000.0, 9400 2025-07-11, 2026-01-13
	The proposed proprietary name / brand name	**ZURIL 2.5% ORAL SOLUTION**
	Label Claim	Each ml contains TOLTRAZURIL ..... 25 MG (As per innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	TOLTRASTAR ORAL SOLUTION (081691)
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
396	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK

		(000991)
	Application Form Dy. No / Tracking ID & date of submission	(T8H-88M-YM74, 2025-07-22)
	Detail of Fee Submitted	37000.0, 9400 2025-07-11, 2026-01-13
	The proposed proprietary name / brand name	**OXOLOX 10% ORAL LIQUID**
	Label Claim	Each 100 ML contains: Ofloxacin USP..... 10 GM (As per innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	OFLOBAK LIQUID (Reg. No 063829)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
397	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Attabak Pharmaceutical Industries** 5-C Industrial Area I-10/3 Islamabad **(000552)**
	Application Form Dy. No / Tracking ID & date of submission	(J6Q-JTM-AWV1, 2026-01-23)
	Detail of Fee Submitted	38700, 2026-01-23,
	The proposed proprietary name / brand name	**Paradol-Z Plus Powder**
	Label Claim	Each 1 kg contains; Paracetamol(USP).....20 gm Vitamin C (BP).....5.0gm Vitamin E (BP).....1.25gm Sodium Bicarbonate (USP)..... 12.5gm Potassium carbonate.....12.5 gm (As per Innovator"s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,25 kg-De-Controlled,250 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Spin-C W/S Powder (Leads Pharma)
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic, Vitamins, Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
398	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Biorific Pharma** Plot 143, Industrial Triangle, Kahuta Road. **(000848)**
	Application Form Dy. No / Tracking ID & date of submission	(67Q-V66-S5PP, 2025-06-13)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	**BROCOST-D ORAL POWDER**
	Label Claim	Each 1000g Powder Contains: - Doxycycline Hyclate USP..... 200g Tylosin Tartrate USP..... 100 g Colistin Sulphate USP..... 19.47g Bromhexine HCl..... 5g Streptomycin Sulphate USP..... 36g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000GM-De-Controlled,2.5KG-De-Controlled,200GM-De-Controlled,500GM-De-Controlled,5KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	BACTO-5 Powder DRAP Reg.# 075609, M/S Noble Pharma Azad Kashmir
	Pharmacotherapeutic Group of (API)	Antibiotics / Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	PANEL RECOMENDED THE RENEWAL OF DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
399	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Biorific Pharma** Plot 143, Industrial Triangle, Kahuta Road. **(000848)**
	Application Form Dy. No / Tracking ID & date of submission	(MW3-HY8-6U4X, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	**TRICLASOL oral Liquid VET**
	Label Claim	Each ml contains, Triclabendazole ..... 50 mg Levamisole HCl BP ..... 37.5 mg Cobalt Sulphate ..... 1.67 mg Sodium Selenite ..... 0.35 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,2.5Liters-De-Controlled,200ml-De-Controlled,5 Liters-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	BENDAVETZ ORAL Liquid DRAP Reg # 079278, M/S. VETZ Pharmaceuticals, SINDH
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
400	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)**
	Application Form Dy. No / Tracking ID & date of submission	(PX7-P4Z-72MT, 2025-08-09)
	Detail of Fee Submitted	38700.0, 2025-08-08,
	The proposed proprietary name / brand name	**SolLinc 40% Oral Powder**
	Label Claim	Each gm Contains: Lincomycin HCl USP equivalent to Lincomycin --------- 400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°c. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Lincosel-40 Oral Powder of M/s Selmore Pharma (Reg. No. 089826)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel is of the opinion to recommend the grant of new drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
401	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	**Attabak Pharmaceutical Industries** 5-C Industrial Area I-10/3 Islamabad **(000552)**
	Application Form Dy. No / Tracking ID & date of submission	(BW6-TJ3-68JQ, 2026-01-23)
	Detail of Fee Submitted	38700, 2026-01-23,
	The proposed proprietary name / brand name	**Lincofin 4.4% Powder**
	Label Claim	Each kg contains: Lincomycin HCL USP.....44g (As per Innovator"s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Lincomin-44 Powder, Reg no.078370 (Symens Pharmaceutical)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
402	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**HAAKS Vethum (Pvt) Ltd.** Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad **(001002)**
	Application Form Dy. No / Tracking ID & date of submission	(BER-B11-RXHW, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**NORFLY ORAL LIQUID**
	Label Claim	Each 100ml Contains: Norfloxacin BP..... 25 gm (Equivalent to Norfloxacin ... 22.43 gm) (Innovator’s specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter, 100 ml, 120 ml, 240ml, 500 ml, 5 Liter, 1-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store in a dry, cool place, typically not exceeding 25°C (77°F). Keep the container tightly closed when not in use and store in a shaded area, protected from direct sunlight. Opened Container: Once
	For generic drugs (me-too Status)	Normak Oral Liquid by M/s M/s A&K Pharmaceutical Faisalabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
403	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**HAAKS Vethum (Pvt) Ltd.** Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad **(001002)**
	Application Form Dy. No / Tracking ID & date of submission	(PGJ-5PN-P4UG, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**PERACIT C Oral Powder**
	Label Claim	Each 100gm contains: Paracetamol BP.....20 gm Potassium Carbonate USP.....12.5gm Sodium Carbonate USP.....12.5gm Vitamin E USP.....12.5gm Vitamin C USP.....5 gm (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg, 500 gm, 250gm, 100 gm, 5 Kg, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store in a dry, cool place, typically not exceeding 25°C (77°F). Keep the container tightly closed when not in use and store in a shaded area, protected from direct sunlight. Opened Container: Once
	For generic drugs (me-too Status)	Cemol Oral Powder by M/s Selmore Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
404	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**HAAKS Vethum (Pvt) Ltd.** Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad **(001002)**
	Application Form Dy. No / Tracking ID & date of submission	(QWD-7JJ-YU2H, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**OXYTRON ORAL POWDER**

	Label Claim	Each Kg contain Oxytetracycline HCl EP.....950gm (Equivalent to Oxytetracycline 880.27gm) (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg, 500 gm, 250gm, 100 gm, 5 Kg, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store in a dry, cool place, typically not exceeding 25°C (77°F). Keep the container tightly closed when not in use and store in a shaded area, protected from direct sunlight. Opened Container: Onc
	For generic drugs (me-too Status)	Oxy-950 Powder by M/s Attabak Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
405	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Medezia pharma** plot no 20 road ss-1 national industrial zone rawat **(01014)**
	Application Form Dy. No / Tracking ID & date of submission	(JM1-QU9-G4J7, 2026-01-23)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Mebate Oral Powder**
	Label Claim	Each gm Contain Amprolium HCL USP..... 200mg Ethopabate USP..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C). Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	ETHOPROL POWDER by M/s Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

406	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**HAAKS Vethum (Pvt) Ltd.** Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad **(001002)**
	Application Form Dy. No / Tracking ID & date of submission	(PUE-X9L-49L1, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**NEPHRATIC ORAL POWDER**
	Label Claim	Each Kg contains: Sodium Benzoate USP.....500gm Ethanol β-Amino Phosphoric Acid.....100gm Vitamin A USP.....10,000,000 IU Vitamin E USP.....2500 mg Vitamin K3 USP.....1000 mg Vitamin C USP..... 2500 mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg, 500 gm, 250gm, 100 gm, 5 Kg, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a dry, cool place, typically not exceeding 25°C (77°F). Keep the container tightly closed when not in use and store in a shaded area, protected from direct sunlight. Opened Container: Once op
	For generic drugs (me-too Status)	Approved
	Pharmacotherapeutic Group of (API)	Electrolytes.
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
407	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(1QX-QEQ-LY2W, 2025-12-15)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-01-13
	The proposed proprietary name / brand name	**ALBO FORD 12.5% ORAL SUSPENSION**
	Label Claim	Each ml contains: Albendazole USP..... 125mg (USP specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be

		used promptly
	For generic drugs (me-too Status)	1VETAZOLE 12.5% ORAL LIQUID (REG NO. 079280) M/S VETZ PHARMA KARACHI
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
408	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(647-Y5S-GX77, 2025-12-13)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-01-13
	The proposed proprietary name / brand name	**ALBO FORD 10% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Albendazole USP..... 10 g (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre, 2.5Litre -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	HANZOLE 10% ORAL SUSLPENSION (REG NO. 102253) M/S D-HAANS PHARMA BHIMBER AJK
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
409	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(BD9-3QQ-MWEG, 2025-12-15)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-01-13

	The proposed proprietary name / brand name	**Albo ford 15% oral suspension**
	Label Claim	Each ml contains: Albendazole USP..... 150mg (USP specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Each ml contains: Albendazole……..…… 150mg (USP specification) -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	ALBENDALEX 15% ORAL LIQUID (REG NO. 2047501) M/S LEXICON PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
410	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(RXH-TNE-PV7S, 2025-12-13)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-01-13
	The proposed proprietary name / brand name	**Albo ford 2.5 % oral suspension**
	Label Claim	Each 100ml contains: Albendazole USP..... 2.5 g (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	: 100ml, , 500ml, 1Litre, 2.5Litre -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	ZELPRO 25 ORAL SUSLPENSION (REG NO. 078389)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

411	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(ZW5-1J6-762G, 2025-12-13)
	Detail of Fee Submitted	38700, 9400 2025-12-11, 2026-01-13
	The proposed proprietary name / brand name	**ALBO FORD 5% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Albendazole USP..... 5g (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 250ml,, 500ml, 1Litre, 2.5Litre -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	HANZOLE 5 % ORAL SUSPENSION (REG NO. 102252) M/S D-HAANS PHARMA BHIMBER AJK
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
412	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Synvest Vet Care Pvt Ltd** 10-km, Sahiwal Road, Arifwala District Pakpattan **(001011)**
	Application Form Dy. No / Tracking ID & date of submission	(4G8-Z9Q-AGTW, 2026-01-18)
	Detail of Fee Submitted	37000, 2025-07-04,
	The proposed proprietary name / brand name	**Hepasyn Injection**
	Label Claim	Each 100ml contains: Closantel (as Closantel Sodium Dihydrate BP) ..... 5 gram Levamisole (as Levamisole HCl USP) ..... 10 gram
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,10ml-De-Controlled,50ml-De-Controlled,5ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Closole Injection (Reg. No. 062158) by Attabak Pharmaceuticals, Islamabad

	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Confirmation of pack size	
	Decision	
	Approved	
413	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Synvest Vet Care Pvt Ltd** 10-km, Sahiwal Road, Arifwala District Pakpattan **(001011)**
	Application Form Dy. No / Tracking ID & date of submission	(77S-ZHM-HA8J, 2026-01-22)
	Detail of Fee Submitted	37000, 2025-07-04,
	The proposed proprietary name / brand name	**Syntrox-34% Injection**
	Label Claim	Each ml contains: Nitroxynil 340mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,10ml-De-Controlled,50ml-De-Controlled,5ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Troxy 34% Injection (Reg. No. 034597) by Selmore Pharmaceutical (Pvt.) Ltd., Lahore
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Confirmation of pack size before issuance of registration letter.	
	Decision	
	Approved	
414	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Medezia pharma** plot no 20 road ss-1 national industrial zone rawat **(01014)**
	Application Form Dy. No / Tracking ID & date of submission	(TBA-ZSV-W695, 2026-01-23)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Oxycin Oral powder**
	Label Claim	Each gm Contain Florfenicol..... 100mg Oxytetracycline hcl BP.....300mg Neomycin

		Sulphate BP.....150mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Floxycin Powder by biorific pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
415	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**HAAKS Vethum (Pvt) Ltd.** Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad **(001002)**
	Application Form Dy. No / Tracking ID & date of submission	(GSP-9A8-UYD3, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**Brotyl D oral Powder**
	Label Claim	Each 1000gm. contains: Doxycycline Hyclate BP.....250gm (Equivalent to Doxycycline 231.03gm) Tylosin Tartrate BP..... 200gm (Eq. to Tylosin 171.84gm) Bromhexine HCl BP.....5gm (Eq. to Bromhexine 4.558 gm) (As per Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg, 500 gm, 250gm, 100 gm, 5 Kg, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a dry, cool place, typically not exceeding 25°C (77°F). Keep the container tightly closed when not in use and store in a shaded area, protected from direct sunlight. Opened Container: Once o
	For generic drugs (me-too Status)	Bromodox WSP by M/s Symans Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
416	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Medhouse Pharmaceuticals (PVT) Ltd** Mouza Mangowal Garbi, 1-Km off Chahmughlan Road **(000949)**
	Application Form Dy. No / Tracking ID & date of submission	(WTX-7W9-LDW9, 2025-06-11)
	Detail of Fee Submitted	37000.0, 2025-05-20,
	The proposed proprietary name / brand name	**MED P-FLOXIN ORAL LIQUID**
	Label Claim	Each 100ml contains: Pefloxacin methanesulfonate (BP) --- 13.96 gm eq. to Pefloxacin .....10 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)1. Store at cool and dry place. 2. Store at temperature (about 25C) 3. Protect from direct sun light and heat. 5. Keep the bottle tightly sealed when not in use
	For generic drugs (me-too Status)	Z-Pfloxin Oral Liquid (Reg. No. 099373)
	Pharmacotherapeutic Group of (API)	Antibacterial / Fluoroquinolone Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted on 27.12.2021. firm applied for GMP certificate.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
417	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(NQU-DLG-8HAR, 2025-07-25)
	Detail of Fee Submitted	37000.0, 9400 2025-07-11, 2026-01-13
	The proposed proprietary name / brand name	**VIABAZINE ORAL LIQUID**
	Label Claim	Each ml contains: Trimethoprim BP.....25mg Sulphamethazine BP.....50mg Sulphamethoxypyradizine BP.....50mg Enrofloxacin BP..... 75mg (As per innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled

	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children
	For generic drugs (me-too Status)	ROLD CINNA-200 ORAL LIQUID (109051)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was granted to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Product contains combination of four antibiotics. Case submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
418	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(RQW-QPE-NUX3, 2025-07-25)
	Detail of Fee Submitted	37000.0, 9400 2025-07-11, 2026-01-13
	The proposed proprietary name / brand name	**VIBAZENE ORAL LIQUID**
	Label Claim	Each ml contains: Trimethoprim BP.....25mg Sulphamethazine BP.....50mg Sulphamethoxypyradizine BP.....75mg Enrofloxacin BP..... 75mg (As per innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	ROLD CINNA-200 ORAL LIQUID (109051)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Product contains combination of four antibiotics. Case submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
419	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(Q7M-XW2-V2TY, 2025-11-20)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-MISOLE DRENCH**
	Label Claim	Each ml Contains: Levamisole Hcl USP.....15mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Nilverm Drench by M/s ICI Pakistan
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was requested to provide a reference for the finished product specifications. In response, the firm stated that the finished product specifications are in accordance with the USP monograph. However, upon evaluation, it was found that the USP does not provide specifications for Levamisole HCl Drench. The firm was informed of this discrepancy and was asked for three times, to revise the specifications to innovator specifications and to submit the required pre-registration variation fee. In response to the final query regarding submission of the pre-registration fee, the firm claimed compliance with BP specifications; however, the BP also does not provide specifications for Levamisole HCl Drench. Submitted for consideration of the Board, please.	
	Decision	
	Approved Approved with innovator specifications and pre-registration variation fee.	
420	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(AQJ-GD5-WN6Y, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-Tylos 10% Powder**
	Label Claim	Each gm Contains: Tylosin Tartrate BP.....100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,25 Kg-De-Controlled,5 Kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	TyloCare by M/s Advacare Pharma USA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
421	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(TLJ-5NN-E4MW, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-Colistin Powder**
	Label Claim	Each gm contains: Colistin Sulphate USP 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Colikam-50 by M.A.kamil Farma Pvt Limited
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was requested to provide a reference for the finished product specifications. In response, the firm stated that the finished product specifications are in accordance with the USP monograph. However, upon evaluation, it was found that the USP does not provide specifications for Colistin Sulfate Oral Powder. The firm was informed of this discrepancy and was asked for three times, to revise the specifications as innovator specifications and to submit the required pre-registration variation fee. In response to the final query regarding submission of the pre-registration fee, the firm claimed BP specifications; however, the BP also does not provide specifications for Colistin Sulfate Oral Powder. Submitted for consideration of the Board, please.	

	Decision	
	Approved Approved with innovator specifications and pre-registration variation fee.	
422	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(U7P-2DH-RG83, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-Tilmicosin Oral Solution**
	Label Claim	Each ml Contains: Tilmicosin as Phosphate USP.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Tilsin Oral Solution by M/s Reference to finished product specifications not mentioned.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm was requested to provide a reference for the finished product specifications. In response, the firm stated that the finished product specifications are in accordance with the USP monograph. However, upon evaluation, it was determined that the USP does not provide specifications for Tilmicosin Oral Solution. The firm was informed of this discrepancy and was asked to provide USP monograph or change specifications from USP to Innovator and submit requisite fee for such change. Upload challan on eAPP for three times. In reply firm claimed Innovator specifications and when they were requested to submit the required pre-registration variation fee. In response, instead of submitting requisite fee the firm claimed compliance with BP specifications; however, the BP also does not provide specifications for Tilmicosin Oral Solution. Submitted for consideration of the Board, please.	
	Decision	
	Approved Approved with innovator specifications and pre-registration variation fee.	
423	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**

	Application Form Dy. No / Tracking ID & date of submission	(23Q-W49-31PY, 2025-06-20)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	**TRIGYNO W/S POWDER**
	Label Claim	EACH KG CONTAINS: Colistin Sulphate BP. .....4 GM Neomycin Sulphate BP.....70 GM Chlortetracycline HCl USP.....80 GM (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)In an airtight container, protected from light
	For generic drugs (me-too Status)	NEO-STIN WATER SOLUBLE POWDER REG NO 059146
	Pharmacotherapeutic Group of (API)	Anti-bactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
424	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(1EQ-U2B-D1JU, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-Doxy 50% Oral Powder**
	Label Claim	Each gram Contains: Doxycycline Hyclate USP.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Seldox Oral Powder by M/s Selmore Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
425	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)**
	Application Form Dy. No / Tracking ID & date of submission	(V5N-Q6M-T1VT, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	**G-Doxy 80% Oral Powder**
	Label Claim	Each gram Contains: Doxycycline as Hyclate (USP).....800mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	DoxyRal 80% by M/s Orient Animal Health Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
426	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(M8T-D14-U4MN, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-02-10,
	The proposed proprietary name / brand name	**Nezo Dry Powder for Oral Suspension 100mg/5ml**
	Label Claim	Each 5ml reconstituted Suspension contains: Linezolid.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 120ml-As per SRO

	Shelf Life (Unit)	2 Year(s)Store bellows 30°C. Protect from heat, sunlight & moisture. Improper storage may deteriorate the medicine.
	For generic drugs (me-too Status)	Brand Name: Newlenz Dry Powder for oral Suspension Strength: 100mg/5ml Dosage Form: Oral Suspension Pack Size: 60ml Regn No. 086587 Manufacturer: Newton Health Care Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	ANTIINFECTIVES FOR SYSTEMIC USE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	3 batches: batch size: 522 bottles, 60mL
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Newton health care E-6221422865243 27.09.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Newlenz Dry Powder for oral Suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Product Name: Zyvox Powder for oral Suspension Strength: 100mg/5ml by Pharmacia & Upjohn Company (USFDA Approved)
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023 mentioned dry powder suspension section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
427	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(P26-4SQ-MVVQ, 2025-04-16)
	Detail of Fee Submitted	37000.0, 2025-03-11,
	The proposed proprietary name / brand name	**Tacro**
	Label Claim	Each gram contains: Tarolimus..... 0.03% w/w
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
	For generic drugs (me-too Status)	Imunol 0.03% w/w by saffron pharmaceuticals (RN 46443)
	Pharmacotherapeutic Group of (API)	D11AH01: Agents for dermatitis, excluding corticosteroids.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturer: umar BioTech LLP BY Plot No: 12,113,114,GIDC Estate Gozariya, Dist: Mehsana,382825,Gujarat, India Phone: +91-

		2763-264939,Email: nfo@sumarbiotech.com,inquiry@sumarbiotech.co
	Detail of stability batches of drug product	200 tubes 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan from M/s sharooq pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Imunol 0.03%
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Protopic Ointment (USFDA Approved)
	GMP status of the firm	New Dml
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023 mentioned cream/ointment section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
428	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(QB1-TNN-H7RP, 2025-07-04)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**SNRI**
	Label Claim	Each capsule contains: Venlafaxine HCL sustained release pellets eq. to Venlafaxine 75mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x14's, 2x7's,1x12's,1x10's,10x10's & As per S.R.O-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
	For generic drugs (me-too Status)	VENICE XR by Medisure laboratotries
	Pharmacotherapeutic Group of (API)	SNRI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23,Industrial Triangle,Kahuta Road,Islamabad-Pakistan
	Detail of stability batches of drug product	Three batch were perform Accelerated: 40 °C ± 2 °C/75% RH ± 5% RH Long term :30 °C ± 2 °C/65% RH ± 5% RH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Vision Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE Perform Against VENICE XR by Medisure laboratotries
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Drug substance stability is perform As per Zone IV

	The status in reference regulatory authorities	EFFEXOR XR by M/s Upjohn (USFDA Approved)
	GMP status of the firm	New Dml
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
429	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(RBH-WWR-M8ZH, 2025-04-07)
	Detail of Fee Submitted	37000.0, 9000.0 2024-12-19, 2025-07-29
	The proposed proprietary name / brand name	**Momera**
	Label Claim	ach bottle contains: Mometasone Furoate .....0.1% w/v
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	20ml , 30ml, 60ml an-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
	For generic drugs (me-too Status)	Momate Lotion
	Pharmacotherapeutic Group of (API)	corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ENVEE DRUGS PVT.LTD. N. H. No. 8,Dumral-387 355,Ta. Nadiad, Dist: heda, Gujarat,India.
	Detail of stability batches of drug product	3 batches 100 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan from M/s madera invoice no E-676320489571
	Pharmaceutical Equivalence and Comparative Dissolution Profile	hivate lotion m/s saffron
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Iv-A
	The status in reference regulatory authorities	Mometasone Furoate 0.1% w/v lotion by Sandoz limited
	GMP status of the firm	new Dml
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023 mentioned lotion section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
430	Case Category	New License (Shahrukh Ali)

	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(41Z-GDS-PWDR, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 250mg/5ml Dry Powder Suspension**
	Label Claim	Each 5ml contains: Ampicillin Trihydrate equivalent Ampicillin 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x60ml, 1x120ml, 1x100ml As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ampicillin Oral Suspension 250mg/ 5ml of M/s Pliva Pakistan Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited Add: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	Took 3 trial batches of 250 Bottles per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampicillin Oral Suspension 250mg/ 5ml of M/s Pliva Pakistan Pvt. Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Oral Suspension BP 250 mg/5 ml of M/s Athlone Laboratories Limited Ballymurray Co. Roscommon. (EMA & HPRA Approved)
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned dry powder suspension penicillin
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
431	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(5UM-LZ4-A5GU, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-07,
	The proposed proprietary name / brand name	**Skylac 50mg Tablet**

	Label Claim	Each Film coated Tablet contains: Lacosamide.....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Lakil 50mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Lacosamide is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist, Pin Code: 503101 Telangana State, India
	Detail of stability batches of drug product	Took 3 trial batches of 2000 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lakil 50mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd. E-3560782884125 25-Nov-2022
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Lacosamide 50 mg film-coated tablets of M/s G.L Pharma UK Limited Addrress: Suite 3A, 30 St Thomas Place, Cambridgeshire Business Park, Ely, Cambridgeshire, CB7 4EX, UK
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned tablet section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
432	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(PGT-9PA-RQLZ, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-07,
	The proposed proprietary name / brand name	**Skylac 100mg Tablet**
	Label Claim	Each Film coated Tablet contains: Lacosamide.....100mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	1x10’s, 2x7’s, 2x10’s, 4x7’s, 3x10’s As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Lakil 100mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Lacosamide is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist, Pin Code: 503101 Telangana State, India
	Detail of stability batches of drug product	Took 3 trial batches of 2000 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd. E-3560782884125
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lakil 100mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Lacosamide 100 mg film-coated tablets of M/s G.L Pharma UK Limited Addrress: Suite 3A, 30 St Thomas Place, Cambridgeshire Business Park, Ely, Cambridgeshire, CB7 4EX, UK
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	F.2-11/2017-Lic issued on 27-10-2023 mentioned tablet section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
433	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(9TA-RSG-QQXD, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 250mg Capsule**
	Label Claim	Each Capsule contains: Ampicillin Trihydrate equivalent Ampicillin 250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10’s, 2x10’s, 4x7’s, 3x10’s,5x10’s, 10x10’s As p-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30

	For generic drugs (me-too Status)	Ampicillin Capsule 250mg of M/s Pliva Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited Add: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Capsules per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampicillin Capsule 250mg of M/s Pliva Pakistan Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Capsules BP 250 mg of M/s Athlone Laboratories Limited Ballymurray Co. Roscommon. (EMA & HPRA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
434	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(MHQ-QT9-LGML, 2026-02-13)
	Detail of Fee Submitted	1700, 38700 2025-08-15, 2025-10-07
	The proposed proprietary name / brand name	**Ampisky 500mg Injection**
	Label Claim	Each Vial contains: Ampicillin Sodium Equivalent to Ampicillin.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ampin Injection 500mg of M/s Bosch Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vardhman Chemtech Limited, D-5 & D-6, Industrial Focal Point Derabassi, Distt. Mohali, Punjab, INDIA
	Detail of stability batches of drug product	Took 3 trial batches of 800 vials per batch and submitting stability

	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampin Injection 500mg of M/s Bosch Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Sodium for Injection BP 1gm of M/s Auro Pharma Inc., 3700 Steeles Avenue West suite 402, woodbridge Ontario, L4L 8K8, Canada (HEalth Canada Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned dry powder injection penicillin
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
435	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(UZW-DSP-W99S, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 125mg/5ml Dry Powder Suspension**
	Label Claim	Each 5ml contains: Ampicillin Trihydrate equivalent Ampicillin 125mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x60ml, 1x120ml, 1x100ml As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Ampicillin Oral Suspension 125mg/ 5ml of M/s Pliva Pakistan Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited Add: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	Took 3 trial batches of 250 Bottles per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampicillin Oral Suspension 125mg/ 5ml of M/s Pliva Pakistan Pvt. Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C,

		Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Oral Suspension BP 125 mg/5 ml of M/s Athlone Laboratories Limited Ballymurray Co. Roscommon. (EMA & HPRA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned dry powder suspension penicillin
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
436	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(VGE-D22-RDZE, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 500mg Capsule**
	Label Claim	Each Capsule contains: Ampicillin Trihydrate equivalent Ampicillin 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x10's, 4x7's, 3x10's,5x10's, 10x10's As p-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Ampicillin Capsule 500mg of M/s Pliva Pakistan Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited Add: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Capsules per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampicillin Capsule 500mg of M/s Pliva Pakistan Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Capsules BP 500 mg of M/s Athlone Laboratories Limited Ballymurray Co. Roscommon. (EMA & HPRA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
	Evaluation Remarks	

	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
437	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(WNW-X8Q-VD7Z, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 250mg Injection**
	Label Claim	Each Vial contains: Ampicillin Sodium Equivalent to Ampicillin.....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Ampin Injection 250mg of M/s Bosch Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vardhman Chemtech Limited, D-5 & D-6, Industrial Focal Point Derabassi, Distt. Mohali, Punjab, INDIA
	Detail of stability batches of drug product	Took 3 trial batches of 800 Vials per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Ampin Injection 250mg of M/s Bosch Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Sodium for Injection BP 250mg of M/s Auro Pharma Inc., 3700 Steeles Avenue West suite 402, woodbridge Ontario, L4L 8K8, Canada (HEalth Canada Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
438	Case Category	New License (Shahrukh Ali)

	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(YYB-2VA-9SVP, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-08-15,
	The proposed proprietary name / brand name	**Ampisky 1gm Injection**
	Label Claim	Each Vial contains: Ampicillin Sodium Equivalent to Ampicillin.....1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Zampicillin Injection 1g of M/s Zafa Pharmaceutical Laboratories
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vardhman Chemtech Limited, D-5 & D-6, Industrial Focal Point Derabassi, Distt. Mohali, Punjab, INDIA
	Detail of stability batches of drug product	Took 3 trial batches of 800 Vials per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Stallion Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zampicillin Injection 1g of M/s Zafa Pharmaceutical Laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ampicillin Sodium for Injection BP 1gm of M/s Auro Pharma Inc., 3700 Steeles Avenue West suite 402, woodbridge Ontario, L4L 8K8, Canada (HEalth Canada Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
439	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(MLW-MYV-APBG, 2025-09-08)
	Detail of Fee Submitted	37000.0, 2025-03-17,
	The proposed proprietary name / brand name	**Hepa-Guard Sachet**

	Label Claim	Each Sachet contains: L-Ornithine L-Aspartate.....3g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x5's, 1x1's, 1x10's, 1x20's, 1x50's As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Hepa Merz Granules of M/s Brookes Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	L Ornithine L Aspartate is used to treat liver diseases such as acute and chronic hepatitis, chronic alcoholic liver damage, fatty liver, jaundice, liver cirrhosis, and non-alcoholic steatohepatitis (non-alcoholic fatty liver disease). It helps improve liver function and supports healthy digestion. It works by reducing harmful toxins in the body, promoting liver cell regeneration, and improving overall metabolism. It is beneficial for managing liver disorders, especially those associated with high ammonia levels and digestive issues.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hebei Changhao Biotechnology Co., Ltd, Address: East of Yueliang Village, Jizhou Town, Jizhou District, Hengshui City, 053200, Hebei Province, China
	Detail of stability batches of drug product	Took 3 trial batches of 600 Sachets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	took loan from M/s Jawa Pharmaceuticals. E-8460182809782 Date of issue: 26-Feb-2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hepa Merz Granules of M/s Brookes Pharma Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Hepa-Merz granules, 3 g Granules for oral solution of M/s Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100 60318 Frankfurt am Main, Germany (Federal Institute for Drugs and Medical Devices Approved)
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned sachet section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
440	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura

	road **(000971)**
Application Form Dy. No / Tracking ID & date of submission	(1VD-T9Q-R6R4, 2025-10-06)
Detail of Fee Submitted	38700, 2025-09-12,
The proposed proprietary name / brand name	**Skytor 10/160mg Tablet**
Label Claim	Each Film Coated Tablet contains: Amlodipine (as Besylate).....10mg Valsartan.....160mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
Shelf Life (Unit)	2 YearStore at room temperature below 30
For generic drugs (me-too Status)	Valta-AM 10mg/160mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
Pharmacotherapeutic Group of (API)	Amlodipine is in a class of medications called calcium channel blockers. It lowers blood pressure by relaxing the blood vessels so the heart does not have to pump as hard. It controls chest pain by increasing the supply of blood to the heart. Valsartan belongs to the angiotensin II receptor blocker (ARB) family of drugs, which selectively bind to angiotensin receptor 1 (AT1) and prevent angiotensin II from binding and exerting its hypertensive effects.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002 .Gujarat, INDIA,Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China
Detail of stability batches of drug product	Took 3 trial batches of 1500 Tablets per batch and submitting stability
Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Valta-AM 10mg/160mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
The status in reference regulatory authorities	Exforge 10mg/160mg film coated tablets of M/s Novartis Pharmaceuticals UK Ltd (MHRA Approved)
GMP status of the firm	N/A
Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
Evaluation Remarks	
"The application is complete as per codal formalities for consideration by the Registration Board"	
Decision	
Approved	

441	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(ABR-T8S-523V, 2025-10-06)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**Skytor 5/160mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Amlodipine (as Besylate).....5mg Valsartan.....160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Valta-AM 5mg/160mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Amlodipine is in a class of medications called calcium channel blockers. It lowers blood pressure by relaxing the blood vessels so the heart does not have to pump as hard. It controls chest pain by increasing the supply of blood to the heart. Valsartan belongs to the angiotensin II receptor blocker (ARB) family of drugs, which selectively bind to angiotensin receptor 1 (AT1) and prevent angiotensin II from binding and exerting its hypertensive effects.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002 .Gujarat, INDIA,Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Valta-AM 5mg/160mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Exforge 5mg/160mg film coated tablets of M/s Novartis Pharmaceuticals UK Ltd (MHRA Approved)
	GMP status of the firm	New Dml
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned tablet section general

	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
442	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(V8T-6SM-X7JV, 2025-10-02)
	Detail of Fee Submitted	37000, 1700 2025-07-14, 2025-09-12
	The proposed proprietary name / brand name	**Omewell Sachet 20mg**
	Label Claim	Each Sachet contains:- Omeprazole....20mg & Sodium BIcarboante 1680 (Innovators)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5 s, 10 s, 25 s(As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Risek Insta Sachet 20mg + 1680mg M/s. Getz Pharma (Pvt) Limited.Reg 058547
	Pharmacotherapeutic Group of (API)	Antiulcer agent / Gastrointestinal drug
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API Private ltd. Plot No.: 75, Flat No. 302, Bhanu Enclave, Sunder Nagar
	Detail of stability batches of drug product	Three batches having 150 sachet
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-30DCD in name of M/s Pharmazone chemicals dated: 17-01-2025 and loan agreement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Risek Insta sachet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	No. F.1-37/2020-LIC (Vol-1) dated 3 -02-2025 mentioning sachet general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
443	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(4T6-6HH-HXTD, 2025-10-01)
	Detail of Fee Submitted	37000, 1700 2025-07-14, 2025-09-12

	The proposed proprietary name / brand name	**Omewell 40mg Sachet**
	Label Claim	Each Sachet contains:- Omeprazole....40mg & Sodium BIcarboante 1680
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5 s,10 s,25 s As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree celsius
	For generic drugs (me-too Status)	Risek Insta Sachet 40mg + 1680mg M/s. Getz Pharma (Pvt) Limited. 058548
	Pharmacotherapeutic Group of (API)	Anti-Ulcer
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API Private ltd. Plot No.: 75, Flat No. 302, Bhanu Enclave, Sunder Nagar Erragadda, Hyderabad – 500038 Telangana State, India.
	Detail of stability batches of drug product	Three batches having 150 sachet
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-30DCD in name of M/s Pharmazone chemicals dated: 17-01-2025 and loan agreement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Risek Insta sachet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	No. F.1-37/2020-LIC (Vol-1) dated 3 -02-2025 mentioning sachet general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
444	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(WLU-LSA-W3LM, 2025-10-06)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**Skytor 5/80mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Amlodipine (as Besylate).....5mg Valsartan.....80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Valta-AM 5mg/80mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Amlodipine is in a class of medications called calcium channel blockers. It lowers blood

		pressure by relaxing the blood vessels so the heart does not have to pump as hard. It controls chest pain by increasing the supply of blood to the heart. Valsartan belongs to the angiotensin II receptor blocker (ARB) family of drugs, which selectively bind to angiotensin receptor 1 (AT1) and prevent angiotensin II from binding and exerting its hypertensive effects.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cadila Pharmaceuticals Limited. Address: 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002 .Gujarat, INDIA,Zhejiang Tianyu Pharmaceutical Co., Ltd. Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Manufacturer took Loan from Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Valta-AM 5mg/80mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Exforge 5mg/80mg film coated tablets of M/s Novartis Pharmaceuticals UK Ltd (MHRA Approved)
	GMP status of the firm	n7
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
445	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(NZP-THQ-SPPN, 2025-07-16)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Dilozen 600mg Tablet**
	Label Claim	Each Film coated Tablet contains: Linezolid.....600mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10’s, 2x6’s, 2x7’s-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dilozen 600mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.

	Pharmacotherapeutic Group of (API)	Oxazolidinones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Optrix Laboratories Private Limited Address: Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri- Bhuvanagiri (Dist) – 508 126. Telangana, India
	Detail of stability batches of drug product	Took 3 trial batches of 1200 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dilozen 600mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	ZYVOX® (linezolid) 600mg tablets of M/s Pharmacia & Upjohn Co. LLC A sub. of Pfizer Inc., NY, NY 10001 75098987 (USFDA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	DML No. 000971 issued on 18-09-2023
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
446	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(SZJ-W8N-HNNQ, 2025-09-08)
	Detail of Fee Submitted	38700.0, 2025-08-15,
	The proposed proprietary name / brand name	**Skycip 500mg Tablet**
	Label Claim	Each Film coated Tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10’s, 2x7’s, 2x10’s, 4x7’s, 3x10’s As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Solocip 500mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Ciprofloxacin is an antibiotic agent in the fluoroquinolone class used to treat bacterial infections such as urinary tract infections and pneumonia.
	Name, address of Manufacturing site:	Self Manufacturing

	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
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Solocip 500mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	We have provided the Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ciprofloxacin 500 mg film-coated tablets of M/s SUN PHARMA UK LIMITED 6-9 The Square, Stockley Park, Uxbridge, UB11 1FW United Kingdom (EMA & HPRA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned tablet section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
447	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(DL6-WQR-2NZW, 2025-07-16)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Dilozen 400mg Tablet**
	Label Claim	Each Film coated Tablet contains: Linezolid.....400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10’s, 2x6’s, 2x10’-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Dilozen 400mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Oxazolidinones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Optrix Laboratories Private Limited Address: Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri- Bhuvanagiri (Dist) – 508 126. Telangana, India
	Detail of stability batches of drug product	Took 3 trial batches of 1200 Tablets per batch and submitting stability

	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dilozen 400mg Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data as per Zone IV-A
	The status in reference regulatory authorities	ZYVOX® (linezolid) 400mg tablets of M/s Pharmacia & Upjohn Co. LLC A sub. of Pfizer Inc., NY, NY 10001 75098987 (USFDA Approved)
	GMP status of the firm	N/A
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned tablet section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
448	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(ZT6-2MR-44RM, 2025-11-13)
	Detail of Fee Submitted	38700, 2025-11-08,
	The proposed proprietary name / brand name	**IKOZOL 150mg Capsule**
	Label Claim	Each Capsule contains: Fluconazole.....150mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Fantizol Capsule BY Apex Karachi
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RUTU CHEMICALS Plot No. 2924/2, GIDC Industrial Estate Panoli – 394 116, Dist.: Bharuch State: Gujarat, India
	Detail of stability batches of drug product	1500 Capsules each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Denont research laboratories k-656022807314 form-5 .
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diflucan cap of M/s Pfizer Pharma Pvt. Ltd..
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	F.1-24/2015-Lic issued on 29-04-2024 mentioned cap general section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
449	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(MUW-XJU-WJ55, 2024-09-18)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Doin 8mg Tablet**
	Label Claim	Doin 8mg Tablet Each film coated tablet contains: - Ondansetron as Hydrochloride Dihydrate.....8mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Onsetron Tablets 8mg (Dyson Research Laboratories (Pvt.) Ltd) Reg. No. 062816
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches of 1500 tab each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Denont research laboratories k-2278922801827 17.08.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	onset -8 M/s pharmedic
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet)
	GMP status of the firm	new dml
	Evidence of approval of manufacturing facility	F.1-24/2015-Lic issued on 29-04-2024 mentioned tabgeneral section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
450	Case Category	New License (Shahrukh Ali)

	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(9XZ-3S9-MLGP, 2025-09-30)
	Detail of Fee Submitted	37000.0, 1700.0 2025-07-14, 2025-09-09
	The proposed proprietary name / brand name	**Cyanowell 1000mcg/ml Injection**
	Label Claim	Each ml contains:- Cyanocobalamin....1000mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x 5's, 1ml x 10's,1 x 25's 1ml x 100's (Price - Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Celsius
	For generic drugs (me-too Status)	Cynacob injection M/s. Genix Pharma (Pvt) Ltd.Reg No.088931
	Pharmacotherapeutic Group of (API)	Vitamin B12 preparation (Anti-anemic)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HEBEI HUARONG PHARMACEUTICAL CO., LTD. Add?Eastroad?North circle?Shijiazhuang? Tel: 0086-311-86810066?86838967-8239
	Detail of stability batches of drug product	Attached
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-19E96 dated 5.3.25m/s Trigon loan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cyanocob Injection Genix Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Cytamen 1000mcg Injection, MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	No. F.1-37/2020-LIC (Vol-1) dated 3 -02-2025 mentioning liq injectible ampoule general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
451	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(GWM-34E-4ZLY, 2025-09-17)
	Detail of Fee Submitted	37000.0, 1700.0 2025-07-14, 2025-09-09
	The proposed proprietary name / brand name	**ketowell 30mg per ml Injection**
	Label Claim	Each ml contains:- Ketorolac Tromethamine....30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10 s,1 x 25 s, 1 x 50 s, 1x 100 s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C

	For generic drugs (me-too Status)	Tekac30mg/ml Injection SAMI Pharmaceuticals Pvt. Ltd.Reg No. 092855
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Perkin Laboratory Telangana State,India
	Detail of stability batches of drug product	3 batches 1L
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-AF65D4 m/s trigon dated 6.2.25
	Pharmaceutical Equivalence and Comparative Dissolution Profile	tekac inj m/s sammi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Ketorolac Tromethamine Injection30mg/ml, USFDA Approved
	GMP status of the firm	New Dml
	Evidence of approval of manufacturing facility	No. F.1-37/2020-LIC (Vol-1) dated 3 -02-2025 mentioning injectible general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
452	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(9BD-D4D-TH46, 2025-04-21)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-26, 2025-02-19
	The proposed proprietary name / brand name	**FAXIR 550MG TABLET**
	Label Claim	FAXIR 550MG TABLET Each Film Coated Tablet Contains: Rifaximin.....550mg(BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C.
	For generic drugs (me-too Status)	Nimixa 550mg Tablet BY Getz Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Optimus Drugs Private Limited UNIT-III Survey NO,145/A,145/AA &147, RAMALINGAMPALLY(V), BOMMALARAMARAM(M),YADADARI BHUVANAGIRI District 508126,Telangana,INDIA.
	Detail of stability batches of drug product	3 batches

	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Denont research laboratories E-1638122807231 19.06.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nimixia 550mg tab of M/s getz Pharma Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	XIFAXAN 550mg film coated tablets, FDA approved
	GMP status of the firm	New dml
	Evidence of approval of manufacturing facility	F.1-24/2015-Lic issued on 29-04-2024 mentioned tablet general section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
453	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(JZD-1XV-5S3L, 2025-11-14)
	Detail of Fee Submitted	38700, 2025-11-08,
	The proposed proprietary name / brand name	**Onter 8mg/4ml Injection**
	Label Claim	Each Vial contains: Ondansetron as Hydrochloride Dihydrate.....8mg (USP Specs.).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Zedron 8mg Injection by Shaigan Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Serotonin 5-HT_3 receptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District-561203.
	Detail of stability batches of drug product	100 vials of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-2278922801827 17.08.22 m/s demont research labs loan.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zedron Injection m/s shaigan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	No F.1-24/15-Lic (Vol-V-II)dated 03-feb-2025 mentioning liq inj vial general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
454	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat **(000989)**
	Application Form Dy. No / Tracking ID & date of submission	(T7P-6HD-AWZQ, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-05-05,
	The proposed proprietary name / brand name	**Nexil 0.5 g I.M/I.V Injection**
	Label Claim	Each Vial of dry substance contains: 524 mg Cefotaxime Sodium equivalent to 500 mg of Cefotaxime U.S.P
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearAs per USP
	For generic drugs (me-too Status)	Cefotax 0.5g Injection [Bocsh Pharma]
	Pharmacotherapeutic Group of (API)	Shandong Salubris Pharmaceuticals co.Ltd., China
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Import form Shandong Salubris Pharmaceuticals.CoLtd China
	Detail of stability batches of drug product	Stability studies for 3 batches with details enclosed in Module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Enclosed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Documents Enclosed under relevent section in Module 3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Documents Enclosed in Module 3
	The status in reference regulatory authorities	Claforan 0.5 g I.M/I.V Injection registered under sanofi-aventis US-FDA , Link is in Module 1
	GMP status of the firm	GMP Certified Company
	Evidence of approval of manufacturing facility	Relevent Documents Enclosed in Module 3
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
455	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat

		(000989)
	Application Form Dy. No / Tracking ID & date of submission	(9W4-LU4-QXJ5, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-05-05,
	The proposed proprietary name / brand name	**Nexil 1 g I.M/I.V Injection**
	Label Claim	Each vial of Dry Substance contains: 1048 mg of Cefotaxime Sodium equivalent to 1000 mg of Cefotaxime U.S.P.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	-2 Year(s)As per USP
	For generic drugs (me-too Status)	Fustexim 1 g Injection {Global Pharmaceuticals}
	Pharmacotherapeutic Group of (API)	cephalosporin antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Import form Shandong Salubris Pharmaceuticals.CoLtd China
	Detail of stability batches of drug product	Stability studies for 3 batches with details enclosed in Module 3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Enclosed
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Claforan 1 g I.M/I.V Injection registered under sanofi-aventis
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Claforan 1 g I.M/I.V Injection registered under sanofi-aventis US-FDA , Link is in Module 1
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	No F.1-5/2018-Lic (Vol-I)dated 25-January-2024 mentioning dry powder injection cephalosporin section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
456	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(GUV-SMG-B4Q1, 2025-06-25)
	Detail of Fee Submitted	37000.0, 2025-03-07,
	The proposed proprietary name / brand name	**Ortem Dry Powder Suspension 15/90mg/5ml**
	Label Claim	Each 5ml reconstituted Suspension contains: Artemether.....15mg Lumefantrine.....90mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	30ml & 60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sun light and heat. Store in a cool, dry place.

For generic drugs (me-too Status)	Brand Name: Luther Dry Powder for oral Suspension Strength: 15mg/90mg/5ml Dosage Form: Oral Suspension Pack Size: 30ml Regn No. 086583 Manufacturer: Newton Health Care Pvt. Ltd.
Pharmacotherapeutic Group of (API)	P01BF01: ANTIMALARIALS
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Calyx Chemicals and Pharmaceuticals Limited. Plot No. N – 102,91,90,MIDC, Tarapur, Biosar, District Palghar – 401 506, Maharashtra India.
Detail of stability batches of drug product	3 batches; batch size: 500 bottles of 30mL each
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Luther Dry Powder for oral Suspension of M/s Newton Health Care Pvt. Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted as per Zone IVa
The status in reference regulatory authorities	Product Name: Artemther & Lumefantrine Strength: 15mg& 90mg/5ml Dosage Form: Oral Powder Reference Regulatory Authority: WHO Approved.
GMP status of the firm	new dml
Evidence of approval of manufacturing facility	f2.11/2017 27.10.23
Evaluation Remarks	
3.2.P.8: In chromatograms of testing of stability batches, the elution time for artemether is 14 minutes and Lumefantrine is 10 minutes whereas the elution time as per IP should be 19 minutes and 34 minutes respectively. Clarify the observed disparity in the retention time of both active substances.	Pharmacopoeial methods allow suitable adjustments in chromatographic conditions, provided that system suitability criteria are met and method performance characteristics remain compliant. The developed method used for routine quality control and stability studies follows the same chromatographic principle as described in IP but utilizes optimized parameters to improve run time efficiency while maintaining chromatographic integrity. Although the absolute retention time differs numerically (approximately three-fold in the case of Lumefantrine), this difference is attributable to optimized chromatographic parameters such as column characteristics and flow rate. Although the absolute retention time differs numerically (approximately three-fold in the case of Lumefantrine), this difference is attributable to optimized chromatographic parameters such as column characteristics and flow rate. The variation does not affect: Peak identity (confirmed with reference standard). Resolution between critical peaks. System suitability parameters (resolution, tailing factor, theoretical plates, %RSD). Assay accuracy and precision. Specificity and stability indicating capability.
Decision	
Deferred	

	Registration board was briefed that a significant difference was observed in elution time between pharmacopeial limits and studies performed. International pharmacopoeia monograph specifies elution time as (19 minutes for artemether and 34 minutes for Lumefantrine) however conducted studies chromatogram shows the elution time for artemether is 14 minutes and Lumefantrine is 10 minutes. As firm claims that they have used exact parameters as specified in monograph for assay and performed validation studies in view of above the Board after through deliberation decided that a sample of the above product may be forwarded to Testing laboratory DTL/CDL for verification of firm claim.	
457	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(WL5-J4U-GZ5A, 2025-03-04)
	Detail of Fee Submitted	37000.0, 2025-01-27,
	The proposed proprietary name / brand name	**Candirid Dry Powder for Oral Suspension 50mg/5ml**
	Label Claim	Each 5ml reconstituted Suspension contains: Fluconazole.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	35ML-As per SRO
	Shelf Life (Unit)	2 Year(s)Store bellow 30°C. Protect from heat, sunlight & moisture. Improper storage may deteriorate the medicine.
	For generic drugs (me-too Status)	Flucaton Powder for oral Suspension by Newton Health Care Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rutu Chemicals, Plot No.2924/2, GIDC, Panoli Tal Ankleshwar Distt: Bharuch
	Detail of stability batches of drug product	3 batches: 529 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from m/s orta
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flucaton dry powder for oral suspension 50mg/5ml of Newton Health Care: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per zone IV-A
	The status in reference regulatory authorities	Diflucan Powder for oral Suspension (10mg/ml) (USFDA Approved)
	GMP status of the firm	27-10-2023: New DML issued
	Evidence of approval of manufacturing facility	27-10-2023: DML issuance letter specifies Dry powder suspension (General) section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	

Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)

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Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**SacBio Pharma** Model town b bahawalpur **(03-312-0162-110919D)**
	Application Form Dy. No / Tracking ID & date of submission	(QQG-QDV-U5N2, 2024-01-22)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-29, 2025-02-18
	The proposed proprietary name / brand name	**CHORIOTEC 5000**
	Label Claim	Each vial contains Chorionic Gonadotrophin BP 5000IU Excipients q.s. Each ampoule of solvent contains Sterile water for Injection BP....2ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	White to off-white l-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 25 Degrees Celsius. Protect from light.
	For generic drugs (me-too Status)	IVF-C 5000 IU (Galaxy Pharma (Pvt) Ltd., Karachi) Reg. No.: 039811
	Pharmacotherapeutic Group of (API)	Hormone. Code ATC: G03GA01
	Name, address of Manufacturing site:	M/s United Biotech (P) Ltd.-Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	M/s United Biotech (P) Limited, Bagbania, Baddi-Nalagarh Road, Distt. Solan, Himachal Pradesh (174 101), India., India
	Details of Certificates (CoPP/FSC/cGMP):	Firm has attached CoPP (HFW-H(DRUGS) 427/05/25-95) valid up to 21-02-2026 issued by Office of State Drug Controller, Licensing and Controlling Authority, Health and Family Welfare Department, Himachal Pardesh, India. The CoPP specifies that the product
	Details of Authorization Letter :	The firm has provided LOA dated 25-07-2023 which is valid for 05 years.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as under; Long term testing conditions: Batch No: 010401, 010402, 010403 at 2-8oC for 36 months.
	The status in reference regulatory authorities	Pregnyl 5000IU of M/s Merk Sharp & Dohme, UK.
	Evaluation Remarks	

	Decision of 352nd meeting: Registration Board deferred the case for the submission of safety and efficacy data of applied product i.e. lyophilized chorionic gonadotrophin. Evaluation by BE&R: The firm has submitted following phase III clinical study report; "A multicenter, open label, randomized comparative, parallel group, active controlled phase IIIclinical trial to evaluate efficacy and safety of CHORIOTEC 5000 IU INJECTION (HumanChorionic Gonadotropin For Injection) of United Biotech (P) Limited, India comparison withPREGNYL (Human Chorionic Gonadotropin For Injection) of Merck & Co Inc., USA inPatients for Triggering of Final Follicular Maturation in Women Undergoing Controlled OvarianStimulation."	
	Decision	
	Approved Registration Board approved the product subject to compliance of current Import Policy for finished drugs along with submission of valid legalized COPP before issuance of registration letter.	
2	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(1LG-83L-Q1EG, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 12.5mg single dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these	

batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

3	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(2G1-47B-T9W5, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 15mg single dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-	

related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

4	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(6SS-2DQ-NN7S, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 2.5mg Injection in Prefilled Single Dose Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

5	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(J9E-MDW-G729, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 5mg Injection in Prefilled single dose Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5.0mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

6	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(RGB-AXQ-BZEE, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 10mg Injection in Prefilled single dose Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into

the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

7		
	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(VJJ-LL8-5M7D, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 7.5mg Injection in Prefilled single dose Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep Injection, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

8	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(71E-X8B-1QYN, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 10mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

9	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(AGZ-DJN-B941, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 2.5mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

	3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
10	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(BRN-ZD6-EAPW, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 5mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract	

testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

11	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(E5Z-L91-B64U, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 7.5mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352

Evaluation Remarks

The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.

Decision

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

12	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(GLM-UQ9-JPTB, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 12.5mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

13	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(ZB6-DXV-7Y4A, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Terza 15mg Single Dose Prefilled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Tirzep, DRB 352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

14	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(5S3-GS1-D48W, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 15 mg/0.5 ml Injection (Single Dose) Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains:Tirzepatide.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 15mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA (USA), MHRA(UK), EMA (Mounjaro)
	Detail of previous approval	TERZA 15 mg/0.5 ml Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

15	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(B3D-SD8-YZPG, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 2.5mg /0.5ml single dose Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 5mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA, MHRA(UK) and EMA (Mounjaro)
	Detail of previous approval	TERZA 2.5MG/0.5ML Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

16	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(UG6-ME7-5QEG, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 12.5 mg/0.5 ml Injection (Single Dose) Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains:Tirzepatide.....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 12.5mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA (USA), MHRA(UK), EMA (Mounjaro)
	Detail of previous approval	TERZA 12.5 mg/0.5 ml Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract	

testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

17	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(XZY-1ME-VL2D, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 5mg/0.5 ml Injection (Single Dose Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 5mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA (USA), MHRA(UK), EMA (Mounjaro)
	Detail of previous approval	TERZA 5MG/0.5ML Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

18	Case Category	Contract Manufacturing (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(JMH-1W2-ZHV6, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 10 mg/0.5 ml Injection (Single Dose) Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 10 mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA (USA), MHRA(UK), EMA (Mounjaro)
	Detail of previous approval	TERZA 10 mg /0.5 ml Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

	the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
19	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(98Y-NXN-YSRX, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Semozen 2mg/1.5ml Vial**
	Label Claim	Each 1.5ml Vial contains:- Semaglutide.....2mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	Seglutide Injection by Macter Pharma
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma, DRB 350
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

	the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
20	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(J64-V3L-HE83, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Semozen 4mg/3ml Vial**
	Label Claim	Each 3ml contains:- Semaglutide.....4mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma, DRB 350
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

21	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(N6B-1VG-JAML, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Semozen 1mg Solution for Injection in Prefilled Syringe**
	Label Claim	Each 0.74ml contains: - Semaglutide.....1.0mg (Solution for Injection for Subcutaneous Use) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	Semma Injection by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma, DRB 350
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into	

	the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
22	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(PU4-QJV-XSYP, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Semozen 0.5mg Solution for Injection in Prefilled Syringe**
	Label Claim	Each 0.37ml contains: - Semaglutide.....0.5mg (Solution for Injection for Subcutaneous Use) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	Semma Injection by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma, DRB 350
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the	

	Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
23	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(VPJ-T8U-ET7G, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	**Semozen 0.25mg Solution for Injection in Prefilled Syringe**
	Label Claim	Each 0.19ml contains: - Semaglutide.....0.25mg (Solution for Injection for Subcutaneous Use) (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	Semma Injection by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	Semma, DRB 350
	Evaluation Remarks	
	The applied formulation is already approved in name of proposed manufacturer in 350th meeting of Registration Board and letter has been issued vide F. No. 3-1/2021-ADC(BD)(M-350) dated 22-09-2025.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

24	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(5GN-N31-ADLU, 2026-02-17)
	Detail of Fee Submitted	97200, 2026-01-16,
	The proposed proprietary name / brand name	**Magra 7.5 mg/0.5 ml Injection (Single Dose) Pre-Filled Pen**
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore at 2°C–8°C. Do not freeze.
	For generic drugs (me-too Status)	Terza 7.5mg/0.5ml Single Dose Prefilled Pen by Weatherfolds
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot # 69/2. Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA (USA), MHRA(UK), EMA (Mounjaro)
	Detail of previous approval	TERZA 7.5MG/0.5ML Injection in PreFilled Pen, 352 Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	

	2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
25	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(AGW-8HN-EYMB, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-06-20,
	The proposed proprietary name / brand name	**Hepatex-B**
	Label Claim	Each ml Contains: Heparin Sodium 5000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's * 5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Product Name:: HEPARINOL 5000 STERILE SOLUTION FOR INJECTION. ,Registration No: 045680 ,Company Name: Bio Medics Medical system ,Company Address: F-597, F-Block, Satellite town ,Route of Admin: intrav
	Pharmacotherapeutic Group of (API)	Anticoagulants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	KIN MASTER PRODUTOS QUIMICOS LTDA, RUA MIGUEL VARGAS 595
	Detail of stability batches of drug product	Firm has submitted stability study data of 3 batches of drug product at real time conditions for 12 months and accelerated conditions for 6 months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No. RO-882D17
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches 120813HEP, 290813HEP, 110214HEP at accelerated and real time conditions.
	The status in reference regulatory authorities	Heparin Sodium Injection 5,000 USP units/mL, Manufactured by: Hikma Pharmaceuticals USA

		Inc. Eatontown, NJ 07724 USA , FDA Approved
	GMP status of the firm	GMP certificate of M/s Rotex Pharma is valid till 19-02-2027
	Evidence of approval of manufacturing facility	GMP certificate of Drug substance manufacturer is valid till 22-07-2026
	Evaluation Remarks	
	Case may be approved.	
	Decision	
	Approved Registration Board approved the product with change of brand name.	
26	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Rotex Pharma Pvt Ltd** Plot No 206 207 Industrial Triangle Kahuta Road **(000651)**
	Application Form Dy. No / Tracking ID & date of submission	(27D-9BX-1EGG, 2025-07-02)
	Detail of Fee Submitted	37000.0, 2025-06-20,
	The proposed proprietary name / brand name	**Hepatex-P**
	Label Claim	Each ml Contain: Heparin Sodium..... 5000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's * 5ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Product Name:: Inhixa Solution for Injection , Registration No: 115185, Company Name: Macter International Limited
	Pharmacotherapeutic Group of (API)	Anticoagulants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Yino Pharma Ltd., 2 Cuiping Erxiang, Yubei District, Chongqing, 401120, China
	Detail of stability batches of drug product	Real time and accelerated data of 3 pilot batches till 6 months is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate No. E-4155962088537
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The real time stability data is conducted at 25°C±2°C and 60%RH±5% RH, at the intervals of every 3 months over the first year, every 6 months over the second year, and annually thereafter till 72 months on batches YN01011150801, YN01011R1151101, YN01011R1151102. Accelerated is conducted at temperature at 40°C±2°C and 75%RH±5% RH the time points are 0, 1, 2, 3, and 6 months on 3 batches YN01011150801, YN01011R1151101, YN01011R1151102.
	The status in reference regulatory authorities	Heparin Sodium Injection 5,000 USP units/mL, Manufactured by: Hikma Pharmaceuticals USA Inc. Eatontown, NJ 07724 USA , FDA Approved

	GMP status of the firm	GMP certificate of M/s Rotex Pharma is valid till 19-02-2027
	Evidence of approval of manufacturing facility	A letter from Chongqing Municipal Medical Products Administrator is submitted which states that the plant complies with requirements of Chinese Good Manufacturing Practice for Medical Products.
	Evaluation Remarks	
	Decision of 352nd meeting: Registration Board deferred the case for submission of following documents/clarifications; i. Manufacturing process of raw heparin is required. ii. Identification by NMR is not a part of finished product specifications as required in BP. iii. Revised finished product specifications required including following tests; • Identification by NMR. • Ratio of anti-factor Xa activity to anti-factor IIa activity. • Test for related substances. iv. All tests as mentioned in finished product specifications should be a part of stability studies also. v. Document/evidence for procurement of API is required. Remarks: The firm has submitted the required documents/data, so the case may be approved.	
	Decision	
	Approved Registration Board approved the product.	
27	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Medipak Limited** 132, Industrial Estate, Kot Lakhpat **(000257)**
	Application Form Dy. No / Tracking ID & date of submission	(JL6-S6R-VTRU, 2025-10-24)
	Detail of Fee Submitted	38700, 2025-10-10,
	The proposed proprietary name / brand name	**Epomed 4000IU PFS**
	Label Claim	Each PFS Contains: Recombinant Human Erythropoietin alpha....4000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x100's-As per SRO
	Shelf Life (Unit)	2 Year2-8 degree
	For generic drugs (me-too Status)	ROPO (M/s Sami Pharmaceuticals Pvt. Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s BF Biosciences Limited-5 Km Sunder Raiwind Road, Raiwind Lahore-
	Name & address of API manufacturer	Zelltek S.A (Parque Tecnológico del Litoral Centro (PTLC), on RN 168, Paraje El Pozo, Santa Fe, Argentina)
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA (Eprex)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Firm has requested to withdraw the application because same product with another pack size is already submitted in DRAP for registration. "We will withdraw this application or you can reject/cancel this application. We will proceed initially with 1x1's pack size."	
	Decision	
	Rejected Registration Board acceded to the request of the firm for withdrawal of Epomed 4000IU PFS (1x100's).	
28	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Medipak Limited** 132, Industrial Estate, Kot Lakhpat **(000257)**
	Application Form Dy. No / Tracking ID & date of submission	(UG3-WUW-DP8U, 2025-10-24)
	Detail of Fee Submitted	38700, 2025-10-10,
	The proposed proprietary name / brand name	**Epomed 10000IU PFS**
	Label Claim	Each PFS contains: Recombinant Human Erythropoietin alpha....10000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x100's-As per SRO
	Shelf Life (Unit)	2 Year2-8 degree
	For generic drugs (me-too Status)	ROPO (M/s Sami Pharmaceuticals Pvt. Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s BF Biosciences Limited-5 Km Sunder Raiwind Road, Raiwind Lahore-
	Name & address of API manufacturer	Zelltek S.A (Parque Tecnológico del Litoral Centro (PTLC), on RN 168, Paraje El Pozo, Santa Fe, Argentina)
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA (Eprex)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has requested to withdraw the application because same product with another pack size is already submitted in DRAP for registration. "We will withdraw this application or you can reject/cancel this application. We will proceed initially with 1x1's pack size."	
	Decision	
	Rejected Registration Board acceded to the request of the firm for withdrawal of Epomed 10,000IU PFS (1x100's).	
29	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Medipak Limited** 132, Industrial Estate, Kot Lakhpat **(000257)**

	Application Form Dy. No / Tracking ID & date of submission	(Z5W-QVS-8E8G, 2025-10-24)
	Detail of Fee Submitted	38700, 2025-10-10,
	The proposed proprietary name / brand name	**Epomed 4000IU Injection**
	Label Claim	Each Vial Contains: Recombinant Human Erythropoietin alpha...4000IU
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x100's-As per SRO
	Shelf Life (Unit)	2 Year2-8 degree
	For generic drugs (me-too Status)	Mac Epo (Macter International Limited Karachi)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s BF Biosciences Limited-5 Km Sunder Raiwind Road, Raiwind Lahore-
	Name & address of API manufacturer	Zelltek S.A (Parque Tecnológico del Litoral Centro (PTLC), on RN 168, Paraje El Pozo, Santa Fe, Argentina)
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA (Epogen Injection)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has requested to withdraw the application because same product with another pack size is already submitted in DRAP for registration. "We will withdraw this application or you can reject/cancel this application. We will proceed initially with 1x1's pack size."	
	Decision	
	Rejected Registration Board acceded to the request of the firm for withdrawal of Epomed 4000IU Injection vial (1x100's).	
30	Case Category	Priority As Per 257-M of RB (Anam Saeed)
	Name, address of Applicant.	**Bristol Mayer Biotech Pakistan** 73 B Guldasht Town Zarrar Shaheed Lahore **(05-352-0068-109282D)**
	Application Form Dy. No / Tracking ID & date of submission	(XYA-Q92-B4HX, 2025-08-13)
	Detail of Fee Submitted	300000.0, 2025-05-26,
	The proposed proprietary name / brand name	**SUYA-FIX**
	Label Claim	Each vial contains Human coagulation factor IX .....500 IU (10ml after reconstitution)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial/box-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8°C. Protect from light
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	Anti-haemorrhagics: blood coagulation factor IX ATC code: B02BD04.
Name, address of Manufacturing site:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd-Address: No. 888, Antai 5th Road, Hi-Tech Zone, Chengdu, Sichuan, P.R. China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Grand Shuyang Life Sciences (Chengdu) Co., Ltd, Address: No. 888, Antai 5th Road, Hi-Tech Zone, Chengdu, P.R. China, China
Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted Apostile COPP No. Sichuan 20250108 issued by Sichuan Medical Products Administration, China valid till 09-04-2027. The certificate confirms that the product is actually on the market in the exporting country and facilities and operation
Details of Authorization Letter :	Firm has submitted Apostile Letter of Authorization dated 29-04-2025. Brand name is not mentioned in the Letter.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The Human Coagulation Factor IX bulk is not stored. To assess the stability of the active components during the brief storage period of the bulk before preparation, three batches (202303F01, 202303F02 and 202303F03) of thawed bulk are kept for 10 hours and tested at 0,4,6,8 and 10 hours intervals.
The status in reference regulatory authorities	MHRA approved (ALPHANINE 500 I.U. POWDER AND SOLVENT FOR SOLUTION FOR INJECTION)

Evaluation Remarks

Decision of 352 meeting: Registration Board deferred the case for the submission of following documents/clarifications; Approval letters for the plasma collection centers issued by their respective regulatory authorities have not been provided. Test reports for B19 DNA, HAV RNA, total protein, and Factor VIII content of human plasma must be submitted. Details of the collection process for single-donor plasma, small-sample mixed plasma, and pooled plasma are required. Structural characterization of the drug substance has not been provided. Justification for not conducting non-clinical studies on thrombogenicity/thrombogenic potential of the applied product is required, in accordance with the relevant reference guidelines.

Sr.No.	Queries	Response of the firm	Remarks
1	Approval letters for the plasma collection centers issued by their respective regulatory authorities have not been provided.	There are 17 plasmapheresis centers providing plasma for Shuyang. Each plasmapheresis center holds a valid Plasmapheresis License issued and approved by the Health Commission. The complete list of the 17 licensed plasmapheresis centers and their corresponding licenses is provided in Annex 1.	Provided
2	Test reports for B19 DNA, HAV RNA, total protein, and Factor VIII content of human plasma must be submitted.	For B19 DNA and HAV RNA test, We have sent representative plasma samples to the National Institute for Biological	-

		Standards and Control (NIBSC) for B19 DNA and Hepatitis A virus (HAV) RNA testing. Please find test reports in Annex 2 For Total protein content test, Please refer to the test report provided in Annex 3. For VIII content test, please refer to the explanation provided in Annex 4.	
3	Details of the collection process for single-donor plasma, small-sample mixed plasma, and pooled plasma are required.	Please refer to Annex 5 Collection details.	-
4	Structural characterization of the drug substance has not been provided.	Please refer to Annex 6 Drug substance Structure.	-
5	Justification for not conducting non-clinical studies on thrombogenicity/thrombogenic potential of the applied product is required, in accordance with the relevant reference guidelines.	Please refer to Annex 7 Justification of not performing non-clinical studies.	Manufacturer has not performed thrombogenecity studies separatively rather informed that “During the clinical trial, no thrombotic events were reported.” Phase III clinical trial is conducted in patients older than 12 years of age and the firm informed that “In China, completion of the adult and adolescent clinical study allows the product to be approved for marketing and to obtain the corresponding indication for this population. Following marketing authorization, our company has been actively advancing the pediatric clinical development program with the aim of further expanding the indication to include the pediatric population (i.e. all age groups). At present, the pediatric clinical trial has obtained regulatory approval, and the Clinical Study Report (CSR) is expected to be available by September 2027”.

	· Remarks: The manufacturer has conducted clinical trial in age group older than 12 years and the firm has mentioned in SmPC under therapeutic indications as below; “FIX is indicated in adults, adolescents and children aged 12 years and older” EMA “Guideline on the clinical investigation of recombinant and human plasma-derived factor IX products” Revision 2 states that; “Clinical trial data, addressing efficacy and safety with respect to immunogenicity, thrombogenicity and other adverse events in all age groups, are required in an application for a marketing authorisation.” The manufacturer informed that “pediatric clinical trial has obtained regulatory approval, and the Clinical Study Report (CSR) is expected to be available by September 2027”. The manufacturer has not performed thrombogenicity studies rather informed that During the clinical trial, no thrombotic events were reported. As per EMA guidelines “Guideline on the clinical investigation of recombinant and human plasma-derived factor IX products” Revision 2; “For new factor IX products, appropriate tests for markers of activation of coagulation (prothrombin fragment 1+2, thrombin-antithrombin (TAT) and D-dimer) should be carried out in pre- and post-infusion samples obtained in the non-bleeding state. This should be determined in the patients participating in the pharmacokinetic trial.”	
	Decision	
	Deferred Registration Board deferred the case till submission of Pediatric Clinical Trial Report in patients less than 12 years of age.	
31	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**HIPRA PAKISTAN PVT LTD.** House no 86-88, J-1 Sunflower Society, M.A Johar Town, Lahore **(05-352-0058-050528D)**
	Application Form Dy. No / Tracking ID & date of submission	(SVQ-VRD-DUDH, 2025-10-02)
	Detail of Fee Submitted	313500, 9400 2025-09-29, 2026-02-09
	The proposed proprietary name / brand name	**Gumbohatch**
	Label Claim	Each dose contains: Live attenuated Infectious Bursal Disease Virus, strain 1052..... $10^{1.18}$ - $10^{2.80}$PU* * PU: Potency Units
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10-De-Controlled
	Shelf Life (Unit)	24 Year(s)2-8
	For generic drugs (me-too Status)	GUMBOHATCH
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s Laboratorios HIPRA S.A -Carretera C-63,Km 48,300, Poligono Industrial Ei Rireal, 17170 Amer (Girona) Avda la Selva, 135 17170 Amer (Girona)-Spain
	Name, address of Marketing Authorization Holder:	M/s Laboratorios HIPRA S.A , Avda la Selva, 135,17170 Amer Girona, Spain
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille EMA CoPP No. 01/22/172554 dated 07-07-2022.
	Details of Authorization Letter :	Scanned notarized product specific LOA dated 06-08-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 01R1, 06J4, 49L0 Conditions: 2-8C Frequency: 0, 3, 6, 9, 12, 15, 18, 24 Months
	Evaluation Remarks	
	The above product is already registered in other packs i.e. 1000, 2000, 4000, 8000 and 10000 doses. The firm has now submitted application for 5000 doses.	

	Decision	
	Approved Keeping in view Apostille CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
32	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(BBZ-G9S-LG67, 2024-09-13)
	Detail of Fee Submitted	300000.0, 2024-06-10,
	The proposed proprietary name / brand name	**Betrast 150mg (Combipack) r-DNA product**
	Label Claim	Each pack contains: Vial-1 Lyophilized for Powder for concentrate for solution for Intravenous Infusion Trastuzumab (rDNA origin).....150mg Vial-2 Bacteriostatic Water for Injection Each vial contains: Benzyl Alcohol USP..... 1.1% v/v Water for Injection.....q.s 10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a referigerator at 2 - 8 degree centigrade and do not freeze
	For generic drugs (me-too Status)	Herceptin 150 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration no 087086)
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Macter International Limited.-F- 216, S.I.T.E, Karachi 75700, Pakistan-Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted
	Name, address of Marketing Authorization Holder:	Macter International Limited., F- 216, S.I.T.E, Karachi 75700, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP No. 4247174/TS/2023 valid till 03-10-2023
	Details of Authorization Letter :	Scanned legalized Supply Agreement dated 22-09-2022.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P5CTD1801, P5CTD1802, P5CTD1803 Long Term (Real Time Condition) Stability Study : -20°C ± 5°C Accelerated Stability Study: 2°C – 8°C Long term 36M Accelerated 6M
	The status in reference regulatory authorities	Herceptin 150 mg powder for concentrate for solution for infusion available, for intravenous infusion use registered product of Roche Pharma AG Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen Germany approved by European Medicines Agency (EMA) in 28 August 2000
	Evaluation Remarks	

	The case was deferred in 348th meeting as follows: The Registration Board deferred the case for the submission of the Bio similarity studies as per WHO. The firm submitted the response which was evaluated and following are observations: 1. There is difference in %age Low Molecular Weight Impurities in Reference product from your product. Reference product range is from 1.2-1.7 while your product's range is 4.3-5.2. Please explain with scientific rationale? 2. There is difference in Antibody dependent cellular cytotoxicity activity of Reference product from your product. Reference product range is from 43.4-82.4 while your product's range is 97.2-111. Please explain with scientific rationale? 3. There is difference in results of FCϒRIIIa V158 ligand binding affinity of Reference product from your product. Reference product range is from 92.7-97.15 while your product's range is 72.3-75.55. Please explain with scientific rationale? 4. There is difference in results of FCϒRIIIa F158 ligand binding affinity of Reference product from your product. Reference product range is from 354.5-412 while your product's range is 447.5-494.5. Please explain with scientific rationale? The firm submitted the following: The Phase-III Clinical study conducted by Hetero evaluated the efficacy of Hetero-Trastuzumabagainst the Reference Medicinal Product, Roche-Trastuzumab, and a good correlation betweenthe two study groups was demonstrated in terms of efficacy, immunogenicity and safety. Moreover, the stability data of submitted of batches having batch size of 95 vials.	
	Decision	
	Deferred Registration Board deferred the case for following: 1. Stability data provided is of batches having batch size of 95 vials. 2. A clarification from Manufacturer abroad either on their letter head in hard or on official e-mail that as per submitted GMP certificate issued by regulatory authority of country of origin, the product is for Export purpose only.	
33	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(MLV-ZLU-N5JM, 2024-10-08)
	Detail of Fee Submitted	300000.0, 2024-06-10,
	The proposed proprietary name / brand name	**Betrast 440mg (Combipack) r-DNA product**
	Label Claim	Each pack contains: Vial-1 Lyophilized for Powder for concentrate for solution for Intravenous Infusion Trastuzumab (rDNA origin).....440mg Vial-2 Bacteriostatic Water for Injection Each vial contains: Benzyl Alcohol USP..... 1.1% v/v Water for Injection.....q.s 10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 vial-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a referigerator at 2 - 8 degree centigrade and do not freeze
	For generic drugs (me-too Status)	Herceptin 440 mg Lyophilized Powder for infusion of M/s Roche Pakistan Ltd (Registration no 087085)
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Macter International Limited.-F- 216, S.I.T.E, Karachi 75700, Pakistan-Pakistan

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted
	Name, address of Marketing Authorization Holder:	Macter International Limited., F- 216, S.I.T.E, Karachi 75700, Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned legalized CoPP No. 4247187/TS/2023 valid till 03-10-2023
	Details of Authorization Letter :	Scanned legalized Supply Agreement dated 22-09-2022.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: P5CTD1801, P5CTD1802, P5CTD1803 Long Term (Real Time Condition) Stability Study : -20°C ± 5°C Accelerated Stability Study: 2°C – 8°C Long term 36M Accelerated 6M
	The status in reference regulatory authorities	Herceptin 440 mg powder for concentrate for solution for infusion available for intravenous infusion registered product of Roche Pharma (Schweiz) AG Switzerland approved by Swiss medic
	Evaluation Remarks	
	The case was deferred in 348th meeting as follows: The Registration Board deferred the case for the submission of the Bio similarity studies as per WHO. The firm submitted the response which was evaluated and following are observations: 1. There is difference in %age Low Molecular Weight Impurities in Reference product from your product. Reference product range is from 1.2-1.7 while your product's range is 4.3-5.2. Please explain with scientific rationale? 2. There is difference in Antibody dependent cellular cytotoxicity activity of Reference product from your product. Reference product range is from 43.4-82.4 while your product's range is 97.2-111. Please explain with scientific rationale? 3. There is difference in results of FCγRIIIa V158 ligand binding affinity of Reference product from your product. Reference product range is from 92.7-97.15 while your product's range is 72.3-75.55. Please explain with scientific rationale? 4. There is difference in results of FCγRIIIa F158 ligand binding affinity of Reference product from your product. Reference product range is from 354.5-412 while your product's range is 447.5-494.5. Please explain with scientific rationale? The firm submitted the following: The Phase-III Clinical study conducted by Hetero evaluated the efficacy of Hetero-Trastuzumabagainst the Reference Medicinal Product, Roche-Trastuzumab, and a good correlation betweenthe two study groups was demonstrated in terms of efficacy, immunogenicity and safety. Moreover, the stability data submitted of batches having batch size of 95 vials and GMP certificate provided is indicating both Trastuzumab products for Export Purpose.	
	Decision	
	Deferred Registration Board deferred the case for following: 1. Stability data provided is of batches having batch size of 95 vials. 2. A clarification from Manufacturer abroad either on their letter head in hard or on official e-mail that as per submitted GMP certificate issued by regulatory authority of country of origin, the product is for Export purpose only.	
34	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**PACIFICA RESEARCH LABORATORIES (PVT.) LTD.,** Sumya Garden, Plot No.28, Flat No. G-2, Ground Floor, Memon Co-Operative Housing Society, Ltd. Karachi. **(0466)**
	Application Form Dy. No / Tracking ID & date of submission	(BNU-PU2-M44R, 2025-05-27)

	Detail of Fee Submitted	300000.0, 2024-12-10,
	The proposed proprietary name / brand name	**VICENTIS 2.3mg/0.23ml** **Sterile Solution for Injection**
	Label Claim	Each vial (0.23ml) contains: Ranibizumab.....23mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	36 Month(s)2-8 degree centigrade
	For generic drugs (me-too Status)	PATIZRA by Novartis - Pakistan
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Pooyesh Darou Co. (Pooyesh Darou Biopharmaceutical-Fanavari 18 St., Pardis Technology Park, Abali Highway 15 km Road, Tehran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	ARAcell Zist Darou, No. 34, West Saeb Tabrizi Street, Sheikh Bahaei Street, Mollasadra Street, Tehran, Iran
	Details of Certificates (CoPP/FSC/cGMP):	Copy of CoPP No. 665/50754 dated 14-08-2024.
	Details of Authorization Letter :	Copy of commercial agreement dated 12-11-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	B-96-Fab-01, B-96-Fab-01, B-96-Fab-01 900 Vials, 1000 Vials, 1000 Vials Real time at -20C, Accelerated not provided
	The status in reference regulatory authorities	LUCENTIS by Genentech Inc. - USA
	Evaluation Remarks	
	The case was approved in 351st meeting as follows: Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of Repeat dose toxicity as per WHO Guidelines for similar Biotherapeutic products. The firm has submitted single-dose toxicity study data along with a legalized letter from Ministry of Health and Medical Education Iran mentioning the following: "We certify that the Common Technical Document (CTD) of Vicentis (Ranibizumab Biosimilar) has been submitted in IFDA in 2018. The initial batches #97-30-1, manufactured in 03/2019 and # 98-30-1 manufactured in 06/2019 were released and used for Clinical evaluation only. A randomized clinical trial (Iranian Registry of Clinical Trial #IRCT20170303032845NI) was conducted at two major university hospitals, comparing the safety and efficacy of Vicentis with Lucentis (the original brand product). The trial began in 2019, and following submission of the final clinical report, the IFDA issued marketing authorization (Medicine Registration Certificate) on 2022 and renewed on 2024 and 2025. Since approval, batches #R0101, #R0102, and #R0103 (manufactured in 02/2023) and #R0401 (manufactured in 05/2025) have been produced and released in Iran. According to the IFDA regulation, ARA cell Biopharma is conducting a post marketing survey which will be provided by ARA Cell Biopharma. We also note that the ADR centre of IFDA has not received any major side effect reports."	
	Decision	
	Deferred Registration Board deferred the product for submission of repeat-dose toxicity studies under biosimilarity studies.	
35	Case Category	Priority As Per 257-M of RB (M. Zubair Masood)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** 115, Industrial Triangle Kahuta Road

		(017/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission	(ERH-MJS-4Q9Y, 2026-02-27)
	Detail of Fee Submitted	313500, 2025-12-30,
	The proposed proprietary name / brand name	**ZyVac TCV** **Typhoid Vi Conjugate Vaccine**
	Label Claim	Each dose of 0.5 ml contains: Purified Vi-capsular polysaccharide of S.typhi.....25 µg conjugated to Tetanus toxoid (Carrier protein).....16 to 50 µg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	2.5ml (5 doses) x 50's Vials-As per SRO
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Name: Typbar TCV Typhoid Vi Conjugate Vaccine Registration No. : 107998 Manufacturer Vikor Enterprise Pvt Ltd
	Pharmacotherapeutic Group of (API)	Typhoid Vaccine
	Name, address of Manufacturing site:	Zydus Lifesciences Limited., -Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50 Sarkhej-Bavla N.H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Tal: Sanand, Dist. Ahmedabad – 382 213 Gujrat State -India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	WHO PQ Vaccine
	Name, address of Marketing Authorization Holder:	Zydus Lifesciences Limited., , Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50 Sarkhej-Bavla N.H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Tal: Sanand, Dist. Ahmedabad – 382 213 Gujrat State , India
	Details of Certificates (CoPP/FSC/cGMP):	Scanned CoPP No. MFG/WHO/COPP/ZLL/2025 dated 12-12-2025.
	Details of Authorization Letter :	Scanned LOA dated 14-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: CE20013, CE20014, CE20015 Batch Size: 6L Realtime at 2-8 for 36 months Accelerated at 25 for 06 months
	The status in reference regulatory authorities	WHO Prequalified Vaccine .Brand name: ZyVac TCV (Typhoid Vi Conjugate Vaccine) Link:https://extranet.who.int/prequal/sites/default/p-442_typhoid_5doses_zydus_whopar-2024.pdf
	Evaluation Remarks	
	The applied product is WHO PQ vaccine and can be verified @ https://extranet.who.int/prequal/vaccines/p/zyvacr-tcv Moreover, the provided scanned CoPP is not legalized.	
	Decision	
	Approved Keeping in view the WHO prequalification of product; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
36	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**

Application Form Dy. No / Tracking ID & date of submission	(DWH-S1E-8PWS, 2026-02-24)
Detail of Fee Submitted	313500, 2025-10-07,
The proposed proprietary name / brand name	**BCG Vaccine for Intradermal Injection**
Label Claim	Live BCG, after reconstitution as the stated value, 0.5 ml (5 human dose) of the reconstituted vaccine per container contains 0.25mg of BCG. 1 mg BCG shall contain 1.0x10(6)-8.0x10(6) CFU
Reference to Finished product specifications	Any Other
Proposed Pack Size	1x1's (Lyophilized Powder) + 0.5ml Diluent sterile water for injection-As per SRO
Shelf Life (Unit)	36 Month2-8 ºC
For generic drugs (me-too Status)	BCG VACCINE, HOSPITAL SERVICES & SALES (053816)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Shanghai Institute of Biological Products Co., Ltd-No 758 Guangfeng Road, Fengxian District, Shanghai-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Shanghai Institute of Biological Products Co., Ltd, No 758 Guangfeng Road, Fengxian District, Shanghai, China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	WHO Pre-qualified (Pharmaceutical and Medical Devices Agency Japan) https://extranet.who.int/prequal/vaccines/p/bcg-freeze-dried-glutamate-vaccine-0

Evaluation Remarks

Following are the observations/ deficiencies in application: DSL is expired. DML of Manufacturer abroad is expired. Chinese Pharmacopoeia Specs are mentioned. Please clarify that the strain used in BCG vaccine i.e. D_2PB302 is equivalent to WHO recommended strains? Did you perform any laboratory and clinical tests to analyze the efficacy of master seed lots before manufacturing working seed lots? WHO recommends different tests to be performed on final vaccine bulk while you are performing only Bacterial Purity and concentration Determination? Are there any accelerated stability studies performed on final bulk? Section 2.3.S.5, Reference Standard shows "Not Applicable", Please explain? Specifications of excipients are also In-house. Please explain? WHO recommends safety tests of final lot while these tests are not performed by manufacturer, Please explain? Please provide evidence that the excipients used in finished product are same as of Innovator product or products registered in RRAs, if not, then submit Comapatability studies. In Section 3.2.S.3.2 & 3.2.P.5.5, No relevant impurities is mentioned, Please explain? In-house Reference standards are used for quality control of product, Please provide the details of primary reference standard against which these reference standards were standardized. RRA reference of BCG vaccine in vial packaging? Shipping Validation studies. Module-2 & 3 of Diluent Part are not submitted. Immunogenicity studies in non-clinical studies are not performed? Repeated-dose toxicity studies are not performed? Detailed clinical study reports of applied vaccine are required, also confirm if any of the clinical and non-clinical studies have been performed in comparison with a reference or WHO PQ vaccine? Also submit complete SmPC on Format as built in E-App.

Decision

Deferred

Registration Board deferred the case for following:

- DSL is expired.
- DML of Manufacturer abroad is expired.
- Chinese Pharmacopoeia Specs are mentioned.
- Please clarify that the strain used in BCG vaccine i.e. D_2PB302 is equivalent to WHO recommended strains?
- Did you perform any laboratory and clinical tests to analyze the efficacy of master seed lots before manufacturing working seed lots?
- WHO recommends different tests to be performed on final vaccine bulk while you are performing only Bacterial Purity and concentration Determination?
- Are there any accelerated stability studies performed on final bulk?
- Section 2.3.S.5, Reference Standard shows "Not Applicable", Please explain?
- Specifications of excipients are also In-house. Please explain?
- WHO recommends safety tests of final lot while these tests are not performed by manufacturer, Please explain?
- Please provide evidence that the excipients used in finished product are same as of Innovator product or products registered in RRAs, if not, then submit Comapatability studies.
- In Section 3.2.S.3.2 & 3.2.P.5.5, No relevant impurities is mentioned, Please explain?
- In-house Reference standards are used for quality control of product, Please provide the details of primary reference standard against which these reference standards were standardized.
- RRA reference of BCG vaccine in vial packaging?
- Shipping Validation studies.
- Module-2 & 3 of Diluent Part are not submitted.
- Immunogenicity studies in non-clinical studies are not performed?
- Repeated-dose toxicity studies are not performed?
- Detailed clinical study reports of applied vaccine are required, also confirm if any of the clinical and non-clinical studies have been performed in comparison with a reference or WHO PQ vaccine?
- Also submit complete SmPC on Format as built in E-App.

37	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(GZB-R6V-JRL2, 2026-02-26)
	Detail of Fee Submitted	313500, 2025-10-29,
	The proposed proprietary name / brand name	**Combipack of Snake Venom Antiserum with Sterile Water for Injection**
	Label Claim	After reconstitution, each ml of Polyvalent Snake Venom Antiserum neutralizes not less than, • Indian Cobra Venom (Naja naja) 0.60 mg • Common Krait Venom (Bungarus caeruleus) 0.45 mg • Russell·s Viper Venom (Vipera russelli) 0.60 mg • Saw Scaled Viper Venom (Echis carinatus) 0.45 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10ml X 5 vials (Lyophilized Powder) + 10ml X 5 ampoule of sterile wat-As per SRO
	Shelf Life (Unit)	48 MonthBelow 30°C

For generic drugs (me-too Status)	Product Name: Polyvalent Anti Snake Venum Serum (Liquid Injection) Registration No: 056837. Company Name: Amson Vaccines & Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Premium Serums and Vaccines Pvt. Ltd. -S. No. 354-1,354-2A/1, At &post Narayangaon, Tal. Junnar, District Pune 410504, Maharashtra State-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Premium Serums and Vaccines Pvt. Ltd. , S. No. 354-1,354-2A/1, At &post Narayangaon, Tal. Junnar, District Pune 410504, Maharashtra State, India
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	WHO GMP Certificate is provided

Evaluation Remarks

Following are the observations/ deficiencies in application: Drug Sale License is expired. The submitted administrative documents from country of origin (CoPP, LOA, GMP, DML Retention) are Apostilled while Apostille document is not acceptable from India as per Apostille convention. The submitted DML retention document of manufacturer abroad is only indicating Scorpion Venom Antiserum. Finished product specifications are mentioned as Indian Pharmacopoeia Detailed procedure for immunization is required. After Pepsin Digestion WHO recommends pH adjustment at 4.5-5.0 while in your manufacturing process, the pH is adjusted at 5.2-5.8, Please explain? How it is determined that the animal is ready for blood collection after immunization? 10% overages are mentioned. Please justify in light of WHO or other RRAs guidelines? Specifications of excipients are also mentioned as IP? Stability data provided is of batches of year 2019 for lyophilized and diluent part both. Please submit stability data of three commercial batches of year 2021. WHO states that Snake venoms generate a wide range of systemic pathologies, including a variety of haemostasis-disruptive (haemorrhage, pro- and anti-coagulopathic effects), neurotoxic, myotoxic, nephrotoxic and cardiac effects. Supplementary tests are therefore recommended. You have not performed any such preclinical supplementary studies, Please explain? Please provide any WHO OR RRAs Guidelines that allow reliance on Post Marketing Surveillance data for assessment of safety and efficacy of Snake Antivenoms instead of conducting Randomized Clinical Trials. Also submit complete SmPC on Format as built in E-App.

Decision

Deferred

Registration Board deferred the case for following:

- Drug Sale License is expired.
- The submitted administrative documents from country of origin (CoPP, LOA, GMP, DML Retention) are Apostilled while Apostille document is not acceptable from India as per Apostille convention.
- The submitted DML retention document of manufacturer abroad is only indicating Scorpion Venom Antiserum.
- Finished product specifications are mentioned as Indian Pharmacopoeia
- Detailed procedure for immunization is required.
- After Pepsin Digestion WHO recommends pH adjustment at 4.5-5.0 while in your manufacturing process, the pH is adjusted at 5.2-5.8, Please explain?
- How it is determined that the animal is ready for blood collection after immunization?

	• 10% overages are mentioned. Please justify in light of WHO or other RRAs guidelines? • Specifications of excipients are also mentioned as IP? • Stability data provided is of batches of year 2019 for lyophilized and diluent part both. Please submit stability data of three commercial batches of year 2021. • WHO states that Snake venoms generate a wide range of systemic pathologies, including a variety of haemostasis-disruptive (haemorrhage, pro- and anti-coagulopathic effects), neurotoxic, myotoxic, nephrotoxic and cardiac effects. Supplementary tests are therefore recommended. You have not performed any such preclinical supplementary studies, Please explain? • Please provide any WHO OR RRAs Guidelines that allow reliance on Post Marketing Surveillance data for assessment of safety and efficacy of Snake Antivenoms instead of conducting Randomized Clinical Trials. • Also submit complete SmPC on Format as built in E-App.	
38	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** Plot No. 29-30, Sector-27, Korangi Industrial Area, Karachi, Pakistan **(DSL 0655)**
	Application Form Dy. No / Tracking ID & date of submission	(EEJ-SGE-1UY1, 2026-02-25)
	Detail of Fee Submitted	313500, 2025-10-21,
	The proposed proprietary name / brand name	**Pertumab Injection 420mg/14ml**
	Label Claim	Each 14ml vial contains: Pertuzumab.....420mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store in a refrigerator (2°C-8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Perjeta Injection 420mg/14ml (087083) by M/s Roche Pakistan Ltd., Pakistan.
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, monoclonal antibodies,
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co. Ltd. -8888 Lvyou Road, High-tech Zone, Jinan, 250104, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Getz Pharma Private limited, PLOT # 29 30 SECTOR 27, KORANGI INDUSTRIAL AREA, Karachi., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	NA
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies have been conducted for 1 phase I/III clinical batch and 4 process validation batches of drug substance during the clinical study. Among them, long-term and accelerated stability studies have been conducted for the phase I/III clinical batch of the drug substance, and comprehensive stability studies have been conducted for the first 3 process validation batches of drug substance, including high temperature, freeze-thaw, accelerated and long-term stability studies for the drug substance, and high temperature, accelerated and long-term

		stability studies are performed for the 4th batch of drug substance.
	The status in reference regulatory authorities	Perjeta Injection 420mg/14ml by M/s Genetech, Inc. USA.
	Evaluation Remarks	
	The firm has submitted quality safety and efficacy data in line with WHO Guidelines on biosimilars.	
	Decision	
	Approved Keeping in view the CoPP indicating availability of product in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
39	Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Roche Pakistan Ltd** Office # 1101-1104, 11th Floor, Al-Tijarah Centre, Plot # 32-1-A, PECHS Block 6, Karachi, Pakistan **(0493)**
	Application Form Dy. No / Tracking ID & date of submission	(7Z8-3RV-1R2S, 2026-02-26)
	Detail of Fee Submitted	313500, 2025-11-24,
	The proposed proprietary name / brand name	**Hemlibra**
	Label Claim	Each single-use, 3 mL vial contains 300 mg (nominal) of emicizumab per 2 ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2 °C – 8 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antihemorrhagics, other systemic hemostatics; ATC code: B02BX06 Humanized monoclonal modified immunoglobulin G4 (IgG4) antibody
	Name, address of Manufacturing site:	Samsung Biologics Co.,-Ltd 300 Songdo bio-daero, Yeonsu-gu, Incheon 21987, Republic of Korea -South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany
	Details of Certificates (CoPP/FSC/cGMP):	EMA approved product and facility
	Details of Authorization Letter :	MA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance as per ICH requirements is provided
	The status in reference regulatory authorities	EMA
	Evaluation Remarks	
	Hemlibra; Solution for injection, 150 mg/ml; 1 vial (2 ml) is approved by European Medicines Agency	
	Decision	
	Approved Keeping in view the CoPP issued by EMA indicating availability of product in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

40	Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Roche Pakistan Ltd** Office # 1101-1104, 11th Floor, Al-Tijarah Centre, Plot # 32-1-A, PECHS Block 6, Karachi, Pakistan **(0493)**
	Application Form Dy. No / Tracking ID & date of submission	(M52-634-8QEV, 2026-02-26)
	Detail of Fee Submitted	313500, 2025-11-24,
	The proposed proprietary name / brand name	**Hemlibra**
	Label Claim	Each single-use 3 mL vial contains 12 mg (nominal) of emicizumab per 0.4ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator 2 °C – 8 °C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antihemorrhagics, other systemic hemostatics; ATC code: B02BX06 Humanized monoclonal modified immunoglobulin G4 (IgG4) antibody
	Name, address of Manufacturing site:	Samsung Biologics Co.,-Ltd 300 Songdo bio-daero, Yeonsu-gu, Incheon 21987, Republic of Korea -South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany
	Details of Certificates (CoPP/FSC/cGMP):	EMA approved product
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Drug substance data submitted as per ICH guidelines
	The status in reference regulatory authorities	EMA
	Evaluation Remarks	
	Hemlibra 30 mg/mL solution for injection is approved by European Medicines Agency.	
	Decision	
	Approved Keeping in view the CoPP issued by EMA indicating availability of product in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
41	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**SIND MEDICAL STORES** 13-B, Block 6, PECHS, Shahrah e Faisal, **(450)**
	Application Form Dy. No / Tracking ID & date of submission	(RJE-S45-7TZ8, 2026-02-27)
	Detail of Fee Submitted	313500, 2025-12-09,
	The proposed proprietary name / brand name	**HEXASIIL - 1 Dose Vial of 0.5mL**
	Label Claim	Each dose of 0.5 ml contains: Diphtheria Toxoid ≥ 30 IU Tetanus Toxoid ≥ 40 IU B. pertussis (whole cell) ≥ 4 IU HBsAg (rDNA) 15 mcg Inactivated polio vaccine (Salk strains grown on

		vero cells) Type - 1 (Mahoney strain) 40 DU Type - 2 (MEF-1 strain) 8 DU Type - 3 (Saukett strain) 32 DU Hib (PRP) 10 mcg conjugated to TT (carrier protein) 19 to 33 mcg Excipients: Adsorbed on Aluminium Phosphate, Al+++ ≤ 1.25 mg 2-Phenoxyethanol 0.5 % Sodium Chloride (Normal saline), Acetic Acid +++ (Glacial) and Sodium hydroxide are used for pH adjustment.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1 Dose x 0.5mL Vial-Controlled
	Shelf Life (Unit)	24 Month(s)2 to 8°C
	For generic drugs (me-too Status)	HEXAXIM by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	Bacterial and viral vaccines combined,
	Name, address of Manufacturing site:	SERUM INSTITUTE OF INDIA PVT. LTD.-212/2, Hadapsar, Pune 411 028, INDIA.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	SIND MEDICAL STORES, 13-B, BLOCK 6, PECHS, KARACHI., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	WHO Prequalified Product
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of bulk monovalent antigens provided.
	The status in reference regulatory authorities	WHO PQ Vaccine
	Evaluation Remarks	
	The applied vaccine is WHO prequalified and approval can be verified at HEXASIIL | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)	
	Decision	
	Approved Keeping in view WHO PQ status of product; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
42	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**SIND MEDICAL STORES** 13-B, Block 6, PECHS, Shahrah e Faisal, **(450)**
	Application Form Dy. No / Tracking ID & date of submission	(6EX-Z96-GRXS, 2026-02-27)
	Detail of Fee Submitted	313500, 2025-12-09,
	The proposed proprietary name / brand name	**HEXASIIL - 10 Dose Vial of 5mL**
	Label Claim	Each dose of 0.5 ml contains: Diphtheria Toxoid ≥ 30 IU Tetanus Toxoid ≥ 40 IU B. pertussis (whole cell) ≥ 4 IU HBsAg (rDNA) 15 mcg Inactivated polio vaccine (Salk strains grown on vero cells) Type - 1 (Mahoney strain) 40 DU Type - 2 (MEF-1 strain) 8 DU Type - 3 (Saukett strain) 32 DU Hib (PRP) 10 mcg conjugated to TT (carrier protein) 19 to 33 mcg Excipients: Adsorbed on Aluminium Phosphate, Al+++ ≤

		1.25 mg 2-Phenoxyethanol 0.5 % Sodium Chloride (Normal saline), Acetic Acid +++ (Glacial) and Sodium hydroxide are used for pH adjustment.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 Dose x 5mL Vial-Controlled
	Shelf Life (Unit)	24 Month(s)2 to 8°C
	For generic drugs (me-too Status)	HEXAXIM by Sanofi Aventis
	Pharmacotherapeutic Group of (API)	Bacterial and viral vaccines combined
	Name, address of Manufacturing site:	SERUM INSTITUTE OF INDIA PVT. LTD.-212/2, Hadapsar, Pune 411 028, INDIA.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	SIND MEDICAL STORES, 13-B, BLOCK 6, PECHS, KARACHI., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ Product
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of monovalent bulk antigen is provided.
	The status in reference regulatory authorities	WHO PQ Vaccine
	Evaluation Remarks	
	The applied product is WHO PQ and can be verified at HEXASIIL | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)	
	Decision	
	Approved Keeping in view WHO PQ status of product; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
43	Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**CCL Pharmaceuticals Pvt. Ltd.** Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore **(05-352-0066-126587D)**
	Application Form Dy. No / Tracking ID & date of submission	(JT6-AHL-L99A, 2026-01-08)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	**Sejaro**
	Label Claim	Each 0.6ml contains: Tirzepatide.....7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 5±3 °C
	For generic drugs (me-too Status)	Zepatide-Macter International
	Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city, district, Moscow region-Russia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator

Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No. 710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	CoPP issued by Russian Authorities provides the GMP status
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available
The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response
1.	The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required.	The active pharmaceutical ingredient (API) Tirzepatide manufactured by Zhejiang Peptides Biotech Co., Ltd. i amino-acid peptide obtained by chemical synthesis. In with the regulatory requirements for the identification peptides as part of the specification and release, use of orthogonal methods is recommended (EMA/CHMP/CVMP/QWP/387541/2023). Therefore, quality control 2 methods to confirm the identification Tirzepatide (Mass Spectrometry and HPLC) are used w framework of the analysis of the "Identification" param quality specifications of API (sections 3.2.S.4.1 of the dossier). These methods has good specificity and were validated, and shown to be adequate for the purpose of identification confirmation. In addition no biological as required for the routine release of synthetic peptides in with regulatory requirements (EMA/CHMP/CVMP/QWP/387541/2023). However, development of the medicinal product Sejaro, a generic medicinal product Mounjaro®, a comparability study w out, including studies of biological activity by cell test. GIP activation of calcium currents and GLP-1 activatio calcium currents conformed that Mounjaro®, (original product) and Sejaro, generic medicinal product manufa Geropharm, are completely comparable (see sections 3 registration dossier for more details). Therefore, biolog is not included in the specification of Tirzepatide API.
2.	Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale	The COA for drug substance batch No. ZG2723070 is provided along with the clarification statement of pilot from the manufacturer which is as under: “Zhejiang Pe Biotech Co., Ltd hereby respectfully reports the follow concerning request from the Drug Regulatory Authorit Pakistan (DRAP) as part of the registration on the terri Pakistan of Sejaro, solution for subcutaneous injection, manufactured by OOO “GEROPHARM”. Zhejiang Pe Biotech Co., Ltd confirms that the development of the pharmaceutical substance Tirzepatide was initiated in 2 batches at pilot scale were manufactured in 2023 (inclu ZG27230701).
3.	In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced.	Zhejiang Peptides Biotech Co., Ltd. (API manufacture developing of active pharmaceutical substance tirzepat 2023. During the development process optimal parame synthesis conditions were selected and by the end of 2(batches were developed including pilot-scale ones. The

		The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy.	from API manufacturer contains the key information o API batches manufactured in 2024 and information reg pharmaceutical development in 2023 was not included by API manufacturer. Geropharm used tirzepatide batc manufactured in 2023 to develop generic product Sejar purpose of the pharmaceutical development and manuf process validation.
	4.	In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation.	Under the in-house procedure, batch numbers are gene follows: XXXMMYY, where XXX: a serial number o product batch manufactured within a calendar year. Ea product name in each dosage is numbered consecutivel with "01" on 1 January and ending on 31 December of year (format: 01, 02, 03, etc.). MM: digital designatio (month) of manufacture of the batch (format: 01 for Ja February, etc., 12 for December); YY: the last two dig year of manufacture of the batch (format: 25 for 2025; etc.). For example, batch 011023 is the first batch of th manufactured in October 2023.Therefore, different dos Sejaro may have the same batch number.
	5.	Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China.	Invoice for API Lot No. ZG27230701 (100g/Can x5) s Zhejiang Peptides Biotech Co., Ltd., China dated 18.8. provided.
	6.	Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	The manufacturer informed that applied product is bei manufactured on the same line as of insulin and semag containing products.

Decision

Deferred

Registration Board deferred for following:

- justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier.
- Stability data of batches used in manufacturing pilot and commercial scale batches of product.

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Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
Name, address of Applicant.	**CCL Pharmaceuticals Pvt. Ltd.** Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore **(05-352-0066-126587D)**
Application Form Dy. No / Tracking ID & date of submission	(UB8-EW5-6GP4, 2026-01-08)
Detail of Fee Submitted	313500, 2025-12-10,
The proposed proprietary name / brand name	**Sejaro**
Label Claim	Each 0.6ml contains: Tirzepatide.....2.5mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 5±3 °C

For generic drugs (me-too Status)	Zepatide-Macter International
Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city district, Moscow region-Russia
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator
Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	CoPP submitted indicates the GMP of manufacturer
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available.
The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response
1.	The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required.	The active pharmaceutical ingredient (API) Tirzepatide manufactured by Zhejiang Peptides Biotech Co., Ltd. is a 39-amino-acid peptide obtained by chemical synthesis. In accorda with the regulatory requirements for the identification of synth peptides as part of the specification and release, use of at least orthogonal methods is recommended (EMA/CHMP/CVMP/QWP/387541/2023). Therefore, in routi quality control 2 methods to confirm the identification of Tirzepatide (Mass Spectrometry and HPLC) are used within th framework of the analysis of the "Identification" parameter in quality specifications of API (sections 3.2.S.4.1 of the registrat dossier). These methods has good specificity and were verified validated, and shown to be adequate for the purpose of the identification confirmation. In addition no biological assay is required for the routine release of synthetic peptides in accorda with regulatory requirements (EMA/CHMP/CVMP/QWP/387541/2023). However, during th development of the medicinal product Sejaro, a generic of orig medicinal product Mounjaro®, a comparability study was carri out, including studies of biological activity by cell test. Compa GIP activation of calcium currents and GLP-1 activation of cal currents conformed that Mounjaro®, (original medicinal produ and Sejaro, generic medicinal product manufactured by Geropharm, are completely comparable (see sections 3.2.R of t registration dossier for more details). Therefore, biological acti is not included in the specification of Tirzepatide API.

	2.	Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale	The COA for drug substance batch No. ZG2723070 is provided along with the clarification statement of pilot scale ba from the manufacturer which is as under: “Zhejiang Peptites Biotech Co., Ltd hereby respectfully reports the following concerning request from the Drug Regulatory Authority of Pak (DRAP) as part of the registration on the territory of Pakistan c Sejaro, solution for subcutaneous injection, manufactured by C “GEROPHARM”. Zhejiang Peptites Biotech Co., Ltd confirms the development of the active pharmaceutical substance Tirzep was initiated in 2023 and batches at pilot scale were manufactu in 2023 (including batch ZG27230701).
	3.	In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced. The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy.	Zhejiang Peptides Biotech Co., Ltd. (API manufacturer) started developing of active pharmaceutical substance tirzepatide in ea 2023. During the development process optimal parameters and synthesis conditions were selected and by the end of 2023 seve batches were developed including pilot-scale ones. The final D from API manufacturer contains the key information only abou API batches manufactured in 2024 and information regarding pharmaceutical development in 2023 was not included in the D by API manufacturer. Geropharm used tirzepatide batches manufactured in 2023 to develop generic product Sejaro for the purpose of the pharmaceutical development and manufacturing process validation.
	4.	In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows	Under the in-house procedure, batch numbers are generated as follows: XXXMMYY, where XXX: a serial number of medicin product batch manufactured within a calendar year. Each medi

	identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation.	product name in each dosage is numbered consecutively, startir with "01" on 1 January and ending on 31 December of the curr year (format: 01, 02, 03, etc.). MM: digital designation of the (month) of manufacture of the batch (format: 01 for January, 0 February, etc., 12 for December); YY: the last two digits of th year of manufacture of the batch (format: 25 for 2025; 26 for 2 etc.). For example, batch 011023 is the first batch of the year, manufactured in October 2023.Therefore, different dosages of Sejaro may have the same batch number.
5.	Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China.	Invoice for API Lot No. ZG27230701 (100g/Can x5) supplied Zhejiang Peptides Biotech Co., Ltd., China dated 18.8.2023 is provided.
6.	Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	The manufacturer informed that applied product is being manufactured on the same line as of insulin and semaglutide containing products.

Decision

Deferred

Registration Board deferred for following:

- Justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier.
- Stability data of batches used in manufacturing pilot and commercial scale batches of product.

45	Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**CCL Pharmaceuticals Pvt. Ltd.** Plot No. 710 Sundar Industrial Estate, Raiwind Road Lahore **(05-352-0066-126587D)**
	Application Form Dy. No / Tracking ID & date of submission	(VW9-TGH-MJTM, 2026-01-08)
	Detail of Fee Submitted	313500, 2025-12-10,
	The proposed proprietary name / brand name	**Sejaro**
	Label Claim	Each 0.6ml contains: Tirzepatde.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 5±3 °C
	For generic drugs (me-too Status)	Zepatide-Macter International
	Pharmacotherapeutic Group of (API)	GLP and GIP Receptor Agonist: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	GEROPHARM-Bldg. 5, Kvartal A area, Obolensk settlement, Serpukhov city, district, Moscow region-Russia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical characterization is provided with Innovator
	Name, address of Marketing Authorization Holder:	CCL Pharmaceuticals (Pvt.) Ltd., Plot No. 710, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	CoPP indicates GMP of manufacturer
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 12 months real time, stability data of 3 pilot scale batches available. Stability data of batch No. ZG27230701 manufactured in August 2023 is not available.
	The status in reference regulatory authorities	Mounjaro-FDA

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response
1.	The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required.	The active pharmaceutical ingredient (API) Tirzepatide manufactured by Zhejiang Peptides Biotech Co., Ltd. i amino-acid peptide obtained by chemical synthesis. In with the regulatory requirements for the identification peptides as part of the specification and release, use of orthogonal methods is recommended (EMA/CHMP/CVMP/QWP/387541/2023). Therefore, quality control 2 methods to confirm the identification Tirzepatide (Mass Spectrometry and HPLC) are used w framework of the analysis of the "Identification" param quality specifications of API (sections 3.2.S.4.1 of the dossier). These methods has good specificity and were validated, and shown to be adequate for the purpose of identification confirmation. In addition no biological as required for the routine release of synthetic peptides in with regulatory requirements (EMA/CHMP/CVMP/QWP/387541/2023). However, development of the medicinal product Sejaro, a generic medicinal product Mounjaro®, a comparability study w

		out, including studies of biological activity by cell test. GIP activation of calcium currents and GLP-1 activatio calcium currents conformed that Mounjaro®, (original product) and Sejaro, generic medicinal product manufa Geropharm, are completely comparable (see sections 3 registration dossier for more details). Therefore, biolog is not included in the specification of Tirzepatide API.
2.	Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale	The COA for drug substance batch No. ZG2723070 is provided along with the clarification statement of pilot from the manufacturer which is as under: "Zhejiang Pe Biotech Co., Ltd hereby respectfully reports the follow concerning request from the Drug Regulatory Authorit Pakistan (DRAP) as part of the registration on the terri Pakistan of Sejaro, solution for subcutaneous injection, manufactured by OOO "GEROPHARM". Zhejiang Pe Biotech Co., Ltd confirms that the development of the pharmaceutical substance Tirzepatide was initiated in 2 batches at pilot scale were manufactured in 2023 (inclu ZG27230701).
3.	In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced. The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy.	Zhejiang Peptides Biotech Co., Ltd. (API manufacturer developing of active pharmaceutical substance tirzepat 2023. During the development process optimal parame synthesis conditions were selected and by the end of 20 batches were developed including pilot-scale ones. The from API manufacturer contains the key information or API batches manufactured in 2024 and information reg pharmaceutical development in 2023 was not included by API manufacturer. Geropharm used tirzepatide batch manufactured in 2023 to develop generic product Sejar purpose of the pharmaceutical development and manuf process validation.
4.	In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation.	Under the in-house procedure, batch numbers are gene follows: XXXMMYY, where XXX: a serial number o product batch manufactured within a calendar year. Ea product name in each dosage is numbered consecutivel with "01" on 1 January and ending on 31 December of year (format: 01, 02, 03, etc.). MM: digital designatio (month) of manufacture of the batch (format: 01 for Ja February, etc., 12 for December); YY: the last two dig year of manufacture of the batch (format: 25 for 2025; etc.). For example, batch 011023 is the first batch of th manufactured in October 2023.Therefore, different dos Sejaro may have the same batch number.
5.	Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China.	Invoice for API Lot No. ZG27230701 (100g/Can x5) s Zhejiang Peptides Biotech Co., Ltd., China dated 18.8. provided.
6.	Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	The manufacturer informed that applied product is bein manufactured on the same line as of insulin and semag containing products.
Decision		

Deferred

Registration Board deferred for following:

- justification by the manufacturer regarding the quantity of API imported from M/s Zhejiang Peptides Biotech Co., Ltd., China for manufacturing of their pilot and commercial scale batches submitted in the dossier.
- Stability data of batches used in manufacturing pilot and commercial scale batches of product.

46	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(8ZY-98H-TARU, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability conducted on 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability conducted on 3 batches.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o

		20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (P formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached in Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

	2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
47	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(DN9-1ZU-MN1U, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability was conducted on 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (P formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided

7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached in Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

48	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(N1H-Z63-UURP, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability was conducted on 3 batches.
Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (P formulation, phenol is present at a very low concentration (0.012 mg), which remains belo

		Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in sc of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached in Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

49	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(NU5-V4N-WZNH, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each

	Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 2-8°c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability was conducted on 3 batches.
Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The

	dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (F formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached in Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

50	Case Category	New Section (Muneeb Ahmed Cheema)

Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
Application Form Dy. No / Tracking ID & date of submission	(Q8Q-PRQ-DZW8, 2025-11-19)
Detail of Fee Submitted	75000.0, 2025-08-08,
The proposed proprietary name / brand name	**MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 2-8°c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
Detail of stability batches of drug product	Stability was conducted on 3 batches.
Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri

	Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (F formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached in Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

51	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(QRS-B2R-BZHB, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability was conducted on 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.

2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (P formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached i Annexure-7

Decision

Approved

The Registration Board approved the product with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the

Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

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Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
Application Form Dy. No / Tracking ID & date of submission	(9B6-V6N-LUPL, 2026-03-01)
Detail of Fee Submitted	97200, 2025-11-13,
The proposed proprietary name / brand name	**MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 25°c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
Detail of stability batches of drug product	NA
Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	NA

	Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
	Evaluation Remarks	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
53	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(12Q-LN2-4LXS, 2026-03-01)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each multi-dose pre-filled pen contains 20 mg of tirzepatide in 2.4 ml (8.33 mg/ml). Each pen delivers 4 doses of 5 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-

	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
	Detail of stability batches of drug product	NA
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
	Evaluation Remarks	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
54	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(XZX-6WJ-4UBS, 2026-03-01)
	Detail of Fee Submitted	97200, 2025-11-13,

The proposed proprietary name / brand name	**MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs)
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25°c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
Detail of stability batches of drug product	NA
Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
The status in reference regulatory authorities	EMA Approved
GMP status of the firm	NA
Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
Evaluation Remarks	
Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

55		
	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(15Q-G6J-Y75V, 2026-03-01)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
	Detail of stability batches of drug product	NA
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
	Evaluation Remarks	
	Decision	

Approved

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan:

	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
56	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(2RQ-7W3-2JG5, 2026-03-01)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
	Detail of stability batches of drug product	NA
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
	Evaluation Remarks	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
57	Case Category	Contract Manufacturing (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(JPB-SZR-U1JV, 2026-03-01)
	Detail of Fee Submitted	97200, 2025-11-13,
	The proposed proprietary name / brand name	**MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: A10BX16
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang.
	Detail of stability batches of drug product	NA
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted documents regarding procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	M/s Weather Folds Pharmaceuticals (contract manufacturer) submitted data pertaining to Pharmaceutical Equivalence.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	NA
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	Revised section name for pen cartridge vide Licensing Division letter dated 14.11.2025
	Evaluation Remarks	
	Decision	
	Approved The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide□related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
58	Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **(01-**

	374-0006-118530D)
Application Form Dy. No / Tracking ID & date of submission	(P93-TJE-3EH5, 2026-01-09)
Detail of Fee Submitted	313500, 2025-11-17,
The proposed proprietary name / brand name	**CECOLIN 9®**
Label Claim	Each dose (0.5 mL) contains: Recombinant Human Papillomavirus Type 6 L1 protein 30 µg Recombinant Human Papillomavirus Type 11 L1 protein 40 µg Recombinant Human Papillomavirus Type 16 L1 protein 60 µg Recombinant Human Papillomavirus Type 18 L1 protein 40 µg Recombinant Human Papillomavirus Type 31 L1 protein 20 µg Recombinant Human Papillomavirus Type 33 L1 protein 20 µg Recombinant Human Papillomavirus Type 45 L1 protein 20 µg Recombinant Human Papillomavirus Type 52 L1 protein 20 µg Recombinant Human Papillomavirus Type 58 L1 protein 20 µg
Reference to Finished product specifications	Any Other
Proposed Pack Size	10's-As per SRO
Shelf Life (Unit)	18 Year(s)Store at 2-8°C, protecting from light.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Recombinant Human Papillomavirus 9-Valent (Types 6, 11, 16, 18, 31, 33, 45, 52, 58) Vaccine
Name, address of Manufacturing site:	Xiamen Innovax Biotech Co., Ltd.-No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Xiamen Innovax Biotech Co., Ltd., No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China, China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of all 9 monovalent antigen bulks at accelerated and real time are provided.
The status in reference regulatory authorities	Gardasil 9 (9-valent HPV vaccine) Merck & Co. USFDA Approved
Evaluation Remarks	
Registration Board in its 353rd meeting deferred the case for comments of Federal Directorate of Immunization (FDI) regarding need of product for Pakistan. The FDI has forwarded their views which are reproduced as under: Public Health Burden in Pakistan Cervical cancer remains a significant public health concern in Pakistan. According to global cancer estimates (e.g., GLOBOCAN), cervical cancer ranks among the leading cancers affecting women in Pakistan, with a substantial number of new cases and deaths reported annually. Persistent infection with high-risk Human Papillomavirus (HPV) types, particularly types 16 and 18 is responsible for the majority of cervical cancer cases. In addition, other oncogenic HPV types (31, 33, 45, 52 and 58) also contribute to cervical cancer and other cancers, while types 6 and 11 are associated with genital warts. Current Immunization Landscape At present, HPV vaccination is not yet fully integrated into the Expanded Programme on Immunization (EPI) nationwide, although provincial initiatives and phasic introductions have been done in 2 provinces and 2 federating areas for the girls aged 9-14 years. The availability of additional HPV vaccine options in private sector could support to cover the additional age cohort. Added Value of 9-Valent Vaccine A 9-valent HPV vaccine provides broader protection	

	against additional oncogenic HPV types compared to bivalent or quadrivalent vaccines. In the Pakistani context, where cervical cancer screening coverage remains limited and awareness is relatively low, broader strain coverage may offer enhanced preventive benefit. The inclusion of HPV types 31, 33, 45, 52, and 58 potentially increases protection against a greater proportion of cervical cancer cases, which may be particularly relevant in settings where genotyping data suggests circulation of multiple high-risk strains Conclusion Considering the burden of cervical cancer in Pakistan and the preventive potential of HPV vaccination, the availability of a 9-valent HPV vaccine in private sector may provide added public health benefit. Accordingly, from a public health standpoint, the vaccine may be considered beneficial for Pakistan, subject to regulatory evaluation of quality, safety and efficacy. Furthermore, the Federal Directorate of Immunization has introduced the Human Papillomavirus (HPV) Bivalent Vaccine (Cecolin), manufactured by Xiamen Innovax Biotech Co., Ltd., into the EPI schedule under a single-dose regimen, with the support of Gavi, the Vaccine Alliance. It is further submitted that, for vaccines eligible under Gavi support, it is mandatory that the product be prequalified by the World Health Organization. In this context, the case for registration of Cecolin 9 (Recombinant Human Papillomavirus 9-Valent [Types 6, 11, 16, 18, 31, 33, 45, 52, 58] Vaccine) may kindly be processed in accordance with the applicable rules and regulations of the Drug Regulatory Authority of Pakistan.
	Decision
	Deferred Registration Board deferred the application for further deliberation in its forth coming meeting.

Item No. VI. Supplementary Minutes

Registration I&V Section

Case No 01. Registration applications of import cases

a. Deferred cases

i. Veterinary

1.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32050 Dated 23-11-2021
	Fee including differential fee	Rs. 75,000 Deposit Slip No. 69546034807
	Brand Name +Dosage Form + Strength	FLOFENICOL 20% ORAL SOLUTION
	Composition	Each ml contains: Florfenicol…200mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled

	Pack size	50ml,100ml, 150ml, 250ml,500ml, 1L, 2L, 5L
	International availability	Florfenicol 20% Oral Reg. No.THQ-119-XK Registered in Vietnam Validity: 23-11-2022
	Me-too status	Floricol Liquid M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. Reg. No. 073936 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP

		(DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 09219320350. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states**

		that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision M-336: Deferred for the Verification of "Sole Agency Agreement" through email. Reply: Manufacturer confirm via email about agency agreement. Remarks: Same molecule in different strength from same manufacturer already authorization granted in the name of Brand station. Submitted for consideration of the Board.	
Decision 354: Deferred. The Board noticed that the same API-containing molecule, in different strengths, was authorized to two different importers in Pakistan which is against the practice adopted in Pakistan. The manufacturer must clearly authorize only one Importer for both strengths.		
2.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam

	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32060 Dated 23-11-2021

	Fee including differential fee	Rs.75,000 Deposit Slip No. 232268028
	Brand Name +Dosage Form + Strength	PRO-CRD COMPLEX 30/20 WATER SOLUBLE POWDER
	Composition	Each gram powder contains: - Tylosin Tartrate…..200mg Doxycycline HCl.....400 mg Colistin Sulphate…....1MIU Bromhexine HCl.....10 mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g, 500g, 1kg, 5kg, 20kg, 25kg
	International availability	PRO-CRD Complex 30/20 Reg. No.THQ-220-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	MONODOXWATER SOLUBLE POWDER M/s BAARIQ PHARMACEUTICALS, LAHORE Reg. No. 087142
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

		• Revised label • Differential fee of Rs.75000 vide Deposit slip No. 528225379. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied

		formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision M-336: Deferred for the Verification of "Sole Agency Agreement" through email. **Reply:** Manufacturer confirm via email about agency agreement.	
Decision: Approved as per policy for inspection abroad.		
3.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32058 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 66484026
	Brand Name +Dosage Form + Strength	Para Plus Oral Powder
	Composition	Each 100gm Contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm"
	Finished Product Specification	Not stated
	Pharmacological Group	Antipyretic, Multivitamin
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg,25kg
	International availability	Para plus Reg. No.THQ-185-XK Registered in Vietnam Validity: 25-02-2022
	Me-too status	Parascorbic powder M/s Baariq Pharmaceuticals, Lahore. Reg. No. 087190
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years

		(Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for*

		oral use. • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 24778999902. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether**

		the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP). **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	Review of Sub-committee on Veterinary Drugs is awaited regarding therapeutic requirement keeping in view safety, efficacy and quality parameters
	Decision M-336: Deferred for the Verification of "Sole Agency Agreement" through email. **Reply:** Manufacturer confirm via email about agency agreement.	
Decision: Approved as per policy for inspection abroad.		
4.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32059 Dated 23-11-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 43403191338
	Brand Name +Dosage Form + Strength	Tilmicosin Oral Solution
	Composition	Each ml Contains: Tilmicosin Phosphate…250mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic

	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 150ml, 250ml,500ml, 1L, 2.5L
	International availability	Tilmicosin Reg. No.THQ-137-XK Registered in Vietnam Validity: 24-3-2022
	Me-too status	Tilmicobak Oral Liquid M/s Attabak Pharma. Reg.No.075706
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required.

		The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 48617838. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision M-336: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.** **Reply:** Manufacturer confirm via email about agency agreement. Remarks: Same molecule in same strength from same manufacturer already authorization granted in the name of Brand station.	
Decision 354: Deferred. The Board noticed that the same API-containing molecule, in different strengths, was authorized to two different importers in Pakistan which is against the practice adopted in Pakistan. The manufacturer must clearly authorize only one Importer for both strengths.		
5.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi

	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate:
		Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32061 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 5035508680
	Brand Name +Dosage Form + Strength	Pro-Lamox-C WSP
	Composition	Each 100gm Contains: Amoxicillin Trihydrate…20gm Colistin Sulphate…50MIU
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	Pro-Lamox-C Reg. No.THQ-221-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Fagomox M/s Farm Aid Group Reg. No. 087189

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or

		USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 973258620415. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of

		non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules.
	Decision M-336: Deferred for **i.** submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders and **ii.** Verification of letter of authorization through e-mail **Remarks:** Manufacturer confirm via email about agency agreement. Dedicated production line confirmation submitted on company letter head.	
Decision: Approved as per policy for inspection abroad.		
6.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32062 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 474201420
	Brand Name +Dosage Form + Strength	Pro-Cefo Injection
	Composition	Each ml Contains: Ceftiofur as HCl…50mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Pro-Cefo Injection Reg. No.THQ-239-XK Registered in Vietnam Validity: 18-12-2022
	Me-too status	Exefur Injection M/s SJ&G FazulEllahie Reg. No. 063704 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist

		Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Cephalosporin Injectables* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required.

		The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for

		five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 5425865744. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*.**

		• **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for cephalosporin dosage form as required under LRA Rules 1976.
	Decision M-336: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of Cephalosporin injectables and verification of letter of authorization through e-mail. **Remarks:** Manufacturer confirm via email about agency agreement. Dedicated production line confirmation submitted on company letter head.	
Decision: Approved as per policy for inspection abroad.		
7.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above

	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32063 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 9365242748

	Brand Name +Dosage Form + Strength	Pro-Liso 4.4% Feed Premix Powder
	Composition	Each 100gm Contains: Lincomycin HCl…4.4gm
	Finished Product Specification	Not stated; Lincomycin HCl soluble powder is available in USP
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,500g, 1kg,10kg, 5kg, 25kg
	International availability	Pro-Liso 4.4% THQ-222-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Lincos-P Powder M/s A&K Pharmaceuticals. Reg. No. 049667 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between

		manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 251517196. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be

		provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. USP Specifications
	Remarks of evaluator[xxiii]	
	Decision M-336: Deferred for verification of letter of authorization through e-mail. **Remarks**: Manufacturer confirm via email about agency agreement. Further same molecule in same strength from same manufacturer already registered in the name of Brand station with different brand name.	
Decision 354: Deferred. The Board noticed that the same API-containing molecule, in different strengths, was authorized to two different		

	importers in Pakistan which is against the practice adopted in Pakistan. The manufacturer must clearly authorize only one Importer for both strengths.	
8.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad,
		Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32054 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 224432818225
	Brand Name +Dosage Form + Strength	Super T.D Man-70% WSP
	Composition	Each 100gm Powder Contains: Doxycycline Hyclate Eq. to 800gm of Doxycycline…923.32gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,250g,500g, 1kg, 5kg,20kg, 25kg
	International availability	Super T.D Man -70% Reg. No.THQ-224-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Doxyral 80% powder M/s Orient Animal Health Reg. No. 082504 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung

		Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietna & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the

		manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 54195176543. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years

		from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	
	Decision M-336: Approved. Registration Board further decided that registration letter will be issued after submission of following to Registration section: **i. Original, Valid, Legalized Free sales certificate and GMP certificate,** **ii. Original, Valid, notarized letter of authorization/sole agency agreement.** **Remarks**: Same molecule in different strength from same manufacturer already registered in the name of Brand station with different brand name.	
Decision 354: Deferred. The Board noticed that the same API-containing molecule, in different strengths, was authorized to two different importers in Pakistan which is against the practice adopted in Pakistan. The manufacturer must clearly authorize only one Importer for both strengths.		
9.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32053 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 3266953570
	Brand Name +Dosage Form + Strength	Super Lamox-70% WSP
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…700gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50g,100g, 250g,500g, 1kg, 5kg, 10kg
	International availability	Super Lamox-70% Reg. No.THQ-223-XK Registered in Vietnam Validity: 16-12-2022

	Me-too status	Primox 70% WSP M/s Prix Pharma Reg. No. 074032
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam

		in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder for solution.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required.

		The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business".

		• Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 0156607334. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be**

		provided by the issuing authority of the Free Sales Certificate. • **Legalized copy of valid GMP certificate of the manufacturer**. • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision M-336: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders. **Remarks**: Manufacturer confirm on letter head about dedicated production line for manufacturing of ***penicillin*** **oral powders.** Further same molecule in different strength from same manufacturer already authorized to Brand station with different brand name.	
Decision 354: Deferred. The Board noticed that the same API-containing molecule, in different strengths, was authorized to two different importers in Pakistan which is against the practice adopted in Pakistan. The manufacturer must clearly authorize only one Importer for both strengths.		
10.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above

	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32064 Dated 23-11-2021

	Fee including differential fee	Rs.75,000 Deposit Slip No. 468627042483
	Brand Name +Dosage Form + Strength	ProZSB Plus Powder
	Composition	Each 1000gm Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	ProZSB Plus Reg. No.THQ-219-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	PSB 100 M/s Epla Labs Reg. No. 013257

	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e.*

		Penicillin Oral Powder. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 2515097727. Following are still required: • Free Sales Certificate for the applied product in the

		country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**

	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral;

		Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision M-336: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders. **Reply**: Manufacturer has dedicated production line for manufacturing of *penicillin* oral powders as confirmed on letter head.	
Decision: Approved as per policy for inspection abroad.		

Post-Registration-I Section

CASE NO 01: COMPARISON OF COUNTERFEITS OF "PYODINE SOLUTION" IN COMPLIANCE WITH DIRECTIONS OF REGISTRATION BOARD

Registration Board in its 339th meeting held on 06th to 08th of August, 2024, on the directions of the Honorable Islamabad High Court, Islamabad (Order dated 03-07-2024 passed W.P No. 2073/2024) decided as under:

*"**M/s Brooks Pharma (Pvt.) Ltd. Karachi (Complainant) through representative Dr. Arif Hussain Siddique along with Council Mr. Umar Hameed Advocate appeared before Board for personal hearing/representation and presented physical samples /Bottles of allegedly counterfeit Pyodine manufacturers along with list of 26 alleged counterfeit Pyodine Products and urged their claim that these products have close resemblance and imitation with their product Pyodine.***

The Board after hearing the arguments of the firm in detail and after thorough discussion and deliberation and nominated Director QA&LT to review each individual claimed counterfeit product in comparison with Pyodine for resemblance of packs for lookalike imitation of label which may deceive the patients. The shortlisted reviewed imitation product cases on individual basis would be presented by QA/LT division before next Board meeting for consideration and further decision of the Board."

Accordingly, after extensive review by QA&LT division, following imitated / counterfeit products of "Pyodine Solution" of M/s Brookes Pharma, Karachi have been shortlisted below:

Resemblance status of Counterfeit Products of "Pyodine Solution" (Reg No. 009528)

Sr. No.	Name of the Manufacturer	Brand name	Reg. No / Product enlistment number	Resemblance parameters				Final Remarks
				Brand name	Color Scheme	Text	Graphic	
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Yes	Yes	Yes	Yes	Both label and Brand name
2.	M/s Zanctok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Yes	Yes	Yes	Yes	Both label and Brand name
3.	M/s Oval Pharmaceuticals, Lahore. (DML No. 000156)	Septodine Solution	049925	No	No	Yes	No	Only label
4.	M/s Lahore Pharma, Sheikhupura. (DML No. 000084)	Plasodine liquid	014228	Yes	Yes	Yes	Yes	Both label and Brand name
5.	M/s Paradise Pharma, Lahore. (DML No. 000742)	Povidone Iodine solution	071551	No	No	No	No	No resemblance
6.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Yes	No	Yes	No	Both label and Brand name
7.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Poviderm Solution	094559	No	No	Yes	No	Only label revision
8.	M/s Pharmawise Labs, Lahore. (DML No. 000182)	Povine Solution	037527	Yes	No	No	No	Only Brand name
9.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	No	No	Yes	No	Only label
10.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	No	Yes	Yes	Yes	Only Label
11.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	No	Yes	No	Yes	Only Label
12.	M/s Perfect Pharma (Pvt.) Ltd. Lahore.	Povidone Iodine Solution	026935	No	Yes	Yes	Yes	Only Label

	(DML No. 000469)							
13.	M/s Irza Pharma, Sheikhupura. (DML No. 000108)	Wondseptic Solution	030073	No	No	No	No	No resemblance
14.	M/s IS IS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	No	No	Yes	Yes	Only label
15.	M/s A. Mannan Lab. Karachi.	Payodine Solution	004377	Yes	Yes	Yes	Yes	Both label and Brand name
16.	M/s Glorious Laboratories, Islamabad. (Mfg. Enl. No. 002)	Pyogon Solution	002. 0062	Yes	Yes	Yes	Yes	Both label and Brand name
17.	M/s Zaiam Pharma Nutraceuticals, Lahore. (Mfg. Enl. No. 00233)	Pyoline Solution	00233. 0001	Yes	Yes	Yes	Yes	Both label and Brand name

The findings of the Division of QA&LT are submitted for consideration by the Board.

Proceedings and Decision of 343rd Meeting of Registration Board

QA&LT Division presented the case in the light of decision of 339th meeting of Registration Board. After thorough deliberation, the Registration Board decided to proceed in the light of the findings / recommendations of Division of Quality Assurance and Laboratory Testing. Keeping in view findings / remarks of QA&LT Division, the Board decided to refer the cases as follows: -

a. **Registered Drugs under Section 7 of the Drugs Act, 1976 to the Pharmaceutical Evaluation & Registration (PE&R) Division for issuance of letters to the firms for respective variations.**

b. **Enlisted products under SRO 412 (I)/2014 to Health & OTC Division for necessary action at their end.**

3. In the light of the decision of the Registration Board, letter no. F-12/2025 (PR-I) E-App dated 15th January, 2025 was forwarded to the respective firms regarding change of brand name. label claim or both within 07 days for further necessary action.

4. The brand name resemble letter communicate to the firm vide letter no. F-12/2025 (PR-I) E-App vide 15th January, 2025 (Annex-I). However seven firms have submitted reply and the same are reproduced as below:

M/s Kohinoor industries Sahiwal submitted a reply against our letter of even number in which they stated that:-

- Why brookes Pharma used the door of honorable high court, this act is showing de-interest on respectable government institute DRAP for lable claim & similar brand name. Even this brand name allotted us from respectable institute DRAP in 1996, because we have owned the name **prodine Solution** despite of this Brookes Pharma has owned the Name of Pyodine Solution. These brand names cannot match from each other & this brand name was registered after the approval of DRAP.
- Our registered brand also does not fall under the category of counterfeit drugs. Accordingly section 3 clause (F) of The Drug Act 1976, Counterfeit Drug" means a drugs the label or outer packing of which is an imitation of or resembles or so nearly resembles as to be calculated to deceived the label or outer packing of a drug of another manufacturer. We deny any intention to deceive the public with our product label or banding.
- With reference to letter no. 14280/2020DRAP (L-IV) we have already changed the label of this brand name through legal process. That time same competitor filed letter to your respective institute & we fully complied your letter & immediately change the label of this registered brand name **Prodine Solution.**
- The department has proceeded without giving us a fair opportunity to plead or differentiate the differences, which is in contradiction with Article-10 of constitution of Pakistan 1973. We hereby agitate the same as our fundamental right of fair trial has been breached.
- Moreover, the subject letter is based on the facts. Based on the missing facts which area necessary to be incorporated as following
- **Label differences:**
- We have already changed the label of this brand through legal process. "Prodine's" label is brown & Peach in long rectangular shape. While the label color of Brookes products "Pyodine Solution" is red and orange in color and it is in oval shape.
- **Font Style:**
- The font style of both solution is totally different from each other. Prodine Solution is written in Arial Style on bottle, while pyodine solution is pasted in Times New Roman Style on bottle
- **Pronunciation:**
- Here is vital difference in pronunciation of both words between prodine solution & pyodine solution. The Oval sound getting no break in word of prodine solution but this sound gets a break when we speak the word Pyodine Solution.
- Here are some actual facts that we area oppressed under the hand of Brookes Pharma, this firm has attached us several time by different ways.
    1. This firm filed a f=grievance in every government institute for the purpose to sale their expensive brand and trying to damage the popularity of our product.
    2. In KPK the DG health KPK rejected this firm due to quoted high rates in this institute.
    3. This firm approaching the government health officers to stop the sale in government semi-government institutes and also in market and finally this firm is declared with low handed thugs in every field. After this the firm has approached at your door.
    4. We are supplying this item in Reputable institute throughout Pakistan and not a single batch is declared substandard.
    5. The firm M/s Brookes Pharma refused to give the supplies in different government institute but the institues approached to us and we given immediate supply o no profit no loss.
    6. Our import raw material is FDA approved, our stability reports on long terms showing the excellent result. Under all the aspects this pharma use those weapon which are just open for to attain illegal means and to establish its monarchy but remain failed every time.

    We humbly request your good office to withdraw the letter keeping in view all the facts narrated above. We also hereby our right to file an appeal against this arbitrary order, if our consideration are not taken into account by your esteemed authority.

Reply of M/s. Pharmawise Lab.

- The matters of Drug & Medicine area highly technical nature which other than a Pharmacist all cannot understand. For the subject matter it is consoling that whole of the DRAP at executive level comprises of pharmacist.
- A minute study of brand names of drug and medicine reveals that the same are extracted from the Generic name of the same drug or from leading proprietary / brand name. Whole of the world market of drugs / medicine is flooded with such names. The Drug and Medicine market of we the Pakistan is no exception. For your ease and ready reference following are Symbolic examples. Not to antagonize the learned Drug Registration Board but to appreciate that now realistically the learned board has adopted it as short of such practices the system will get stuck up.
    a) Tablets / suspension Ponsac of M/s. Brookes Pharma, Karachi. This name was extract from the leading proprietary / brand name Postan of M/s Pfizer. Other name are Phontan of M/s. Pharmwise Lab Protan of Proressive, Nobstan of M/s. Nawabson Lahore. Kindly appreciate that where all the above names, with many other partly qualify to be counterfeit drug as defined in drug act 1976, yet the same are helpful for the prescribed as well the patient as their phonetic sounds ensure all that the same are what the leading propiatory / brand name ponstant is
    b) The same is the case with every other leading Trade Name of every Generic Name of Medicine.
- Now coming to our name Povine Solution Registration no. 037527 alleged to be counterfeit the name Pyodine Solution Registration No. 009528 of our friend M/s. Brookes Pharma Karachi it is to respectfully explain that.
    - The Generic name of both the above drug i.e. Povidine solution and pyodine is povidone iodine.
    - Only a pharmacist can appreciate who each worthy member of registration board is, that phonetic sound the above name guides that both have been extracted from the generic name Povidone Iodine.
    - It is requested to appreciate what while pronouncing loudly both the names each distinguished it from the other being different
    - Every manufacturer has equal right to extract his brand / proprietary name of Drug from it generic name the way our friend M/s. Brookes Pharma Karachi Invented their name Pyodine.
    - It seems the present management of M/s. Brookes Pharma Karachi particularly my friend learned D. Arif Hussain Siddiqui Advisor on Regulatory & Marketing Affair is not well conversant with legalities recorded as above he being not a Pharmacist.
    - In view of the submission tendered as above it is respectfully stated that we need not to tender to worthy Registration Board alternate 3 names.

Reply of M/s. Hoover Pharmaceuticals Pvt Ltd.

It is submitted that DRB in its 339th meeting has announced their decision without taking our point of view or issuing show cause notice to us.

It is incorrect to say that hoover Pharmaceuticals Pvt Ltd is involved to manufacturer any counterfeit product in particular to the alleged drug poviderm solution. The product poviderm having reg. no. 094559 has been properly registered with DRAP and the concerned department of DRAP has given us the name products after thorough and careful consideration.

Complainant Products Pyodine

Our Product Poviderm

You can find that there is a differences in 7 figure regarding sesquences / spelling of alphabet in the name of both brands. Furthermore our product Poviderm is logically based on two terms

Povi from Povidone

Derm from Skin

So there is no question that we have copied / followed that name of the product of complainant. As far as label of primary packaging is concerned it's designed and graphics are totally different from the product of complainant.

In the circumstances stated above as our product is not a counterfeit product, it is requested that initiation of any proceeding may kindly be dropped against us and the said letter may be withdrawn in the interest of justice.

Reply of M/s. ISIS Pharmaceuticals & Chemical Works.

The firm has submitted reply which say that, A close perusal of the minuets of the meeting 339th Pages 397-398 indicate that our particular case, the requirement was to change only in the text, and graphics and as only complainant was present in the meeting with the allegation of labeling, so we request you as follow before forward with change to be made in our labeling.

a) Provide us with a clear copy of the complaint with it legal grounds.
b) Text of label is a regulatory requirement and is already approved by the registration Bo0ard. So please clarify what change has to be made.
c) Same in graphic please clarify what extract has to be change.

As per regulations in place after making changes without violating, we shall follow the procedure as laid down by DRAP, in its guideline on PR variations.

Reply of M/s. Lahore Pharma

M/s. Lahore Pharma products registered as brand name Plasodine Liquid 7.5% with under the Drug Act 1976 Plasodine Liquid 7.5% Registration no. 014228. And colour scheme of lables is not resemble to any other product.

But M/s. Brookes Pharma Karachi registered product with brand name Pyodine Solution 10% brand name & Products of color of label scheme is not resemble to M/s. Lahore Pharma labels.

Kindly accept the letter if any query about for registration of registered product plasodine liquid 7.5% we have fulfilled all requirement of registration of Plasodine liquid 7.5% according to Drug Act 1976.

Reply of M/s. Oval Pharmaceuticals

The firm mentioned that it is not manufacturing counterfeit drug. Our product septodine Antiseptic Solution 049925 packing do not resemble with Pyodine Solution 009528 of M/s. Brookes Pharma Pvt Ltd, Karachi It is stated m/s. oval pharmaceuticals is a well know and well reputed company. We do not believe in unethical marketing practices. Label design of Septodine Antiseptic Solution is of orange color and have different segment in design which do not resemble with pyodine. Furthermore if you are not satisfied with packing we will change our label designed and color.

Reply of M/s. Zanctok Pharmaceuticals Laboratories

With reference to letter of even number dated 15-01-2025 the firm submit following point which is as under:-

- It is to put forth on record that we granted registration of the products "Zyodine " by the Registration Board after thorough review and analysis , approving the stated brand name vide Registration letter dated 09-07-2007 and later in 2009 also received approval for additional pack size 50ml &400ml with the same brand name
- That we had been succefully manufacturing and marketing the said product for the past 17s without having received any complaint regarding drug quality packaging brading etc or any instance of medicine error on account of similarity of the product brand or appearance.
- The due to established high quality efficacy and safety of our products we had obtained considerable market share and good repute among health care professional and patient both. That our brand commercial is well perceived in the market such that the name itself has wide acceptability and patient association.
- That subsequently the federal inspector of drug, Karachi referred the complaint to central drug laboratories Karachi with a sample of Zyodine 7.5% w/v Solution. For their necessary analysis. The CDL vide their test report No. KQ-4-24-000092 dated 09th May 2024 cleared our product of any such j violation an excerpt of the report finding is reproduced hereunder:

  "The sample Zyodine 7.5% w/v solution has been compared with brand leader i.e. Pyodine Solution registration number 009528, manufactured by M/s. Brookes Pharmam, Karachi. The colour scheme of the label and outer packing font size font style and graphic of the sample are different as compared with the brand leader. Therefore the sample cannot be declared as imitation product"

- That the Federal Laboratory CDL Test Report has clearly stated that our product cannot be declared as an imitation product which is to be considered as a conclusive report. The under such circumstances, where a verdict has been given on the matter filling of this suit is just another weak attempt of M/s. Brookes to create nuisance of us.
- That our brand has attained good market repute and acceptability among users over past 17 years such that requiring us to change the brand name will negatively impact our business as well as patient compliance.

In the above mentioned argument and supporting evidence it is request to withdraw the case of change of brand name and label claim. If not an opportunity for personal hearing may be given to appear before the registration board in its forth coming meeting to defend our case.

No reply is received from following firms:

1. M/s Cortex Pharmaceuticals, Rawalpindi.
2. M/s N.B.S. Pharma, Lahore.
3. M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore.
4. M/s Trigon Pharmaceuticals, Lahore.
5. M/s Perfect Pharma, Label.

Decision of the 345th meeting of the Registration Board:-
The Registration Board decided to give an opportunity of Personal Hearing to the respective firms.

M/s Perfect Pharma, Lahore has submitted that the firm will revised the label claim once it is finalized but no request regarding revised label claim is received

In the light of the decision of the Registration Board, all the firms have been called for personal hearing .

In light of above decision of the Board, firms have been called for personal hearing.

Proceedings of 346th meeting of the Registration Board:

Proceedings of Meeting:

Nine firms appeared for person hearing before the Registration Board, the detail is as under:-

S.No.	Name of the Firm	Name of Representative.	Designation.
1.	M/s. Lawrance Pharma.	Naveed Iqbal	Production Manager.
2.	M/s. Kohinoor Industries	Haroon Rashid	Director
3.	M/s. Havoor Pharma	Anjum Ishaq	Chief Executive.
4.	M/s. Pharwise	Ch. Nadir Nuaman Nadir	CEO
5.	M/s. Perfect Pharma	Nasir Hussain	Manager.
6.	M/s. Oval Pharmaceuticals	Wasim Haider	Quality Control Manager.
7.	M/s. Jawa Pharma	Ahmed Ali	Quality Control Incharge.
8.	M/s. Cortex Pharmaceutical	Muhammad Nazir	CEO
9.	M/s. Zanctok Pharmaceutical	Advocate Rashid Mureed Mr. Feroz Lasi Mr. Faisal	Council. Managing Partner. -do-

Majority of the firms contended that their products has no resemblance with the brand name and label of M/s. Brookes Pharma. The firm added that M/s. Brookes Pharma is using these tactics to get the commercial benefits in tender business for which the procurement is made after pre-qualification of the manufacturer. Representatives from M/s. Kohinoor Industries and M/s. Cortex Pharmaceuticals also presented the notice of the Registrar, Intellectual Property Tribunal, Lahore, for Case No. 98/IPT/28, filed by M/s Brookes Pharma. Date of hearing of the case is 10-05-2025.

Decision:

The Registration Board thoroughly discussed the matter and decided as under:

i. The order dated 03.07.2024 passed by the Islamabad High Court in Writ Petition No. 2073 of 2024

filed by M/s Brookes Pharma against DRAP reveals that the contention raised by the petitioner (Brookes Pharma) was of sale of counterfeit versions of PYODINE Solution (see, paragraph 2). Section 3(f) of the Drugs Act, 1976 defines "counterfeit drug" as a drug the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture. Section 3(o) provides a definition of "label" as a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package. Neither the Writ Petition No. 2073 of 2024 nor the representations filed by Brookes Pharma alleged the trademark infringement rather they alleged availability of counterfeit versions of PYODINE Solution in the market.

ii. It is not the prerogative of Registration Board to decide the matter of infringement of trademarks which is an exclusive domain of Intellectual Property Tribunals under section 18 of the Intellectual Property Organization of Pakistan Act, 2012. The aforesaid Act read with the Trade Marks Ordinance, 2001 have adequate provisions and remedies to which an owner or right holder of a registered trademark may resort in case of being aggrieved.

iii. Recently, in Writ Petition No. 3227/2022 titled M/s Vifor International AG Vs Drugs Appellate Board, etc, the Islamabad High Court has held that the Intellectual Property Tribunal has competent jurisdiction over the matter.

iv. Infringement of a trademark (if any) has to be established in a court of law (IP Tribunal) under the provisions of the Trade Marks Ordinance, 2001.

v. Notwithstanding anything stated hereinabove, pharmaceutical trademarks are usually coined from the drug's treatment, indication, salt composition, or any other associated medical word. Therefore, there is more degree of acceptance of resemblance between pharmaceutical trademarks around the world. Like PYODINE, other alleged marks are arbitrary word marks coined from the generic name of the product i.e. POVIDONE IODINE. No one can be allowed exclusive rights to use of generic name of the product POVIDONE IODINE.

vi. The Registration Board considers it appropriate to confine itself to the regulatory jurisdiction of the DRAP Act, 2012 and the Drugs Act, 1976 and not to encroach upon the matter to be dealt under the provisions of the Trade Marks Ordinance, 2001 by specialized IP courts.

vii. Foregoing in view, M/s Brookes Pharma may approach the IP Tribunal for any alleged infringement of its trademark 'PYODINE' (like it has already filed a Suit No, 95/IPT/28 against M/s Kohinoor Industries in the IP Tribunal, Lahore) and this Board will act accordingly in light of the determination(s) made by the Tribunal. The representation of M/s Brookes Pharma is disposed of in above terms.

M/s. Brookes has submitted an appeal against above decision of the Registration Board before the Appellate Board. Decision of 172nd meeting of the Appellate Board is as under:

1. Brookes Pharma Pvt. Ltd. (the '**Appellant**') has challenged the Decision passed by the Registration Board in its 346th Meeting held on 22.04.2025 ('**Impugned Decision**'), whereby its complaint against the manufacture and sale of counterfeits of 'PYODINE' has been disposed of.

2. Mr. Umer Hameed Khan, Advocate appearing on behalf of the Appellant argued in brief that the impugned order is passed without granting an opportunity hearing to the appellant. The drug regulatory framework provides a comprehensive and self-contained mechanism for the identification and determination of a *"counterfeit drug,"* which being 'criminal' in nature, is distinct and independent from the procedures and standards set out under intellectual property laws, which protect the civil property rights.

3. At the very outset, the Board took note of the fact that the Appellant had submitted an Affidavit affirming that no appeal or other proceedings pertaining to the matter in hand are pending before any court of law or forum. However, it was brought to the Board's attention that the Appellant has instituted four separate civil suits before the learned Intellectual Property Tribunal, Lahore, against four different companies for alleged infringement of its intellectual property rights. Upon query, learned Counsel for the Appellant clarified that the subject matter of the said suits is not the Impugned Order passed by the Registration Board in its 346th meeting. Rather, they pertain strictly to the claims of trademark infringement under the Trade Marks Ordinance, 2001. The learned Counsel further contended that the Appellant has approached the DRAP for action under the Drugs Act, 1976 and DRAP Act, 2012 for alleged commission of offence of 'counterfeiting', which is independent of the trademark infringement claims.

4. Be that as it may, the matter is remanded back to the Registration Board to decide afresh after affording an opportunity of hearing to the appellant and all other companies having registration of povidone-iodine solution whose label (i.e. display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of drug package) or outer packing is imitating or resembling or so nearly resembling as to be calculated to deceive the label or outer packing of the appellant's drug.

5. The appeal is disposed of in above terms.

Decision of the 351st meeting of the Registration Board:
The Registration board deliberated the matter and decided that the firms due to resemblance with previously registered product i.e. **Pyodine Solution" (Reg No. 009528)**,will change the brand name, color and packaging design of registered products (as per following details to avoid regulatory action under Section 3(f) read with Section 23 (1) (ii) & 27 (2) (a) of the Drugs Act, 1976:

Sr. No.	Name of the Manufacturer	Brand name	Reg. No	Resemblance
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Brand name
2.	M/s Zanctok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Both label and Brand name
3.	M/s Lahore Pharma, Sheikhupura. (DML No. 000084)	Plasodine liquid	014228	Only label
4.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Only Brand name
5.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Poviderm Solution	094559	Only label revision
6.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	Only label
7.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	Only Label

8.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	Only Label
9.	M/s Perfect Pharma (Pvt.) Ltd. Lahore. (DML No. 000469)	Povidone Iodine Solution	026935	Only Label
10.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	Only Label

The Decision of the 351st meeting of the Registration Board was communicated to the respective firms vide letters dated 22nd October, 2025. Till date, only M/s Hoover Pharmaceuticals, Lahore has submitted application on E-App for change of the label claim of its registered product.

The firms are called for Personal hearing vide letter dated 24th February, 2026.

Decision of the 354th meeting of the Board:

Mr. Haroon Shahid, MD of M/s Kohinoor Industries, Sahiwal, Mr. Atif Ejaz, Production Manager of M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore, Mr. Noor Mehar Advocate on behalf of M/s Cortex Pharmaceuticals, Rawalpindi and Mr. Sohail Qasim representative of M/s ISIS Pharmaceuticals (Pvt) Ltd, Karachi appeared before the Board. The said representatives contended that they will comply the decision of 351st meeting of Registration Board and will apply for change of respective brand names/ label claim.

The Registration Board heard the appeared representatives, noticed the absence of other firms and decided that the registration of the products of the firms which do not comply the decision of the 351st meeting of the Registration Board shall be suspended till the implementation of the orders of the Registration Board.

Product Specific inspection

1. Bio-Labs (pvt) ltd Islamabad (Ketorolac Tromethamine 30mg IM/IV Injection)

The following case was presented in 347th meeting and the Board deferred the case for product specific inspection (PSI) of the firm for verification of authenticity of submitted stability data.

Accordingly, the Chairman Registration Board constituted following panel for the PSI:

i. Saima Hussain, Deputy Director DRAP Islamabad

ii. Farooq Aslam, Deputy Director DRAP Islamabad

The panel visited the firm and noted various observations in the submitted stability data of stability batches. The firm was called upon for personal hearing for clarification of the observations in 351st meeting. After hearing the firm the Board decided as under:

"The Board after hearing the matter from the representatives of the firm, discussed that the firm is manufacturing the commercial batches and decided that the panel shall conduct the PSI again for verification of authenticity of stability data of commercial batches."

In Compliance to the decision of the Board, the panel again visited the firm on 27-01-2026 for verification of stability data of commercial batches.

The stability data of following 02 commercial batches was evaluate and relevant documents were checked.

1st:
Batch Mo. KM-0100324
Mfg. Date : 01-JAN-2024
Exp. Date: 31-DEC-2028

2nd:
Batch Mo. KM-1005924
Mfg. Date : 01-Oct-2024
Exp. Date: 31-Sep-2029

The conclusion of the panel is hereby reproduced below:

Recommendations:

Based upon the proceedings of the inspection and documents including BMRs, GRNs, AMV studies, stability data presented by the firm and relevant reports, the stability data of above-referred commercial batches is verifiable to satisfactory level. However, variations in testing method from USP were noted and the firm was advised to fully comply USP requirements.

Sr. No.	Name and desgnation	Signtaures
Saima Hussain	Deputy Director, DRAP Islamabad	27/02/2026
Farooq Aslam	Deputy Director, DRAP Islamabad	

	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceutical Laboratories, Plot No. 121 industrial Triangle area, Kahuta Road, Islamabad.

	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacture ☐ r Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11388; dated 14-04-2021.
	Details of fee submitted	PKR 50,000/-: dated 26-01-2021.
	The proposed proprietary name / brand name	Kerolac 30mg IV/IM Injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine …….. 30mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1ml x 5's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	GMP status of the Applicant.	GMP certificate issued on 08-10-2020 on the basis of inspection conduct 01-10-2019.
	GMP status of the Finished product manufacturer	GMP certificate issued on 21-05-2019 on the basis of inspection conduct 23-4-2019, valid up to 22-04-2022.
	Evidence of section approval of the Finished product manufacturer.	Liquid ampoule (from GMP certificate.)

		Ampoule general vide letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s. Saurav Chemicals Limited	

	370 Industrial Area, Phase II Panchkula, Haryana, 134109 India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi Barwala Road, Mohali District Punjab India		
API Lot No.	KM-0100918, KTM-180015 & KTM180015.		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-439	A-596	A-611
Batch Size	46,200 Ampoules	16,000 Ampoules	33,000 Ampoules
Manufacturing Date	05-2018	03-2019	03-2019
Date of Initiation	25-06-2018	22-04-2019	20-05-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi Barwala Road, Mohali District Punjab India Valid till 25- 06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice# SCL2018/18-19 dated 29-01-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1	1.4.3	Total number of approved registered products on contract basis could not be confirmed. Complete details of products registered on contract basis shall be submitted.	Applicant has 07 approved sections and applicant has also submitted that they no product is registered on contract manufacturing.
2	1.5.6	Official monograph is available in USP. Firm has claimed innovator's specifications in "1.5.6" section of form 5F.	Firm has provided new Form 5F wherein they have revised their specifications from innovator's specifications to USP specifications without submission of applicable fee.

3	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Valid GMP certificate of API manufacturer is provided. Valid till 25-06-2023.
4	3.2. S.4	• Results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product development and stability studies along with COA of the same batch from drug substance/Active Pharmaceutical ingredient manufacturer. • Detailed analytical procedure for the drug substance by the drug product manufacturer shall be provided. • Analytical method verification studies including specificity, accuracy and repeatability (method precision) for drug substance performed by the drug product manufacturer shall be submitted.	Batch No. A-439 has been manufactured by API lot No. KM-0100918 while COA has only been submitted for API Lot No. KTM-180015 Submitted. Firm has submitted analytical method verification studies but chromatograms for finished product has been submitted.
5	3.2. P.8.3	ADC attested invoices of the drug substance used during product development and stability studies shall be submitted.	ADC attested invoice for API Lot No. KM-0100918 used in Batch No. A-439 has not been provided by the firm.
6	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product.	Firm has submitted that we cannot perform terminal sterilization of ketorolac injection because it is heat sensitive product. Melting point of the API mentioned in DMF is 165-170 ^{o}C.
7	3.2. P.5.2	Detailed analytical procedure for the drug product by the drug product manufacturer shall be provided.	Submitted.
8	3.2. P.5.3	In process validation protocol 30.45mg of ketorolac Tromethamine is used. Justification is required whether overage or potency adjustment.	Firm has submitted that it is potency adjustment. The potency as per COA of drug substance on as is basis is 98.5%. On the basis of as is potency the quantity of powder to be dispensed is calculated as 30.45mg {(100/98.5) x 30 = 30.45}
9	3.2. P.8.3	Submit raw data sheets for stability studies, reflecting the details of Standard weight, Sample dilution preparation, Potency of Reference standard and Calculation formula applied for the Assay test.	Submitted.

Decision of 313th meeting of the Registration Board: Deferred for following;

- Submission of documents/commercial invoice for the procurement of API Lot No. KM-0100918 with approval from DRAP.
- Submission of scientific justification for not performing terminal sterilization of the drug
- product. Submission of 7500/- fee for revision of finished product specifications as per notification No. F. 7- 11/2021-B&A/DRAP dated 13-07-2021.

Submission by the firm;

Sr. No.	Reason for deferment.	Submission/Justification by the firm.

1.	Submission of documents/commercial invoice for the procurement of API Lot No. KM-0100918 with approval from DRAP.	Firm has submitted clearance certificate attested by AD - I&E, DRAP, Islamabad dated 27-04-2018 for the ketorolac tromethamine B# KM-0100918.
2.	Submission of scientific justification for not performing terminal sterilization of the drug product.	Firm has submitted that we were not performing terminal sterilization earlier but now we started terminal sterilization. They have also attached review document.
3.	Submission of 7500/- fee for revision of finished product specifications as per notification No. F. 7-11/2021-B&A/DRAP dated 13-07-2021.	Firm has submitted fee of 7500/- vide slip No. 31868295920 dated 06-01-2022 for revision of specifications.

Decision of 316th meeting of the Registration Board: Deferred for scientific rationale of performing terminal sterilization, with reference to the innovator product.

Submission by the firm;

Firm has submitted a document with title of "ketorolac tromethamine injection-Google patents" wherein they have provided details of a product of a Chinese pharmaceutical i.e. Tianjin Chase Sun Pharmaceutical Co. Ltd. The document discloses a prescription of ketorolac tromethamine injection and preparation method. The invention can not only effectively solve the problem that the existing ketorolac tromethamine injection containing ethanol causes irritation while being injected and improve the safety of the drugs and compliance of the drugs but also completely avoid the white points caused by the traditional technology after sterilization treatment, and thus the ketorolac tromethamine injection is good in stability, high in safety, reliable in quality and significant in efficacy.

The document has also shown that the said injection is terminally sterilized.

Remarks of the Evaluator [XIII]

In actives mentioned in the formulation of the above said document has no Ethyl alcohol, while the applied formulation has followed the innovator product which contain ethyl alcohol as solvent which makes the difference between the two formulations.

Furthermore, the document provided by the firm is not from RRA.

Decision of 321st meeting of Registration Board: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or otherwise.

Submission by the firm;

Firm has submitted that that the same molecule of BIO-Labs has already been evaluated and approved in the 343rd Meeting of DRB of the applicant M/s Lawari International Valley Road, Gulkada Saidu Sharif, Swat with brand name Katwari 30mg/ml Injection. They also submitted minutes of the meeting. They requested to please consider the evaluation of the above product as per the approved product Katwari 30mg/ml Injection by considering the submitted corrected data valid for Kerolac 30mg IV/IM (Ketorolac Tromethamine) as well in the upcoming meeting of the registration board.

Decision: Deferred for Product Specific Inspection.

Decision: The Board considering the recommendations of the panel, decided to approve the case.

Miscellaneous Decision:- The Board was informed that the Summary Evaluation Report for some new cases has not been included in the agenda due to the workload and the same was noted by the Board.

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

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Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(NZA-49L-ZNDH, 2025-06-18)
	Detail of Fee Submitted	37000.0, 2025-01-17,
	The proposed proprietary name / brand name	**Vee-dol 30mg/ml injection**
	Label Claim	Each ml contains: Ketorolac Tromethamine (USP).....30mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml x5ampoules,As pe-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Celsius temperature
	For generic drugs (me-too Status)	Toradol 30mg/ml injection by M/S Martin Dow Marker Ltd.
	Pharmacotherapeutic Group of (API)	M01AB15: analgesic/ anti inflammatory for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S SYMED LABS LIMITED UNIT-VI, SY.744, 745,750,751,752 & 753, MANDOLLAGUDEM VILLAGE, CHOUTUPPAL VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT,PINCODE 508204,TELANGANA STATE,INDIA
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Cunnigham
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Toradol injection Batch no 27289 by Martin Dow
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Ketorolac Tromethamine Injection, USP by M/S Peckforton Pharmaceuticals Limited CreweHall, Crewe, Cheshire, CW16UL, United Kingdom(MHRA Approved)
	GMP status of the firm	GMP certificate dated 02.01.2024
	Evidence of approval of manufacturing facility	Renewal of licnese letter dated 29.02.2024 mentioning Ampoule Section (General) Human

		(New)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to verification of API loan	
2	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(SBD-QV7-YMM1, 2025-04-21)
	Detail of Fee Submitted	37000.0, 2024-12-24,
	The proposed proprietary name / brand name	**Dobaxel 250mg/20ml injection**
	Label Claim	Each ml contains: Dobutamine (as Hydrochloride)USP.....12.5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20ml x 5 ampoules,As-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25 Degree celcius
	For generic drugs (me-too Status)	Dobutine 250mg/20ml injection by M/S Bajwa Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	C01CA07: Cardiac stimulants excluding glycosides
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Panchsheel Organics Limited
	Detail of stability batches of drug product	02 batches of 2000 ampoules on long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from MTI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dobutine Injection by Bajwa Pharmaceuticals Batch No. DB 0923
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches on long term and accelerated conditions
	The status in reference regulatory authorities	DOBUTAMINE INJECTION, USP 250mg PER 20mL by M/S HF Acquisition Co LLC, DBA HealthFirst,Mukilteo, WA (USFDA APPROVED)
	GMP status of the firm	GMP certificate dated 02.01.2024
	Evidence of approval of manufacturing facility	Renewal of licnese letter dated 29.02.2024 mentioning Ampoule Section (General) Human (New)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to verificaiton of API loan	

3	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(E62-G99-PS3U, 2026-02-03)
	Detail of Fee Submitted	38700.0, 2025-08-22,
	The proposed proprietary name / brand name	**Axafine Cream 1%**
	Label Claim	Each gram cream contains: Terbinafine Hydrochloride 10mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10gm-As per SRO
	Shelf Life (Unit)	24 Year(s)15 Degree Celsius - 25 Degree Celsius
	For generic drugs (me-too Status)	LAMISIL 1% w/w Cream by M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd Reg #084005
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China.(251400)
	Detail of stability batches of drug product	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm Imported Material against DIL, Form-6# K-400580286971 and Clearance Certificate# E-1091780282981 Complete Import Document Attached in MOD-III (3.2.S.1)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE Conducted against LAMISIL 1% w/w Cream by M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd Reg #084005
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months
	The status in reference regulatory authorities	MHRA APPROVED DRUG
	GMP status of the firm	GMP Certified and New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evidence of approval of manufacturing facility	New license granted- Lic. dated 13/09/2021. Tablet (general), Capsule (general), Cream/Ointment (Topical)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
4	Case Category	New License (Abdul Mughees)

	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(LXV-4XH-VY8T, 2026-02-04)
	Detail of Fee Submitted	30000.0, 7000.0 2023-12-12, 2025-02-18
	The proposed proprietary name / brand name	**Axalid 400mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Linezolid.....400mg USP Specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 x 6s-As per SRO
	Shelf Life (Unit)	24 Month(s)
	For generic drugs (me-too Status)	ZYVOXID 400mg Tablet
	Pharmacotherapeutic Group of (API)	J01XX08: Oxazolidinone; other antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Optimus Drugs Private Limited, unit III, Survey no. 145/A,145/AA & 147,, Ramalingampally(V), Bommala Ramaram (M), Yadadri Bhuvanagiri (D), Telangana State, India.
	Detail of stability batches of drug product	03 batches at long term and accelrated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelrated conditions
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML 14 September 2021
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
5	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**AKHSAH PHARMACEUTICALS (PVT) LTD.** Plot No. 47, Street No. S-10, RCCI INDUSTRIAL ESTATE RAWAT ISLAMABAD **(000943)**
	Application Form Dy. No / Tracking ID & date of submission	(N6S-3VU-MATL, 2026-02-04)
	Detail of Fee Submitted	30000.0, 7000.0 2023-12-12, 2025-02-18
	The proposed proprietary name / brand name	**Axalid 600mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Linezolid.....600mg USP Specification
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	2 x 6s-As per SRO
	Shelf Life (Unit)	24 Month15 Degree Celsius - 25 Degree Celsius
	For generic drugs (me-too Status)	ZYVOXID 600mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Optimus Drugs Private Limited, unit III, Survey no. 145/A,145/AA & 147,, Ramalingampally(V), Bommala Ramaram (M), Yadadri Bhuvanagiri (D), Telangana State, India.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA APPROVED
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved subject to GMP Inspection report.	
6	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(PJN-UND-SVZS, 2026-01-28)
	Detail of Fee Submitted	38700, 2025-12-24,
	The proposed proprietary name / brand name	**V-gron Tablet 75mg**
	Label Claim	Each film coated tablet contains: Vibegron.....75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100s-De-Controlled,10s-De-Controlled,12s-De-Controlled,14s-De-Controlled,1s-De-Controlled,20s-De-Controlled,28s-De-Controlled,2s-De-Controlled,30s-De-Controlled,3s-De-Controlled,40s-De-Controlled,4s-De-Controlled,50s-De-Controlled,5s-De-Controlled,7s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30oC.
	For generic drugs (me-too Status)	Virbeg Tablet 75mg Genix Pharma
	Pharmacotherapeutic Group of (API)	Jiangxi Synergy Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangxi Synergy Pharmaceutical Co., Ltd.

	Detail of stability batches of drug product	T2-25 (1000 tablets), T3-25 (1000 tablets), T4-25 (1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	RO-E4D935
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gemtesa 75mg Tablets, Batch # 3220513
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	AZP/50031216, AZP/50041216, AZP/50051216
	The status in reference regulatory authorities	GEMTESA Tablet 75mg, Urovant Sciences.
	GMP status of the firm	19/01/2027
	Evidence of approval of manufacturing facility	DS: Jiangxi Synergy Pharmaceutical Co., Ltd. DP: CCL Pharmaceuticals Ltd. DML holder
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
7	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(SU7-69B-L4J3, 2025-12-10)
	Detail of Fee Submitted	75000.0, 2025-08-19,
	The proposed proprietary name / brand name	**SUZI 50mg Tablet**
	Label Claim	Each film-coated tablet contains: Suzetrigine.....50mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's & 30's/ As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Non-opioid analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Chongqing Asincan Biotech Co., Ltd. Address: 2-2 No. 8 Gangqiao Branch Road, Jiangbei District, Chongqing, P.R of China, 400026.
	Detail of stability batches of drug product	3 batches of 500 Tablets each; B. No T223;B. No T224; B. No T225;
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Clearance Certificate is herewith attached in Module 3 Computerized No: RO-655F54
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Journavx 50 mg tablets by Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions

	The status in reference regulatory authorities	USFDA Approved; Journavx 50 MG TABLETS; Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210
	GMP status of the firm	GMP certificate issued dated 19-12-2023 declares availability of Tablet General section
	Evidence of approval of manufacturing facility	GMP certificate issued dated 19-12-2023 declares availability of Tablet General section
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
8	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(QS9-3Q7-EE7T, 2025-10-16)
	Detail of Fee Submitted	38700.0, 2025-08-13,
	The proposed proprietary name / brand name	**Maxflow-S 0.4/6mg Tablet**
	Label Claim	Each modified-release tablet contains: Solifenacin succinate 6mg, corresponding to 4.5mg Solifenacin. Tamsulosin hydrochloride 0.4 mg corresponding to 0.37 mg Tamsulosin.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30C.
	For generic drugs (me-too Status)	Tamsolin S 0.4/6mg Tablet Company: Getz Pharma Pvt. Limited.
	Pharmacotherapeutic Group of (API)	relief of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ALPHAMED FORMULATIONS PRIVATE LIMITED.
	Detail of stability batches of drug product	THREE BATCHES: T2-25, T3-25, T4-25 (1000 TABLETS)
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC clearance# RO-945964
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vesomni Tablet Batch# 23H2235/3
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per zone IVa
	The status in reference regulatory authorities	Vesomni Tablet 0.4/6mg Company: Astellas Pharma. (MHRA)

	GMP status of the firm	Valid till 18.12.2028
	Evidence of approval of manufacturing facility	Section approval letter dated 14.11.2025
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Approved. The firm shall submit applicable fee for import of pellets.	
9	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(8M4-T1V-X2PW, 2025-09-30)
	Detail of Fee Submitted	75000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Nalpro Tablet 8/90mg**
	Label Claim	Each film coated extended-release tablet contains: Naltrexone HCl .....8mg Bupropion HCl.....90mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Naltrexone HCl: Micro Orgo-Chem, Gujrat India. Bupropion HCl:Zhejiang Supor Pharmaceutical Co Ltd.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	THREE BATCHES: T2-22, T3-22, T4-22 (3000 TABLETS)
	Documents for the procurement of API with approval from DRAP (in case of Import)	E-1053144886857 & E-1310744882784
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against CONTRAVE TABLET - Batch # CDHMG
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per zone IVa
	The status in reference regulatory authorities	CONTRAVE, Nalpropion Pharmaceuticals LLC. (USFDA)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

	Approved	
10	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(T3B-ZU8-3Y7X, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	**Dexmedine 100mcg/ml injection**
	Label Claim	Each ml contains: Dexmedetomidine .....100mcg (as Dexmedetomidine HCl...USP) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x2ml , As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30 degree celsius temperature
	For generic drugs (me-too Status)	Precedix Injection 100mcg/ml by M/S Brook Pharma Private Limited.
	Pharmacotherapeutic Group of (API)	It is a selective alpha-2 adrenergic receptor agonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Shandong Chenghui Shuangda Pharmaceutical Co. ,Ltd
	Detail of stability batches of drug product	02 batches having batch no.(TR-021,TR-022) ,Batch sizes :2000 ampoules/batch are developed and performed stabilities for 06months and continued upto 24months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Final clearance certificate no.RO-A673F8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is performed against brand leader namely, Precedix Injection 100mcg/ml by M/S Brook Pharma Private Limited.While, Comparative dissolution profile is not applicable in injectables.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches having batch no. 5216121501,5216121502,5216121503 are taken and stabilities data performed on both accelerated conditions(Temp:40± 2˚C RH:75 ± 5%) for 06 months and Real time stabilities conditions at (Temp:30±2˚C RH:65 ± 5%) for 6 months
	The status in reference regulatory authorities	Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion by M/S Martindale Pharma, an Ethypharm Group Company Address: Jupiter House, Mercury Park, Wooburn Green, High Wycombe, Buckinghamshire,HP10 0HH, UK 9USFDA Approved)
	GMP status of the firm	Ref. No. 04/2024-DRAP(AD-46168323) , Dated:02-01-2024
	Evidence of approval of manufacturing facility	Valid DML No. is 000300
	Evaluation Remarks	

	The applicant claimed testing of enantiomer purity but did not provide evidence of procurement of Levomedetonidine Hydrochloride impurity.	
	Decision	
	Deferred Deferred. The firm shall perform testing as per USP and submit results.	
11	Case Category	Export Facilitation (Abdul Mughees)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(8WL-29H-6U4M, 2025-10-28)
	Detail of Fee Submitted	75000.0, 2025-05-19,
	The proposed proprietary name / brand name	**Alopexa 50 mg capsule**
	Label Claim	Each Capsule contains: Ritlecitinib Tosylate Equivalent to Ritlecitinib....50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,28's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	kinase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches manufactured each having 2500 capsules batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate dated 15-01-2025 specifies 0.7000Kg import of Riilicitinib
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Litfulo ® 50 mg of By Pfizer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 lots of Ritlicitinib were subjected to storage conditions as per Zone IV-A
	The status in reference regulatory authorities	Litfulo ® 50 mg of By Pfizer. USA
	GMP status of the firm	GMP Compliant ; certificate issued on the basis of inspection dated 15-06-2023 i.e. valid till 15-06-2025
	Evidence of approval of manufacturing facility	Letter for issuance of DML dated 09-09-2021 specifies Capsules General Section section
	Evaluation Remarks	
	The application fulfills codal formalities	
	Decision	
	Approved	
12	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(YTJ-4E4-ZLW7, 2025-10-24)
	Detail of Fee Submitted	75000, 2025-09-17,

	The proposed proprietary name / brand name	**Trigine 50mg Tablets**
	Label Claim	Each film coated tablet contains: Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degrees Celsius
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Sodium channel blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches manufactured each having 1500 tablets batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate dated 30-04-2025 specifies 0.30Kg import of Suzetrigine
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Journavx ® 50 mg Manufactured By Vertex Pharmaceuticals Incorporated,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 lots of Suzetrigine were subjected to storage conditions as per Zone IV-A
	The status in reference regulatory authorities	Journavx ® 50 mg Manufactured By Vertex Pharmaceuticals Incorporated, USFDA ; https://www.accessdata.fda.gov/scripts/cder/daf/index.event=BasicSearch.process
	GMP status of the firm	GMP Compliant ; certificate issued on the basis of inspection dated 15-06-2023 i.e. valid till 15-06-2025
	Evidence of approval of manufacturing facility	Letter for issuance of DML dated 09-09-2021 specifies Tablet General Section
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
13	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(H2Q-PXQ-VUEQ, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-03-25,
	The proposed proprietary name / brand name	**Vee-Dope 200mg/5ml injection**
	Label Claim	Each ampoule (5ml) contains: Dopamine Hydrochloride U.S.P.....200mg (Equivalent

		to 161.5mg Dopamine) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's,As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30 degree celsius temperature
	For generic drugs (me-too Status)	Dopamine injection 200mg/5ml by M/S Lahore Chemicals and Pharmaceutical Works (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	C01CA04: Cardiac stimulant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Panchsheel Organics ltd.,India
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from MTI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Dopamine Injection by Howards Batch 35087
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Dopamine Hydrochloride Injection, USP,200mg/5ml(40mg/ml) by M/S Hikma Farmaceutica (Portugali),SA.
	GMP status of the firm	GMP certificate dated 02.01.2024
	Evidence of approval of manufacturing facility	Renewal of licnese letter dated 29.02.2024 mentioning Ampoule Section (General) Human (New)
	Evaluation Remarks	
	Decision	
	Approved	
14	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(TLU-Y1G-QTW5, 2025-12-10)
	Detail of Fee Submitted	75000.0, 2025-08-25,
	The proposed proprietary name / brand name	**Darix 25mg Tablets**
	Label Claim	Daridorexant 25mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Daridorexant: Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China

	Detail of stability batches of drug product	03 batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided DRAP clearance
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Against QUVIVIQ
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated conditions
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets, for oral use Tablets: 25 & 50 mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	GMP status of the firm	GMP certificate (for Afghanistan) dated 09.05.2024
	Evidence of approval of manufacturing facility	DP Manufacturer: MedizanLaboratories (Pvt) Ltd. DML dated 13.05.2015
	Evaluation Remarks	
	The application fulfills codal formalitites.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
15	Case Category	New Molecule/Formulation (Abdul Mughees)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(9WH-EUU-9Y1V, 2025-10-01)
	Detail of Fee Submitted	75000.0, 2025-08-25,
	The proposed proprietary name / brand name	**Darix 50mg Tablets**
	Label Claim	Daridorexant 50mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Daridorexant: Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District,

		Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	03 batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided DRAP clearance
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Against QUVIVIQ
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated conditions
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets, for oral use Tablets: 25 & 50 mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	GMP status of the firm	GMP certificate (for Afghanistan) dated 09.05.2024
	Evidence of approval of manufacturing facility	DP Manufacturer: MedizanLaboratories (Pvt) Ltd. DML dated 13.05.2015
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
16	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Magns Pharmaceuticals** Plot # 7B Value Addition City Sahianwala Road Khurrianwala **(000849)**
	Application Form Dy. No / Tracking ID & date of submission	(3NH-G9P-YDSN, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-30,
	The proposed proprietary name / brand name	**Magra 100mg Tablet**
	Label Claim	Each film coated tablet contain: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's-De-Controlled,4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)stored at room temperature (15°C-25°C) and protected from freezing
	For generic drugs (me-too Status)	Silden 100 mg Tablets
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	M/s. Rakshit Pharmaceuticals Plot No: 68/A, Jawaharlal Nehru Pharma City, Parawad (M), Visakhapatnam District, Andhra Pradesh India.
	Detail of stability batches of drug product	3 batches, 100 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg, B. No. B808204U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 60 months
	The status in reference regulatory authorities	VIAGRA® (sildenafil citrate)
	GMP status of the firm	GMP Attached
	Evidence of approval of manufacturing facility	Section approval letter dated 07.06.2022 is submitted.
	Evaluation Remarks	
	Priority as per Decision of 214th meeting of Authority. Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
17	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Magns Pharmaceuticals** Plot # 7B Value Addition City Sahianwala Road Khurrianwala **(000849)**
	Application Form Dy. No / Tracking ID & date of submission	(7WA-Y6D-U14U, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-30,
	The proposed proprietary name / brand name	**Magra 25mg tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil..... 25 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)stored at room temperature (15°C-25°C) and protected from freezing
	For generic drugs (me-too Status)	Silden 25 mg Tablets
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Rakshit Pharmaceuticals Plot No: 68/A, Jawaharlal Nehru Pharma City, Parawad (M), Visakhapatnam District, Andhra Pradesh India.
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg, B. No. B819305U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 60 months
	The status in reference regulatory authorities	VIAGRA® (sildenafil citrate)
	GMP status of the firm	GMP Attached

	Evidence of approval of manufacturing facility	Section approval letter dated 07.06.2022 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of RB. Application fulfills codal formalities recommended for consideration of board.	
	Decision	
	Approved	
18	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Magns Pharmaceuticals** Plot # 7B Value Addition City Sahianwala Road Khurrianwala **(000849)**
	Application Form Dy. No / Tracking ID & date of submission	(8TT-H64-48GT, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-10-30,
	The proposed proprietary name / brand name	**Magra 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil ..... 50 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2's-De-Controlled,4's-De-Controlled
	Shelf Life (Unit)	2 Year(s)stored at room temperature (15°C-25°C) and protected from freezing
	For generic drugs (me-too Status)	Silden 50 mg Tablets
	Pharmacotherapeutic Group of (API)	Section approval letter dated 07.06.2022 is submitted.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Rakshit Pharmaceuticals Plot No: 68/A, Jawaharlal Nehru Pharma City, Parawad (M), Visakhapatnam District, Andhra Pradesh India.
	Detail of stability batches of drug product	3 batches, 1100 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg, B. No. B799704U
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 60 months
	The status in reference regulatory authorities	VIAGRA® (sildenafil citrate)
	GMP status of the firm	GMP Attached
	Evidence of approval of manufacturing facility	Section approval letter is submitted,
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
19	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(1BD-M2N-JEGR, 2026-02-11)

	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**Sil-Fil 100mg Tablet**
	Label Claim	Each film coated tablet contains; Sildenafil citrate eq. to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,12's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,21's-De-Controlled,24's-De-Controlled,28's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	i-Pill 100mg Tablet
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Novamed, clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	I-Pill 100mg B. No. 0002T669 Genix Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 100mg Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate valid till 01.12.2028 is submitted.
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
20	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(HVS-UQU-DUHW, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**Sil-Fil 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil citrate eq. to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,12's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,21's-De-Controlled,24's-De-Controlled,28's-De-Controlled,30's-De-Controlled,4's-De-

		Controlled,5's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	i-Pill 50mg Tablet
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Novamed, clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	I-Pill 50mg B. No. 0002T668 Genix Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 50mg Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate valid till 01.12.2028 is submitted.
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
21	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur **(000977)**
	Application Form Dy. No / Tracking ID & date of submission	(JGJ-91M-59MB, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**Sil-Fil 25mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil citrate eq. to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,14's-De-Controlled,1's-De-Controlled,2's-De-Controlled,20's-De-Controlled,24's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	I-Pill 25mg Tablet
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drug Private Limited
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Novamed, clearance certificate and loan letter is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	I-Pill 100mg B. No. 0002T667 Genix Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 25mg Tablet (USFDA Approved)
	GMP status of the firm	GMP certificate valid till 01.12.2028 is submitted.
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No. [000977] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
22	Case Category	Priority As Per 257-M of RB (Adil Saeed)
	Name, address of Applicant.	**Getz Pharma (Pvt.) Ltd. - (Unit I)** Plot No. 1, Sector 25, Korangi Industrial Area **(000933)**
	Application Form Dy. No / Tracking ID & date of submission	(UQM-PBM-2QZW, 2026-02-18)
	Detail of Fee Submitted	75000, 2025-10-23,
	The proposed proprietary name / brand name	**Etrasim Tablets 2mg**
	Label Claim	Each film-coated tablet contains: Etrasimod Arginine equivalent to Etrasimod.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	L04AE05 Sphingosine-1-Phosphate (S1P) Receptor Modulators, L04AE05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Neutan Pharma?Anhui?Co., Ltd. No. 1018 Jin'an Road, Economic&Technology Development District, Suzhou, Anhui, China
	Detail of stability batches of drug product	2 batches, 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 150grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velsipity 2mg tablet B. No. 030273 Mfg Pfizer Canada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa,
	The status in reference regulatory authorities	Velsipity Tablets 2mg by M/s Pfizer Labs, Division of Pfizer Inc, USA.
	GMP status of the firm	GMP certificate valid till 16.01.2028 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 07.06.2021 is submitted.
	Evaluation Remarks	
	Application fulfils codal formalities. Recommended for consideration of board.	

	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
23	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Caliph Pharmaceuticals (Pvt) Ltd.** Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK **(000748)**
	Application Form Dy. No / Tracking ID & date of submission	(5RT-XBQ-SNQU, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-12-08,
	The proposed proprietary name / brand name	**SILDENACAL 50MG TABLET**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil..... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Denafil 50mg Tablets Reg No. 131800
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited.
	Detail of stability batches of drug product	3 batches, 1500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. E-10694860606934 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: VIAGRA 50MG TABLET B. No. 4469571
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	VIAGRA (sildenafil citrate) tablets
	GMP status of the firm	GMP certificate issued on basis of inspection dated 02.03.2021 is submitted.
	Evidence of approval of manufacturing facility	Section Approval Date: 17-01-2019
	Evaluation Remarks	
	Prioirty as per decision of 214th meeting of Authority Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
24	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Caliph Pharmaceuticals (Pvt) Ltd.** Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK **(000748)**

	Application Form Dy. No / Tracking ID & date of submission	(952-L8E-GD44, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-08,
	The proposed proprietary name / brand name	**SILDENACAL 100MG TABLET**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)25°C
	For generic drugs (me-too Status)	Denafil 100mg Tablets Reg No. 131801
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	3 batches, 1500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate No. E-10694860606934 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product: VIAGRA 100MG TABLET B. No. 394681
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	VIAGRA (sildenafil citrate) tablets
	GMP status of the firm	GMP certificate issued on basis of inspection dated 02.03.2021 is submitted.
	Evidence of approval of manufacturing facility	Section Approval Date: 17-01-2019
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities, recommended for consideration of board.	
	Decision	
	Approved	
25	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Medisure Laboratories Pakistan Pvt Ltd** A-115 S.I.T.E-II Super Highway Karachi **(000503)**
	Application Form Dy. No / Tracking ID & date of submission	(5YZ-E53-7S7D, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Sildenafil 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C, protect from heat, moisture & sunlight.
	For generic drugs (me-too Status)	I-Pill Tablet 50mg
	Pharmacotherapeutic Group of (API)	Anti-erectile dysfunction agent.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 4000 tablets each.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug Import License is Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	I-pill tablet 50mg B. No. 0001T668 Mfg Genix
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Sildenafil Actavis 50 mg film-coated tablets
	GMP status of the firm	Last GMP Inspection dated: 4th December 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 21.07.2023 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
26	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Medisure Laboratories Pakistan Pvt Ltd** A-115 S.I.T.E-II Super Highway Karachi **(000503)**
	Application Form Dy. No / Tracking ID & date of submission	(PRT-1WQ-M6JB, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Sildenafil 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	i-Pill Tablet 100mg
	Pharmacotherapeutic Group of (API)	Anti -erectile dysfunction agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug Import License is Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	I-pill tablet 100mg B. No. 0001T669 Mfg Genix
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Sildenafil Actavis 100 mg film-coated tablets
	GMP status of the firm	Last GMP Dated: 04th December 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 21.07.2023 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
27	Case Category	Any Other (Adil Saeed)

	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(86G-1T4-8727, 2026-02-09)
	Detail of Fee Submitted	38700, 2025-11-25,
	The proposed proprietary name / brand name	**Vigoril 25mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	24 Year(s)store below 30°C
	For generic drugs (me-too Status)	I-Pill 25mg Tablet (Reg. No. 123441) by Genix Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited. 103-106, GIDC, Halol Dist. Panchmahals- 389 350
	Detail of stability batches of drug product	Batches: 001, 002 and 003 (Batch size: 1500 Tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 22-08-2024 for 2.5kg material is submitted. Copy of commercial invoice dated 25-07-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Viagra 25mg by Viatris Specialty LLC
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months real time and 06 months accelerated stability data according to the conditions of zone IV-A for 03 batches is submitted
	The status in reference regulatory authorities	Viagra 25mg by Viatris Specialty LLC (USFDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Data submitted is new from previously submitted application that was rejected in 351st meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved Subject to product specific inspection which shall be conducted by panel constituted by the chairman registration board.	
28	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(QP3-VAA-6AAT, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-11-25,

	The proposed proprietary name / brand name	**Vigoril 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil..... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	24 Monthstore below 30°C
	For generic drugs (me-too Status)	I-Pill 100mg Tablet (Reg. No. 123443) by Genix Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited. 103-106, GIDC, Halol Dist. Panchmahals- 389 350,
	Detail of stability batches of drug product	Batches: 001, 002 and 003 (Batch size: 1500 Tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 22-08-2024 for 2.5kg material is submitted. Copy of commercial invoice dated 25-07-2024 is also submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Viagra 100mg by Viatris Specialty LLC
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months real time and 06 months accelerated stability data according to the conditions of zone IV-A for 03 batches is submitted
	The status in reference regulatory authorities	Viagra 100mg by Viatris Specialty LLC (USFDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Data submitted is new from previously submitted application that was rejected in 351st meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved Subject to PSI conducted by panel constituted by the chairman Registration Board.	
29	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(DXX-G9G-AL73, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-11-25,
	The proposed proprietary name / brand name	**Vigoril 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to Sildenafil..... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	24 Monthstore below 30°C

	For generic drugs (me-too Status)	I-Pill 50mg Tablet (Reg. No. 123442) by Genix Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited. 103-106, GIDC, Halol Dist. Panchmahals- 389 350,
	Detail of stability batches of drug product	Batches: 001, 002 and 003 (Batch size: 1500 Tablets) 06 months accelerated and 06 months real time stability data according to zone IV-A is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of form 6 dated 22-08-2024 for 2.5kg material is submitted. Copy of commercial invoice dated 25-07-2024 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Viagra 50mg by Viatris Specialty LLC
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months real time and 06 months accelerated stability data according to the conditions of zone IV-A for 03 batches is submitted
	The status in reference regulatory authorities	Viagra 50mg by Viatris Specialty LLC (USFDA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 01-07-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Data submitted is new from previously submitted application that was rejected in 351st meeting. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved Subject to PSI which shall be conducted by panel constituted by the Chairman Registration Board.	
30	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)**
	Application Form Dy. No / Tracking ID & date of submission	(BH3-M87-A3XQ, 2026-01-05)
	Detail of Fee Submitted	38700.0, 2025-08-26,
	The proposed proprietary name / brand name	**SILDORA 100MG TABLET**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate USP equivalent to Sildenafil.....100mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,1x14's-De-Controlled,1x2's-De-Controlled,1x20's-De-Controlled,1x30's-De-Controlled,1x4's-De-Controlled,1x6's-De-Controlled,1x8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at (20°C-25°C). Excursion permitted between 15°C-30°C.
	For generic drugs (me-too Status)	Hilagra Tablets 100mg, Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	3 batches, 1666 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 2kg drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hilagra 100mg Tablet B. No. 159629
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 100mg tablet, PFIZER LABORATORIES, USFDA Approved
	GMP status of the firm	GMP Certificate No. 17/2024-DRAP(K) Valid till 24th Jan 2027
	Evidence of approval of manufacturing facility	Approved Section Letter No. F.2-12/2006-Lic (Vol-III) Dated 20th Sep 2021 is attached
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfils codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
31	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore **(000395)**
	Application Form Dy. No / Tracking ID & date of submission	(TXB-1XM-PR4A, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	**Drivex 100mg tablet**
	Label Claim	Each Film-coated Tablet contains: Sildenafil Citrate eq. to Sildenafil ...100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 10's, 15's, 30's, 100's-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	Lovento Tablet 100mg manufactured by Organic Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Urologicals, drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg tablet B. No. B837203
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra Tablets 100mg USFDA Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Submitted

	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Applciation fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
32	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**FYNK Pharmaceuticals** 19-KM, G.T. Road, Kala Shah Kaku, Tehsil Ferozwala District Sheikhupura. **(000494)**
	Application Form Dy. No / Tracking ID & date of submission	(WG8-2UV-Q6SU, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	**Silafin Tablets 100mg**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO,4-As per SRO,7-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30 oC.
	For generic drugs (me-too Status)	Hilagra Tablets by M/s Hilton pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RAKSHIT PHARMACEUTICALS LTD
	Detail of stability batches of drug product	3 batches, 800 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra tablets 100mg B837203
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	GMP Certificate issued by DRAP Lahore 30-9-2024
	Evidence of approval of manufacturing facility	Tablet Section approved
	Evaluation Remarks	
	Priority as per 214th meeting of Authority Application fulfills codal formalties. recommended for consideration of board.	
	Decision	
	Approved	
33	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**FYNK Pharmaceuticals** 19-KM, G.T. Road, Kala Shah Kaku, Tehsil Ferozwala District Sheikhupura. **(000494)**
	Application Form Dy. No / Tracking ID & date of submission	(Z85-P72-7SN9, 2026-01-07)
	Detail of Fee Submitted	38700, 2025-12-02,
	The proposed proprietary name / brand name	**Silafil Tablet 50mg**

	Label Claim	Each Film Coated Tablet Contains: Sildenafil citrate Equivalent to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO,4-As per SRO,7-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30 oC
	For generic drugs (me-too Status)	Hilagra 50mg by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RAKSHIT PHARMACEUTICALS LTD
	Detail of stability batches of drug product	3 batches, 800 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra Tablet 50mg B. No. 3189219
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	GMP Certificate issue date 24/9/2024
	Evidence of approval of manufacturing facility	Tablet Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfils codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
34	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(AQB-VNH-Q2S3, 2026-02-17)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**VYTALIX 100mg TABLETS**
	Label Claim	Each Film coated Tablet contains: SILDENAFIL CITRATE equivalent to SILDENAFIL 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's & 10x10's-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Condition
	For generic drugs (me-too Status)	Product Name:: Ripple 100mg Tablet Registration No: 127631 Company Address: Plot No. 08, Street No. S-1, RCCI,
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited
	Detail of stability batches of drug product	3 batches, 1000 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Tablet Batch no. 19659824 Mfg. Date: 06-2024 Manufacturer Pfizer Inc.,

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 20mg, 25mg, 100mg & 100mg (sildenafil) tablets, USFDA approved
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	Priority as pr decision of 214th meeting of Authority Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
35	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore **(000872)**
	Application Form Dy. No / Tracking ID & date of submission	(JXV-7ER-B5SD, 2026-01-29)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Edegris 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil..... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	i-Pill Tablets 100mg (123443)- Genix Pharma (PVT.) LTD
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Urologicals; Drugs used in erectile dysfunction ATC code: G04B E03
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: E103, E104, E105 (Batch size: 1500 Tablets) 6 months real time and 6 months accelerated stability study data as per zone IVA
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (DIL-C-A8DE34) dated 05-03-2025 is submitted (2 kg) along with other procurement documents.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against i-Pill Tablets 100mg of Genix Pharma (PVT.) LTD B. No. 0002T669
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 001-SDC, 002-SDC, 003-SDC Real time data till 60 months and Accelerated till 6 months time point as per zone IVA
	The status in reference regulatory authorities	VIAGRA 100 mg film-coated tablets (MHRA Approved)
	GMP status of the firm	Pharmasol: GMP certificate issued on the basis of inspection conducted on 24-09-2024 & 25-09-2024
	Evidence of approval of manufacturing facility	Tablet section (General) Human
	Evaluation Remarks	
	Priority as per 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	

	Decision	
	Approved	
36	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore **(000872)**
	Application Form Dy. No / Tracking ID & date of submission	(9PN-QY1-N17T, 2026-01-29)
	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Edegris 25mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	i-Pill Tablets 25mg (123441)- Genix Pharma (PVT.) LTD
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Urologicals; Drugs used in erectile dysfunction ATC code: G04B E03
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: E112, E113, E114 (Batch size: 1500 Tablets) 6 months real time and 6 months accelerated stability study data as per zone IVA
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (DIL-C-A8DE34) dated 05-03-2025 is submitted (2 kg) along with other procurement documents.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against i-Pill Tablets 25mg of Genix Pharma (PVT.) LTD B. No. 0002T667
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 001-SDC, 002-SDC, 003-SDC Real time data till 60 months and Accelerated till 6 months time point as per zone IVA
	The status in reference regulatory authorities	VIAGRA 25 mg film-coated tablets (MHRA Approved)
	GMP status of the firm	Pharmasol: GMP certificate issued on the basis of inspection conducted on 24-09-2024 & 25-09-2024
	Evidence of approval of manufacturing facility	Tablet section (General) Human
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
37	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Pharmasol (Pvt) Ltd.** Plot No. 549, Sundar Industrial Estate, Lahore : Head office: SPL House No. 82, R-1 Johar Town, Lahore **(000872)**
	Application Form Dy. No / Tracking ID & date of submission	(VWP-ZPP-3UUL, 2026-01-29)

	Detail of Fee Submitted	38700, 2026-01-20,
	The proposed proprietary name / brand name	**Edegris 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil..... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	i-Pill Tablets 50mg (123442)- Genix Pharma (PVT.) LTD
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Urologicals; Drugs used in erectile dysfunction ATC code: G04B E03
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: E115, E116, E117 (Batch size: 1500 Tablets) 6 months real time and 6 months accelerated stability study data as per zone IVA
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (DIL-C-A8DE34) dated 05-03-2025 is submitted (2 kg) along with other procurement documents.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against i-Pill Tablets 50mg of Genix Pharma (PVT.) LTD
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: 001-SDC, 002-SDC, 003-SDC Real time data till 60 months and Accelerated till 6 months time point as per zone IVA
	The status in reference regulatory authorities	VIAGRA 50 mg film-coated tablets (MHRA Approved)
	GMP status of the firm	Pharmasol: GMP certificate issued on the basis of inspection conducted on 24-09-2024 & 25-09-2024
	Evidence of approval of manufacturing facility	Tablet section (General) Human
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
38	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)**
	Application Form Dy. No / Tracking ID & date of submission	(Z1T-NUL-AWM6, 2025-11-19)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Eropril 100 mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....100 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-De-Controlled,20s-De-Controlled,30s-De-Controlled,4s-De-Controlled,8s-De-Controlled
	Shelf Life (Unit)	2 Year(s)15 to 30

	For generic drugs (me-too Status)	Hilagra 100 mg Tablet By Hilton Pharma Pvt Ltd
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India Telephone number +91 2676 220912, +91 2676 223220 Fax number +91 265 2226023 E Mail ra@centurypharma.com
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	It is attached and conducted against Hilagra 100 mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=overview.process&ApplNo=020895
	GMP status of the firm	GMP Valid till 01-07-2027
	Evidence of approval of manufacturing facility	Tablet Section approval letter submitted.
	Evaluation Remarks	
	Priority as per 214th meeting of Authority Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
39	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(XZ4-3A7-VR8M, 2025-09-25)
	Detail of Fee Submitted	75000.0, 2024-12-16,
	The proposed proprietary name / brand name	**Hilsil Tablets 20mg**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to sildenafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,15's-De-Controlled,16's-De-Controlled,2's-De-Controlled,20's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,6's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C . Protect from Sunlight and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Drugs used in pulmonary hyertension
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 13333 tablets each
	Documents for the procurement of API with approval from DRAP	License to Import drug substance is submitted

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Revatio 20mg tablet B. No. B699304 Mfg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA Approved - Revatio 20mg tablets by Pfizer Inc
	GMP status of the firm	GMP certificate issued on basis of inspection dated 23.01.2023 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 04.12.2014 is submittedd
	Evaluation Remarks	
	Application fulfils codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
40	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Jawa Pharmaceuticals (Pvt) Ltd** 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore **(000150)**
	Application Form Dy. No / Tracking ID & date of submission	(XLN-8J9-21D1, 2025-11-12)
	Detail of Fee Submitted	37000, 2025-07-24,
	The proposed proprietary name / brand name	**Nexafil Tablet 100mg**
	Label Claim	Each Film coated Tablet Contains: Sildenafil citrate eq. to sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1×4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from light and moisture.
	For generic drugs (me-too Status)	I-PILL 100MG TABLETS by GENIX PHARMA (Pvt.)Ltd.
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE-5) inhibitors.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 2000 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Tablet B. No. 4049500
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	VIAGRA 100MG FILM COATED TABLETS by PFIZER HEALTHCARE IRELAND
	GMP status of the firm	Submitted.
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
41	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi **(000333)**
	Application Form Dy. No / Tracking ID & date of submission	(6J6-JSD-YE76, 2025-09-29)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**BEPTASIL 1.5% w/v Ophthalmic Solution**
	Label Claim	Each mL contains: Bepotastine Besilate 15mg (equivalent to 10.7mg bepotastine)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	(1x1s)-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30
	For generic drugs (me-too Status)	nil
	Pharmacotherapeutic Group of (API)	Bepreve™ is a histamine H1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches, 500 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 140 grams drug substance is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Bepreve 1.5% w/v Ophthalmic Solution (Baush & Lomb incorporated) Mfg Valeant Pharma North America. B. No. 480361
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 24 months.
	The status in reference regulatory authorities	Bepreve 1.5% w/v Ophthalmic Solution (Baush & Lomb incorporated)
	GMP status of the firm	GMP certificate valid upto 15.02.2027 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 30.10.2019 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities recommended for consideration of board.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
42	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi

		(000333)
	Application Form Dy. No / Tracking ID & date of submission	(WYX-G92-37L5, 2025-11-10)
	Detail of Fee Submitted	38700, 2025-10-08,
	The proposed proprietary name / brand name	**X-BLU 100mg Tablets**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate equivalent to 100mg Sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30
	For generic drugs (me-too Status)	Vilagra Tablets Hilton Pharma
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	T-001 T-002 T-003
	Documents for the procurement of API with approval from DRAP (in case of Import)	05/03/2025
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg Tablets (Pfizer USA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	001-SDC 002-SDC 003-SDC
	The status in reference regulatory authorities	Viagra 100mg Tablets (Pfizer USA)
	GMP status of the firm	20th feb,2024
	Evidence of approval of manufacturing facility	1st July 1993
	Evaluation Remarks	
	Priority as per decision of 214th meeting. Application fulfils codal formalities. submitted for consideration of board.	
	Decision	
	Approved Subjection to PSI to be conducted by panel constituted by the Chairman Registration Board.	
43	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)**
	Application Form Dy. No / Tracking ID & date of submission	(V3B-TWX-NH1M, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-09-17,
	The proposed proprietary name / brand name	**Viridio Chewable Tablet 100mg**
	Label Claim	Each chewable tablet contains: Sildenafil Citrate equivalent to Sildenafil 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,25's-As per SRO,28's-As per SRO,30's-As per SRO,5's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of 3 batches on Zone IV-A provided 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 specifying the import of 'Sildenafil Citrate from Century Pharmaceuticals' is provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed against innovator product "Direktan 100 mg Chewable Tablet Mfg. by GEROT LANNACH" B. No. 233193
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches on Zone IV-A provided
	The status in reference regulatory authorities	Sildenafil STADA 100mg Chewable tablets (HPRA - Ireland Approved)
	GMP status of the firm	GMP (Valid till 02-08-2027)
	Evidence of approval of manufacturing facility	Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of baord.	
	Decision	
	Approved	
44	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(JSH-N2J-LLUV, 2025-12-09)
	Detail of Fee Submitted	38700.0, 2025-08-25,
	The proposed proprietary name / brand name	**SATIS 100mg TABLETS**
	Label Claim	Each Film coated Tablet contains: SILDENAFIL CITRATE equivalent to SILDENAFIL ..... 100mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,20's,30's,40's& 100's-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Temperature
	For generic drugs (me-too Status)	Product Name:: Ripple 100mg Tablet Registration No: 127631 Company Name: Solaris Life Sciences Private Limited,
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	viagra 100mg tablet batch no. 19659824AH mfg date: 06-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved

	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	section approval letter submiited
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of baord.	
	Decision	
	Approved	
45	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)**
	Application Form Dy. No / Tracking ID & date of submission	(A2P-21N-9LB9, 2025-12-04)
	Detail of Fee Submitted	38700.0, 2025-08-25,
	The proposed proprietary name / brand name	**SATIS 50mg TABLETS**
	Label Claim	Each Film coated Tablet contains: SILDENAFIL CITRATE equivalent to SILDENAFIL ..... 50mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's,20's,30's,40's& 100's-As per SRO
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	Product Name:: Ripple 50mg Tablet Registration No: 127630 Company Name: Solaris Life Sciences Private Limited
	Pharmacotherapeutic Group of (API)	PDE5 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India
	Detail of stability batches of drug product	Batch no.TOA1 size 1500 Table Mfg Date: 03-2025 Batch no.TOB2 size 1500 Table Mfg Date: 03-2025 Batch no.TOC3 size 1500 Tablets Mfg Date: 03-2025
	Documents for the procurement of API with approval from DRAP (in case of Import)	Imported from Palam Pharma India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	viagra 50mg tablet batch no. 19990545AG mfg date: 11-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batch No 01706001-SDC Date of Manufacture: JUNE-2017 Batch No 01708003-SDC Date of Manufacture: August-2017 Batch No 01707002-SDC Date of Manufacture: JULY-2017
	The status in reference regulatory authorities	Century Pharmaceuticals Limited 103 to 106, GIDC, Halol City,- Halol -389 350 Dist,- Panchmahal Gujarat State, India India
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	section approval attached in module 1
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfills codal formalities. Recommended for consideration of baord.	
	Decision	
	Approved	

46	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**NovaMed Pharmaceuticals(Pvt.)Ltd** 28-KM Ferozepur Road Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(95Q-M41-4UWQ, 2026-02-06)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**Tadralis 2.5mg Tablet**
	Label Claim	Each film coated tablet contains : Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Fildil 2.5mg Tablet (REG. No. 127632)
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited (Address: 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India)
	Detail of stability batches of drug product	RD/PR25-102/T1/S1, RD/PR25-102/T1/S2, RD/PR25-102/T1/S3 (Batch size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate# RO-0E259D dated 15-03-2025 for 1kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Both PE & CDP applicable and attached performed against Fildil Tablet by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Tadalafil 2.5mg Tablet MHRA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-11-2023.
	Evidence of approval of manufacturing facility	Tablet Section (General)is approved
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
47	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(3PX-WZW-7PV7, 2026-02-09)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	**Consista 20mg Tablets**
	Label Claim	Each Film coated tablet contains: Tadalafil....20mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	12's-De-Controlled-De-Controlled, 15's-DeControlled-De-Controlled,10's-De-Controlled-De-Controlled,16's-De-Controlled-De-Controlled,2's-De-Controlled-Controlled,20'sDe-Controlled-De-Controlled,30's-De-Controlled-De-Controlled,4's-De-Controlled-De-Controlled,5'sDe-Controlled-De-Controlled,6's-De-Controlled-De-Controlled,8's-De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Tadalis Tablet 20mg
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE-5) Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited.
	Detail of stability batches of drug product	stability studies for the Drug Product were conducted under Zone IVa conditions. The stability batch numbers are: T-489, T-490, T491 batch size: 1500 tablets 06 months accelerated and 06 months realtime accoridng to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-02-2025 for 1kg of material along with unattested invoice. The firm has not submitted clearance certificate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis Tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to Zone-IV a.
	The status in reference regulatory authorities	Cialis 20mg Tablet (https://www.accessdata.fda.gov/scripts/cder/ob/re Appl_Type=N&Appl_No=02136 8#24783)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
48	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(EGG-SEY-3BYQ, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-24,
	The proposed proprietary name / brand name	**TADAFLO 2.5mg Tablet**
	Label Claim	Each film coated tablet contain Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x2’s, 1x4’s, 1x5’s, 1x6’s, 2x4's, 1x10's, 1x14's, 2x10’s and 3x10’s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC

	For generic drugs (me-too Status)	Fildil tablet by M/s Highnoon
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	03 batches (Batch size: 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-01-2025 for 0.5kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Zalutia tablet by M/s Nippon Shinyaki ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
49	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(WPP-QXW-H3SH, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-24,
	The proposed proprietary name / brand name	**TADAFLO 10mg Tablet**
	Label Claim	Each film coated tablet contain Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x2's, 1x4's, 1x5's, 1x6's, 2x4's, 1x10's, 1x14's, 2x10's and 3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC
	For generic drugs (me-too Status)	Tadala
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	03 batches (Batch size: 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-01-2025 for 0.5kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 10mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A is submitted.
	The status in reference regulatory authorities	Cialis 10mg Tablet
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.

	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
50	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(Y2D-EHL-93S2, 2026-02-09)
	Detail of Fee Submitted	38700, 2025-11-24,
	The proposed proprietary name / brand name	**TADAFLO 5mg Tablet**
	Label Claim	Each film coated tablet contain; Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x2's, 1x4's, 1x5's, 1x6's, 2x4's, 1x10's, 1x14's, 2x10's and 3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Donot store over 30ºC
	For generic drugs (me-too Status)	Tadala
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches (Batch size: 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-01-2025 for 0.5kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	E and CDP studies have been performed against Cialis 5mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A is submitted.
	The status in reference regulatory authorities	Cialis 5mg Tablet
	GMP status of the firm	Valid until 30-06-2027
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
51	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)**
	Application Form Dy. No / Tracking ID & date of submission	(NQD-HBL-XMTQ, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	**Consista 5mg Tablets**
	Label Claim	Each Film coated tablet contains: Tadalafil....5mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	12's-De-Controlled,-De-Controlled, 16's-De-Controlled-De-Controlled,10's-De-Controlled,-De-Controlled,15's-DeControlled-De-Controlled,2's-De-Controlled,-De-Controlled,20'sDe-Controlled,-De-Controlled,30's-De-Controlled-De-Controlled,4's-De-Controlled,-De-Controlled,5'sDe-Controlled,-De-Controlled,6's-De-Controlled,-De-Controlled,8's-De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Ciafil 5mg Tablet
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 (PDE-5) Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Ltd.
	Detail of stability batches of drug product	stability studies for the Drug Product were conducted under Zone IVa conditions. The stability batch numbers are: T-482, T-483, T484 batch size: 1500 tablets 06 months accelerated and 06 months realtime accoridng to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-02-2025 for 1kg of material along with unattested invoice. The firm has not submitted clearance certificate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis Tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to Zone-IV a.
	The status in reference regulatory authorities	Cialis 5mg Tablet - Food and Drug Regulatory Authority USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
52	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)**
	Application Form Dy. No / Tracking ID & date of submission	(92R-Z71-Y4XM, 2025-05-05)
	Detail of Fee Submitted	75000.0, 2025-04-15,
	The proposed proprietary name / brand name	**AVACO 10MG CAPSULE**
	Label Claim	Each capsule contains: Avacopan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's, 60's, & 90's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Inhibitor of complement 5a of C5a receptor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD; NO.11, CHONGQING ROAD, SMALL AND MEDIUM-SIZED ENTERPRISEBUSINESSBASE BAIYIN GANSU P. R. CHINA
	Detail of stability batches of drug product	3 batches of 1500 Capsules each; B. No T166;B. No T167; B. No T168; 06 months accelerated and 06 months real time stability data according to zone IV-A,
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 17-12-2024 for 75grams of material is submitted along with copy of GD.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. TAVNEOS 10mg capsules.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	USFDA Approved; TAVNEOS 10mg capsules; Thermo Fisher Scientific 2110 East Galbraith Road Cincinnati, OH 45237 USA
	GMP status of the firm	GMP certificate issued on 19-12-2023.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule.	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
53	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(267-87V-G319, 2026-02-03)
	Detail of Fee Submitted	38700, 2026-01-29,
	The proposed proprietary name / brand name	**Kezol**
	Label Claim	Each gram of ketaconazole 2% w/w cream contains: Ketaconazole 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10g,15g,30g and 60g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30°C

	For generic drugs (me-too Status)	conaz cream 2% by Atco laboratries
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED by Plot No. E – 21, M.I.D.C., Tarapur, Tal. – Palghar, Dist.: Palghar-401 506, Maharashtra,INDIA
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch Size: 50*10gtubes) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 27-02-2025 for 0.8kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Conaz 2% w/w cream by M/s Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A is submitted.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	NEW DML issued w.e.f. 27-10-2023. Cream/Ointment (General) Section is approved.
	Evaluation Remarks	
	The application fulfills the codal formalities. New License	
	Decision	
	Approved	
54	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(B6X-H75-RZVW, 2026-01-28)
	Detail of Fee Submitted	75000, 2026-01-07,
	The proposed proprietary name / brand name	**Cenova Tablets 150mg**
	Label Claim	Each film-coated tablet contains: Cenobamate 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10’s, -De-Controlled,14’s, -De-Controlled,20’s, -De-Controlled,28’s, -De-Controlled,30’s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 Batches, 1000 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 28-04-2025 for 0.9kg material is submitted. Un attested invoice dated 23-04-2025. GD No. KPAF-4339-2025 Date: 04-05-2025

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 150mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry Tablets 150mg: Angelini Pharma (ITALY) : https://medicinali.aifa.gov.it/en/#/en/risultati?query=ONTOZRY%20(MEDICINALE)&exact=t
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (09&10th 12-2024) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New molecule	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
55	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)**
	Application Form Dy. No / Tracking ID & date of submission	(T6B-T7Q-7QYT, 2026-01-28)
	Detail of Fee Submitted	75000, 2026-01-07,
	The proposed proprietary name / brand name	**Cenova Tablets 25mg**
	Label Claim	Each film-coated tablet contains: Cenobamate 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's, -De-Controlled, 30's-De-Controlled,10's,-De-Controlled,20's, -De-Controlled,28's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children.
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering Co., Ltd., No.5329, Heshuodadao road street avenue, Wuzhi County, Jiaozuo City, 454950 Henan Province, China.
	Detail of stability batches of drug product	03 Batches, 4000 Tablets each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 28-04-2025 for 0.9kg material is submitted. Un attested invoice dated 23-04-2025. GD No. KPAF-4339-2025 Date: 04-05-2025
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP conducted against Ontozry Tablets 25mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
	The status in reference regulatory authorities	Ontozry Tablets 25mg: Angelini Pharma (ITALY) : https://medicinali.aifa.gov.it/en/#/en/risultati?query=ONTOZRY%20(MEDICINALE)&exact=t
	GMP status of the firm	Copy of GMP Certificate valid for 02 years from the date of Inspection (09&10th 12-2024) has been submitted.
	Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Tablet (General) Section has been submitted.
	Evaluation Remarks	
	The application fulfills the codal formalities. New Molecule	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
56	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(YQV-SPG-4RDG, 2026-01-05)
	Detail of Fee Submitted	313500, 2025-10-27,
	The proposed proprietary name / brand name	**REVIBORT Injection 1.0 mg**
	Label Claim	Each Vial Contains: Bortezomib .... 1.0 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	Registration No: 115738, By Revive Health Care
	Pharmacotherapeutic Group of (API)	Antineoplastic agent (Proteasome inhibitor), ATC Code: L01XG01
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-8888 Lvyou Road, High-tech Zone, Jinan, Shandong 250104, China-China
	Name & address of API manufacturer	Qilu Pharmaceutical Co., Ltd. No. 23999 Gong Ye Bei Road, Jinan, Shandong Province 250100, China
	Detail of stability batches of drug product	The stability data of accelerated (6M) and long term (24M) on Zone IVa of 3 consecutive

		commercial scale Batches (16F0012B24, 16F0022B24 & 16F0032B24) provided in 3.2.P.8.3.
	Documents for the procurement of API with approval from DRAP (in case of Import)	CoPP: CoPP No. 20251248 valid till 11-09-2027 is submitted. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 21-05-2027 is submitted. LOA: LOA dated 19-08-2025 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence provided between QILU's Product (Bortezomib for Injection 1.0mg) VS Innovator's product (VELCADE)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 6 months Accelerated and 24 months of long- term performed on four consecutive commercial batches (16D001GF3, 16D002GF3, 16D003GF3 and 3A002GH7). Stability data provided in section 3.2.S.7.3
	The status in reference regulatory authorities	VELCADE 1.0 mg Injection, by Janssen-Cilag, Belgium, EMA Approved
	GMP status of the firm	Valid Eudra GMP Certificate No. ES/046HV/25
	Evidence of approval of manufacturing facility	Valid Eudra GMP Certificate No. ES/046HV/25
	Evaluation Remarks	
	1. The stability data of finished product is submitted for exhibit batches. 2. -20oC is the storage condition in real time stability studies for drug product. 3- The submitted CoPP is not legalized/apostille. 4- Fee for revision of specifications (inclusion of impurity B/isomer in specifications)	
	Decision	
	Deferred For clarification for the following points: 1. As per the innovator's literature, the storage conditions of -20oC is for drug substance. Therefore, the storage conditions of -20oC for real time stability studies for drug product are not acceptable. 2. Stability data of drug product for commercial batches is required till shelf life. 3. Submission of Legalized/apostille CoPP.	
57	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(5WR-8YR-U271, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Yiogra 25mg Tablet**
	Label Claim	Each Film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 25mg USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
58	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(AU2-SA9-DAJV, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Yiogra 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate equivalent to 50mg Sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road ,Lahore.-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 50mg, USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

59	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(XYR-JG2-46WV, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Yiogra 100mg Tablet**
	Label Claim	Each Film coated tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road ,Lahore.-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 100mg, USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
60	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(6JW-24N-J5YS, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Sializ 10mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road ,Lahore.-

	The status in reference regulatory authorities	Tadalafil Tablets, USP 10mg,USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
61	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(GH4-1ZJ-3XY3, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Sializ 20mg Tablet**
	Label Claim	Each Film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 20mg USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
62	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**

	Application Form Dy. No / Tracking ID & date of submission	(RJG-WAA-QM3Y, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Sializ 2.5mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil, USP.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road ,Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 2.5mg,USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
63	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)**
	Application Form Dy. No / Tracking ID & date of submission	(ZB1-DU2-STQT, 2025-01-31)
	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Sializ 5mg Tablet**
	Label Claim	Each Film coated tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's,1x5's, 1x10's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 5mg USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	

	The firm has submitted a General Requst TID SHE-X87-XHNJ wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
64	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(GS6-P8H-6HQV, 2026-02-04)
	Detail of Fee Submitted	97200, 2025-12-05,
	The proposed proprietary name / brand name	**Dyluna Tablet 10mg**
	Label Claim	Each Film Coated Tablet Contain: Dydrogesterone .....10mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet. Ms. OBS Pakistan (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Yangzhou Aurisco Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	M/s Aries Pharmaceuticals Pvt. Ltd.-1-W, Industrial Estate, Hayatabad, Peshawar.-
	The status in reference regulatory authorities	Nalvee 10mg film-coated tablets, (MHRA)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID HEG-A2H-8Q6B wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

65	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(BWQ-47S-RH5A, 2025-09-18)
	Detail of Fee Submitted	93000.0, 2025-02-07,
	The proposed proprietary name / brand name	**Bethani Tablet l0mg**
	Label Claim	Each tablet contain: Bethanechol chloride...10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year Store in a Cool & dry place below 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore-
	The status in reference regulatory authorities	Bethanechol Chloride Tablet 10mg USFDA
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID HEG-A2H-8Q6B wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
66	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)**
	Application Form Dy. No / Tracking ID & date of submission	(2NX-U34-UGDP, 2025-09-18)
	Detail of Fee Submitted	93000.0, 2025-02-07,
	The proposed proprietary name / brand name	**Bethani Tablet 25mg**
	Label Claim	Each tablet contain: Bethanechol chloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year Store in a Cool & dry place below 30°C
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore-
	The status in reference regulatory authorities	Bethanechol Chloride Tablet 25mg USFDA
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Requst TID HEG-A2H-8Q6B wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
67	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Arsons Pharmaceutical Industries (Pvt) Ltd** 22 KM, Multan Road, Off 2.5 KM Defence Road, Lahore **(000514)**
	Application Form Dy. No / Tracking ID & date of submission	(MGM-PL4-4Z27, 2025-04-21)
	Detail of Fee Submitted	37000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Melukast 4mg Sachet**
	Label Claim	Each Sachet contains: Montelukast sodium USP eq to Montelukast 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 14's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Abbott Laboratories Limited Plot No.13 Main Korangi Industrial Road, Sector 20 Landhi Town, Karachi, Pakistan (Floaid Sachet 4mg)
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories Limited (Plant: Village Masulkhana, parwanoo, Distt. Solan, (H.p) lndia 173220)
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-5 M/S MOREPEN LABORATORIES LIMITED. VILLAGE MASULKHANA DISTT. SOLAN HIMACHAL PRADESH PARWANOO-173 220, INDIA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Floaid by Abbott Batch No. 145208-D
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	Module 1 Page No 14
	GMP status of the firm	GMP certificate dated 17.10.2023
	Evidence of approval of manufacturing facility	Sachet vide letter dated 03.02.2025

	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
68	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(EES-4LD-LTDU, 2024-07-14)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**CINKAL 30MG TABLET**
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....30mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Censipar Tablet 30 mg by CCL Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID Q8X-H6B-EDUX wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
69	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)**
	Application Form Dy. No / Tracking ID & date of submission	(EQS-H1S-2Y18, 2024-07-30)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**CINKAL 60MG TABLET**
	Label Claim	Each Film Coated Tablet contains: Cinacalcet Hcl eq. to Cinacalcet.....60MG (Product complies

		Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Censipar Tablet 60 mg by CCL Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID Q8X-H6B-EDUX wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
70	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)**
	Application Form Dy. No / Tracking ID & date of submission	(P8Z-1MM-R82Q, 2024-08-02)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Methyll 500mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500Mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI, PUNJAB-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID TQ4-JLU-MWWA wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and	

	fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
71	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(H9Z-B3V-WQ27, 2024-08-07)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Methyll 125mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....125mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI, PUNJAB-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID TWN-8U8-8W7D wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
72	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(H89-EBJ-7T7L, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-08-05,
	The proposed proprietary name / brand name	**Prexol-P 200/500mg**
	Label Claim	Each Film Coated tablet contains: Paracetamol 500mg

		Ibuprofen.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	: 2x7's, 1x10's, 2x1-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg (SAMI Pharmaceuticals Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets (Reckitt Benckiser Healthcare (UK) Ltd Slough, SL1 3UH UK)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID 88D-PNP-1R7A wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
73	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(LQ6-46N-AWNM, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-08-05,
	The proposed proprietary name / brand name	**Prexol-P 150/500mg**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/150mg (SAMI Pharmaceuticals Pvt. Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Easolief Duo 500mg/150mg Tablet (Clonmel Healthcare Ltd Waterford Road Clonmel, Co. Tipperary Ireland)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID 88D-PNP-1R7A wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken	

	in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
74	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(UE1-TMY-W6DB, 2024-07-17)
	Detail of Fee Submitted	75000.0, 2024-05-15,
	The proposed proprietary name / brand name	**Naprox-D 220mg/25mg Table**
	Label Claim	Each Film Coated tablet contains: Naproxen Sodium.....220mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet (M/s Bayer HealthCare LLC)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	ALEVE PM (diphenhydramine hydrochloride and naproxen sodium) 25mg/220mg tablet (Bayer HealthCare LLC)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID 88D-PNP-1R7A wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
75	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**

	Application Form Dy. No / Tracking ID & date of submission	(ZJE-NRQ-SWVA, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-08-05,
	The proposed proprietary name / brand name	**Prexol DS 200mg/5ml Suspension**
	Label Claim	Each 5ml contains: Ibuprofen.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	: 1x60ml, 1x90ml, 1x-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Brufen DS 200mg/5ml Suspension (Abbott Laboratories (Pakistan)Ltd)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Desloratadine 0.5 mg/ml oral solution (Pinewood Laboratories Ltd Ballymacarbry Clonmel Co. Tipperary Ireland)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID 88D-PNP-1R7A wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
76	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(2YZ-Q3E-85Y6, 2026-02-03)
	Detail of Fee Submitted	75000.0, 48600 2024-06-04, 2026-01-12
	The proposed proprietary name / brand name	**TYMSO PLUS SOFTGEL CAPSULES**
	Label Claim	Each hard gelatin capsule contains: - Dutasteride (as softgelatin capsule).....0.5 mg + Tamsulosin hydrochloride (as modified release pellets).....0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25°C
	For generic drugs (me-too Status)	Maxflow-D Capsule Reg. No. 091571, By: CCL Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	Dutasteride/ Tamsulosin hydrochloride-0.5mg/0.4mg hard capsules By: Milpharm Limited (MHRA Approved)
	Detail of previous approval	Dutaride-T Capsule (DRB M-335)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
77	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(8UA-YTH-U9VB, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	**VARDENA-10mg Tablets**
	Label Claim	Each film coated tablet contains: Vardenafil as Hydrochloride Trihydrate.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Varda-10mg Tablet Reg. No. 132425 By: Medizan Labs, Islamabad.
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003
	Detail of previous approval	Varda-10mg Tablet DRB (M-351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
78	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(PLS-RHZ-GU1T, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**Ligolix-100mg Tablets**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Lingolix 100mg Tablets Reg. No. 132401 By: Medizan Labs (Pvt.) Ltd, Islamabad.
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Yselty 100 mg film-coated Tablets Approved In: MHRA
	Detail of previous approval	Lingolix 100mg Tablets M-351 (Reg. No. 132401)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
79	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(V2P-U6T-XHXY, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	**Ligolix-200mg Tablets**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix.....200mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Lingolix 200mg Tablets Reg. No. 132402 By: Medizan Labs (Pvt.) Ltd, Islamabad.
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Yselty 200 mg film-coated Tablets Approved In: MHRA
	Detail of previous approval	Lingolix 200mg Tablets M-351 (Reg. No. 132402)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
80	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(ZP3-XRW-BNSP, 2026-01-27)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	**VARDENA-5mg Tablets**
	Label Claim	Each film coated Tablet contains: Vardenafil as Hydrochloride Trihydrate.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Varda-5mg Tablet Reg. No. 132424 By: Medizan Labs, Islamabad.
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003
	Detail of previous approval	Varda-5mg Tablet DRB (M-351)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
81	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)**
	Application Form Dy. No / Tracking ID & date of submission	(15U-811-6QVY, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-10-27,
	The proposed proprietary name / brand name	**Tapgen 100 mg IR tablet**
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -------- 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Tapento IR 100mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot # 129, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Palexia IR 100mg Tablet
	Detail of previous approval	Attached
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
82	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)**
	Application Form Dy. No / Tracking ID & date of submission	(9RL-W35-X5H5, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-10-27,
	The proposed proprietary name / brand name	**Tapgen 75mg IR tablet**

	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. to Tapentadol --------- 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Tapento IR 75mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot # 129, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Palexia IR 75mg Tablet
	Detail of previous approval	Attached
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
83	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)**
	Application Form Dy. No / Tracking ID & date of submission	(NN3-ZDG-ENYR, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-10-27,
	The proposed proprietary name / brand name	**Tapgen 50 mg IR tablet**
	Label Claim	Each Film Coated Tablet contains: Tapentadol HCl eq. To Tapentadol -------50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30ºC
	For generic drugs (me-too Status)	Tapento IR 50mg Tablet
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot # 129, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Palexia IR 50mg Tablet
	Detail of previous approval	Attached
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
84	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(1JS-GDJ-1RVV, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**GEO-X Tablet 10mg**
	Label Claim	Each film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICAL (Pvt.) Ltd,-129 sunder industrial estate Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 10mg Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RRG-BLX-D3E6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
85	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(2HQ-7M4-XMDV, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**PDFIL Tablet 50mg (Sildenafil)**
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1X5's, 2x10's, 4x7's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	WIMITS PHARMACEUTICAL (Pvt.) Ltd,-129 sunder industrial estate Lahore.-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 50mg Rubicon Research Private Limited ambernath, Dist. Thane, 421506
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RRG-BLX-D3E6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
86	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(B3A-3EX-RBVJ, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**PDFIL Tablet 100mg**
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5s, 1x10s, 2x10s, -As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 degree
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-129 sunder industrial estate Lahore.-
	The status in reference regulatory authorities	Sildenafil tablet USP 100mg, Rubicon research pvt. ltd., Ambernath, district THANE
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RRG-BLX-D3E6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

87	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(LS6-GJP-LBHD, 2025-02-19)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**GEO-X Tablet 20mg**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s, 1x5s, 1x10s, 2-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 degree
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-129 sunder industrial estate Lahore.-
	The status in reference regulatory authorities	Tadalafil tablets USP 20mg, Ajanta pharma USA, Inc, bridgewater, NJ, 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RRG-BLX-D3E6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
88	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(9JM-P6S-BDQB, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-18,
	The proposed proprietary name / brand name	**Penbro Capsule 500mg**
	Label Claim	Each capsule contains: Amoxicillin Trihydrate eq. to Amoxicillin Base 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Zeemox Capsule 500mg by Searl pharma
	Pharmacotherapeutic Group of (API)	This product is alreday approved on CTD in 336th minutes of meeting held on 4 to 6 june 2025

	Name, address of Manufacturing site:	CSH Pharmaceutical (Pvt.) Ltd-32-Km, Ferozepur Road, Lahore – Pakistan-
	The status in reference regulatory authorities	Amoxicillin capsule 500mg SmithKline Beecham Regulatory Authority Attention: Sharon Shapowal One Franklin Plaza, P.O. Box 7929 Philadelphia, Pennsylvania 19101-7929 USA (FDA Approved)
	Detail of previous approval	zeemox capsule 500mg in 336 DRB
	Evaluation Remarks	
	The firm has submitted a General Request TID 8HQ-V6H-MQ8Y wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

89	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**PDH Laboratories (Pvt.) Ltd.** 9.5 Km Sheikhupura Road, Lahore **(000039)**
	Application Form Dy. No / Tracking ID & date of submission	(G4H-NG8-26XA, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-18,
	The proposed proprietary name / brand name	**Penbro Capsule 250mg**
	Label Claim	Each capsule contains: Amoxicillin Trihydrate Equivalent to Amoxicillin.....250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Zeemox Capsule 250mg by Searl pharma
	Pharmacotherapeutic Group of (API)	This product is alreday approved on CTD in 336th minutes of meeting held on 4 to 6 june 2025
	Name, address of Manufacturing site:	CSH Pharmaceutical (Pvt.) Ltd-32-Km, Ferozepur Road, Lahore – Pakistan -
	The status in reference regulatory authorities	Amoxicillin capsule 250mg SmithKline Beecham Regulatory Authority Attention: Shapowal One Franklin Plaza, P.O. Box 7929 Philadelphia, Pennsylvania 19101-7929 USA (FDA Approved)
	Detail of previous approval	zeemox capsule 250mg in 336 DRB
	Evaluation Remarks	
	The firm has submitted a General Request TID 8HQ-V6H-MQ8Y wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
90	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(VHQ-QAY-TP14, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Perocell IB 500/200mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg of M/s SAMI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets of M/s Reckitt Benckiser Healthcare International Ltd, Nottingham, NG90 2DB (MHRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RHL-4PA-H3QL wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
91	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(UQA-1DS-TXU2, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Zesin 100mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin dihydrate Equivalent to

		Azithromycin 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Genthro (Azithromycin) 100mg/5ml for oral Suspension of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Azithromycin 100mg /5ml for oral suspension of M/s Zydus Lifesciences Limited (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RHL-4PA-H3QL wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
92	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(T9A-VYX-JBAS, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Perocell IB 500/150mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/150mg of M/s SAMI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Easolief Duo 500mg/150mg Film-coated Tablets of M/s Clonmel Healthcare Ltd Waterford Road Clonmel, Co. Tipperary Ireland (HPRA Approved)
	Detail of previous approval	
	Evaluation Remarks	

	The firm has submitted a General Request TID RHL-4PA-H3QL wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
93	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(N1B-LGE-SNZ2, 2025-02-12)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Upacib 15mg PR Tablet**
	Label Claim	Each Film Coated Extended-Release Tablet contains: Upadacitinib Hemihydrate equivalent to Upadacitinib.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rinvoq (upadacitinib) 15mg Extended-release Tablet of M/s AbbVie Inc. (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RHL-4PA-H3QL wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
94	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(P3P-AYP-QSSJ, 2025-02-12)

	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Zesin 200mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin dihydrate Equivalent to Azithromycin 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Zetro(Azithromycin) 200mg/5ml Powder for oral Suspension of M/s SAMI Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	AZITHROMYCIN DIHYDRATE 200mg /5ml powder, for suspension of M/s Slate Run Pharmaceuticals, LLC (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID RHL-4PA-H3QL wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
95	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(WGL-1ET-DZ1J, 2025-11-11)
	Detail of Fee Submitted	93000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Lasmiditan 50mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Lasmiditan hemisuccinate equivalent to Lasmiditan.....50mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 YearStore between 15-30 degree celsius
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Metrochem API Private Limited India
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt.Ltd-Plot .No129, Sundar Industrial Estate, Raiwind Road. Lahore-

	The status in reference regulatory authorities	USFDA approved Manufacturer Name: Eli lilly and Company Address: Lilly USA, LLC Indianapolis, IN46285, USA Product of ireland Brand Name & Strength: REYVOW (Lasmiditan) tablet 50mg Composition: Each tablet contains 50mg Lasmiditan (NDC 0002-4312-08) Dosage Form: Oral tablet
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID M6U-13G-QTYW wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
96	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(1J3-H7X-TGZM, 2026-02-18)
	Detail of Fee Submitted	93000.0, 4200 2025-07-15, 2025-08-07
	The proposed proprietary name / brand name	**Neucillin 250mg/5ml dry suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Amoxicillin trihydrate eq. to Amoxicillin.....250mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	90ml-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	AMOXIL 250mg/5ml Dry suspension
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID M6U-13G-QTYW wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
97	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(BET-AJH-RDYT, 2026-02-18)
	Detail of Fee Submitted	93000.0, 4200 2025-07-15, 2025-08-12
	The proposed proprietary name / brand name	**Neucillin 250mg Capsule**
	Label Claim	Each capsule contains: Amoxicillin trihydrate eq. to Amoxicillin.....250mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's, 100's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	AMOXIL 250mg CAPSULE
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID M6U-13G-QTYW wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
98	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(HY9-HRQ-589L, 2025-09-25)
	Detail of Fee Submitted	93000.0, 4200 2025-07-15, 2025-08-07
	The proposed proprietary name / brand name	**Neucillin 500mg Capsule**
	Label Claim	Each capsule contains: Amoxicillin trihydrate eq. to Amoxicillin.....500mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's, 30's, 100's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	AMOXIL 500mg CAPSULE
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID M6U-13G-QTYW wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
99	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(9XD-2VB-DUT8, 2025-08-08)
	Detail of Fee Submitted	93000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Bezedoc 180/10mg Tablet**
	Label Claim	Each film coated tablet contains: Bempedoic acid.....180mg Ezetimibe.....10mg (As per Innovators Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore between 15-30 degree celsius
	For generic drugs (me-too Status)	Brand Name & Strength: BEMPID EZE Tablet 180mg/10mg Manufacturer: M/s Nabiqasim Industries (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan .Composition: Each Film coated tablet contain
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Metrochem API Pvt.Ltd. , Ezetimibe: Saptagir Laboratories Pvt Ltd
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt.Ltd.-Plot No129, Sundar Industrial Estate, Raiwind Road. Lahore-
	The status in reference regulatory authorities	MHRA Approved .Distributed by: Daiichi Sankyo UK Limited Brand Name & Strength: Nustendi 180 mg/10 mg film-coated tablets Composition: Each Film coated tablet contains 180 mg of bempedoic acid 10 mg of ezetimibe Marketing Authorization Number: PLGB 08265/0039 Dosage Form: Film coated oral solid tablet
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID M6U-13G-QTYW wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken	

	in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
100	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(98Y-RJJ-63YL, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Resliv 60mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 60mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 60mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID A7T-3WU-ZNSU wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
101	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(WQ6-9RZ-5H2M, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,

	The proposed proprietary name / brand name	**Resliv 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 100mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 100mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID A7T-3WU-ZNSU wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
102	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(ZDN-57M-JYQ2, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Resliv 80mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 80mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 80mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	

	The firm has submitted a General Request TID A7T-3WU-ZNSU wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
103	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(JZR-PWY-J2LE, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Resdif 80mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 80mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 80mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID Y9G-WJD-AMY6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
104	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**

	Application Form Dy. No / Tracking ID & date of submission	(TXM-MSE-9EZA, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Resdif 60mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 60mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 60mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID Y9G-WJD-AMY6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
105	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(UL2-HRH-82V8, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Resdif 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Resmet (Resmetirom) 100mg Tablets of M/s Solaris Life Sciences (approved in M-345)
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonists
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-

	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 100mg of M/s Madrigal Pharmaceutical,Inc. West Conshohocken, PA (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID Y9G-WJD-AMY6 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

106	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area **(000106)**
	Application Form Dy. No / Tracking ID & date of submission	(62B-8R9-AMZM, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-08-09,
	The proposed proprietary name / brand name	**Allay-D 75/25mg Tablet**
	Label Claim	Each film coated tablet contains: Tramadol HCI 75mg + Dexketoprofen trometamol Equivalent to Dexketoprofen 25mg. Innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10's-As per SRO,1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,5x10's-As per SRO,7x4's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 Degree
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt. Ltd.-Plot # 129, Sundar Industrial Estate Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Skudexa 75mg / 25mg Tablet, Menarini, Von Heyden GmbH Leipziger Strasse 7-13 01097 Dresden Germany. HPRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID MD8-Q9P-D1Y4 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
107	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area **(000106)**
	Application Form Dy. No / Tracking ID & date of submission	(DHG-QRT-6DM8, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	**Tebem-EZ 180mg/10mg Tablet**
	Label Claim	Each film coated Tablet Contains: Bempedoic acid .....180m Ezetimibe.....10mg innovator's Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10's-De-Controlled,1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,6x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	BEMPID EZE Tablet 180mg/10mg M/s Nabiqasim Industries (PVT) LTD. Approved in 331 minutes
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129, Sunder Industrial Estate Raiwind Road Lahore-
	The status in reference regulatory authorities	Nustendi 180 mg/10 mg,Daich Sankyo UK Limited MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID MD8-Q9P-D1Y4 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
108	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area **(000106)**
	Application Form Dy. No / Tracking ID & date of submission	(SRU-MD6-2Z6Q, 2025-05-14)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	**Tebem 180mg Tablet**
	Label Claim	Each film coated Tablet contains: Bempedoic acid.....180mg Innovator's

		Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 30oC
	For generic drugs (me-too Status)	Bempid 180mg Tablet Regn. No. 120221 Nabiqasim Industries (Pvt). Lt
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd-Plot No.129, Sunder Industrial Estate Raiwind Road Lahore-
	The status in reference regulatory authorities	Nexletol 180mg Tablet, Esperion Theurapeutics Inc.USFDA Approved.
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID MD8-Q9P-D1Y4 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
109	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(23S-DVY-R9H9, 2025-04-21)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Carbomit 50mg/ml Injection**
	Label Claim	Each ml Contains: Ferric Carboxymaltose equivalent to Elemental Iron.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10ml, 1x2ml, 1x20m-As per SRO
	Shelf Life (Unit)	2 YearSould be store below 25 celcius
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection M/S Pharmasol Pvt Ltd Registration number 115449
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Ferinject 50mg/ml Injection M/s Vifor Pharma MHRA Approved Batch Number 2120122EA
	Detail of previous approval	
	Evaluation Remarks	

	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
110	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(59H-A2E-J555, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Lakil 10mg/ml Injection**
	Label Claim	Each ml contains: Lacosamide.....10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Lalap (Lacosamide) Infusion 200mg/20ml of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Vimpat 10 mg/ml solution for infusion of M/s UCB Pharma Limited Address 208 Bath Road, Slough, Berkshire, SL1 3WE (MHRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
111	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(59S-MT6-J266, 2025-09-29)

	Detail of Fee Submitted	93000.0, 2025-05-12,
	The proposed proprietary name / brand name	**Linzol 100mg/5ml Powder for Suspension**
	Label Claim	Each 5ml contains: Linezolid.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x60ml, 1x90ml, 1x12-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	NEZKIL (linezolid) 100mg/5ml Powder for Oral Suspension of M/s S.J. & G. Fazul Ellahie (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Oxazolidinones
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Zyvox 100 mg/5 ml Granules for Oral Suspension of M/s Pfizer Limited (HPRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
112	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(5LB-9Q9-URY8, 2025-04-05)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Azotrax 200mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin dihydrate Equivalent to Azithromycin 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Zetro(Azithromycin) 200mg/5ml Powder for oral Suspension of M/s SAMI Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-

	The status in reference regulatory authorities	AZITHROMYCIN DIHYDRATE 200mg /5ml powder, for suspension of M/s Slate Run Pharmaceuticals, LLC (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

113	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(5MB-8P5-VVET, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	The proposed proprietary name / brand name	**Foswim 500mg Capsule**
	Label Claim	Each Capsule contains: Fosfomycin Calcium equivalent to Fosfomycin.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x6's, 2x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Focin 500mg Capsule of M/s Tabros Pharma
	Pharmacotherapeutic Group of (API)	Phosphonic Antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	FOSFOCINA 500 MG CAPSULAS of M/s LABORATORIOS ERN, S.A. Peru, 228 08020 Barcelona (CIMA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

114	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(8MH-BA8-9M6V, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Amoxiwim 1g Injection**
	Label Claim	Each vial contains: Amoxicillin Sodium eq. to Amoxicillin.....1000mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Amoxil injection 1000mg of GSK
	Pharmacotherapeutic Group of (API)	Aminopenicillin
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Amoxicillin 1000mg Powder for Solution for Injection of M/s Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK (MHRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
115	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(AQA-YAB-PX7X, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Ebalin 300mg Capsule**
	Label Claim	Each Capsule contains: Pregabalin..... . .300mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x5's, 1x 10's, 2x6'-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Gabica 300mg Capsule of M/s Getz Pharma
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	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)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
116	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(LDS-NDE-2D13, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Amoxiwim 500mg Capsule**
	Label Claim	Each capsule contains: Ammoxicillin trihydrate eq. to Amoxicillin.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Amoxil 500mg Capsule of M/s GSK
	Pharmacotherapeutic Group of (API)	Aminopenicillin
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Amoxicillin 500mg Capsules of M/s Aurobindo Pharma - Milpharm Ltd, UK (EMA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
117	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(PBX-JQD-19BW, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	The proposed proprietary name / brand name	**Foswim 250mg/5ml Dry Powder Suspension**
	Label Claim	Each 5ml contains: Fosfomycin Calcium equivalent to Fosfomycin.....250mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1x30ml, 1x60ml, 1x90-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Focin 250mg/5ml Suspension of M/s Tabros Pharma
	Pharmacotherapeutic Group of (API)	Phosphonic Antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	FOSFOCINA 250 MG/5 ML POWDER FOR ORAL SUSPENSION of M/s LABORATORIOS ERN, S.A. Peru, 228 08020 Barcelona (CIMA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
118	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(PTA-GLZ-VNRU, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-15,
	The proposed proprietary name / brand name	**Amoxiwim 250mg/5ml Dry Powder Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Ammoxicillin trihydrate eq. to Amoxicillin.....250mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Amoxil 250mg/5ml Dry suspension of M/s GSK
	Pharmacotherapeutic Group of (API)	Aminopenicillin
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Amoxil 250mg/5ml Dry Suspension of M/s GlaxoSmithKline Research Triangle Park, NC 27709 (FDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
119	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(TXJ-ENR-W579, 2025-05-08)
	Detail of Fee Submitted	93000.0, 2025-04-25,
	The proposed proprietary name / brand name	**Foswim 3gm Sachet**
	Label Claim	Each Sachet contains: Fosfomycin Trometamol equivalent to Fosfomycin 3g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's, 1x14's, 1x28'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Focin Ultra Sachet of M/s Tabros Pharma
	Pharmacotherapeutic Group of (API)	Phosphonic Antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Monurol 3000mg Granulat (Fosfomycin) Zambon Switzerland Ltd. Division of Zambon Group, SpA Via Industria 13 6814 Cadempino, Switzerland (EMA & FDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of	

	already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
120	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(W28-2SG-RQT8, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2025-01-29,
	The proposed proprietary name / brand name	**Steron 5mg Tablet**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet of M/s OBS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Primolut N Tablet 5mg of M/s Bayer plc (MHRA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
121	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(WMS-219-PREE, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-20,

	The proposed proprietary name / brand name	**Azotrax 100mg/5ml Powder for Oral Suspension**
	Label Claim	Each 5ml of reconstituted Suspension contains: Azithromycin dihydrate Equivalent to Azithromycin 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x15ml, 1x30ml, 1x60-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	Genthro (Azithromycin) 100mg/5ml for oral Suspension of M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Azithromycin 100mg /5ml for oral suspension of M/s Zydus Lifesciences Limited (USFDA Approved)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

122	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(XQU-Q88-UEBR, 2025-05-13)
	Detail of Fee Submitted	93000.0, 2025-02-28,
	The proposed proprietary name / brand name	**Estrawim 2/0.5mg Tablet**
	Label Claim	Each of the 11 white tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown tablets contains: Estradiol Valerate.....2mg Norgestrel.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 21's , 3x21's As-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet of M/s Bayer Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-

	The status in reference regulatory authorities	Progyluton Coated Tablet of M/s Bayer Weimar GmbH und Co. KG, Weimar, Germany. (National Drug Registry of the Ministry of Health)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID DM8-YGA-M798 wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

123	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**OBS Pharma (Pvt) Ltd** 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan **(000243)**
	Application Form Dy. No / Tracking ID & date of submission	(Y5A-S9M-JRDT, 2025-07-09)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Estragest Tablet**
	Label Claim	11 White tablets, Each Containing Estradiol Valerate U.S.P.....2mg 10 Light Brown tablets, Each Containing Estradiol Valerate U.S.P.....2mg Norgestrel U.S.P.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 degree
	For generic drugs (me-too Status)	PROGYLUTON by Bayer Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No 01, Al badar industrial estate, Phase II, Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Federal Institute for Drugs and Medical Devices, Approved
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID LTG-UUY-2VAD wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
124	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(EV2-WSN-ML9X, 2025-10-01)
	Detail of Fee Submitted	97200.0, 2025-08-27,
	The proposed proprietary name / brand name	**Teagra 10mg/ml Suspension**
	Label Claim	Each ml contains: Sildenafil as citrate.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	112ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degrees Celsius
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of Cyclic Gmp-Specific Phosphodiesterase (Type V) With Vasodilator Action; Urologicals; Drugs Used In Erectile Dysfunction (ED).
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Revatio 10mg/ml Oral Suspension ; Upjohn UK Limited, MHRA UK
	Detail of previous approval	Ripple 10mg/ml Suspension ; DRB 344 DRB Meeting ; Item No. V. Applications submitted on e-App Sr # 1
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
125	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(B5X-229-2N75, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-27,
	The proposed proprietary name / brand name	**Denafit 50mg Tablets**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil 50mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x5's ; 1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Pfizer - USFDA - https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted an application for the change of contract manufacturer of Sildenafil 50mg Tablets having TID (B5X-229-2N75) from Medizan to Solaris through the online tracking number V5T-PZE-A7H5 (Application Type: General Request Form) along with fee of Rs. 48,600/- under the head of Pre-registration variation. Sildenafil 50mg tablet of Solaris Life Sciences Pvt. Ltd having factory located at Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-Pakistan (DML No: 000992) under contract manufacturing policy 2014, has already been approved in 345th meeting of DRB.Therefore, the instant contract manufacturing case considered for cross-reference of already approved data on Form 5F.	
	Decision	
	Approved	

126	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(PX3-57A-TYE8, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-27,
	The proposed proprietary name / brand name	**Denafit 100mg Tablets**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x5's ; 1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Pfizer - USFDA - https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted an application for the change of contract manufacturer of Sildenafil 100mg Tablets having TID (PX3-57A-TYE8) from Medizan to Solaris through the online tracking number WT3-DVW-LVN4 (Application Type: General Request Form) along with fee of Rs. 48,600/- under the head of Pre-registration variation. Sildenafil 100mg tablet of Solaris Life Sciences Pvt. Ltd having factory located at Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-Pakistan (DML No: 000992) under contract manufacturing policy 2014, has already been approved in 345th meeting of DRB..Therefore, the instant contract manufacturing case considered for cross-reference of already approved data on Form 5F.	

	Decision	
	Approved	
127	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(NVE-4JY-9GP2, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	**Zeal 20mg Tablets**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x5's ; 1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	GSK GlaxoSmithKline - USFDA Approved - https://www.accessdata.fda.gov/drugsatfda_docs/n 400_Levitra.cfm
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted an application for the change of contract manufacturer of Vardenafil 20mg Tablets having TID (NVE-4JY-9GP2) from Medizan to Solaris through the online tracking number 5X6-6TA-43QM (Application Type: General Request Form) along with fee of Rs. 48,600/- under the head of Pre-registration variation. Vardenafil 20mg tablet of Solaris Life Sciences Pvt. Ltd having factory located at Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-Pakistan (DML No: 000992) under contract manufacturing policy 2014, has already been approved in 351st meeting of DRB..Therefore, the instant contract manufacturing case considered for cross-reference of already approved data on Form 5F.	
	Decision	
	Approved	
128	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(U7U-LGA-43ZZ, 2025-04-17)
	Detail of Fee Submitted	93000.0, 2025-01-23,
	The proposed proprietary name / brand name	**Zealus 5mg Tablets**
	Label Claim	Each film coated tablet contains: Tadalafil ... 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO,2x5"s-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	USFDA Aproved - https://www.accessdata.fda.gov/drugsatfda_docs/n 368_cialis.cfm#:~:text=Approval%20Date%3A%2
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted an application for the change of contract manufacturer of Tadalafil 5mg Tablets having TID (U7U-LGA-43ZZ) from Medizan to Solaris through the online tracking number QWV-JV9-V1AB (Application Type: General Request Form) along with fee of Rs. 48,600/- under the head of Pre-registration variation. Tadalafil 5mg tablet of Solaris Life Sciences Pvt. Ltd having factory located at Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-Pakistan (DML No: 000992) under contract manufacturing policy 2014, has already been approved in 352nd meeting of DRB..Therefore, the instant contract manufacturing case considered for cross-reference of already approved data on Form 5F.	
	Decision	
	Approved	
129	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(ZZP-D6H-378R, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-31,
	The proposed proprietary name / brand name	**Zealus 20mg Tablets**
	Label Claim	Each film-coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x5's ; 1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	Lilly ICOS LLC - https://www.accessdata.fda.gov/drugsatfda_docs/n 368_cialis.cfm#:~:text=Approval%20Date%3A%2
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted an application for the change of contract manufacturer of Tadalafil 20mg Tablets having TID (ZZP-D6H-378R) from Medizan to Solaris through the online tracking number JMM-MWU-4PME (Application Type: General Request Form) along with fee of Rs. 48,600/- under the head of Pre-registration variation. Tadalafil 20mg tablet of Solaris Life Sciences Pvt. Ltd having factory located at Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-Pakistan (DML No: 000992) under contract manufacturing policy 2014, has already been approved in 352nd meeting of DRB..Therefore, the instant contract manufacturing case considered for cross-reference of already approved data on Form 5F.	
	Decision	

	Approved	
130	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(8AB-X8Y-116H, 2025-10-15)
	Detail of Fee Submitted	93000.0, 2025-06-23,
	The proposed proprietary name / brand name	**Nalget 10mg/ml Injection**
	Label Claim	Each ampoule Contains: Nalbuphine HCl.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)30C
	For generic drugs (me-too Status)	Global Pharmaceuticals(Nalbin Injection 10mg/ml)
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
131	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(4TR-QQX-ANJ7, 2026-02-12)
	Detail of Fee Submitted	38700, 58500 2025-12-26, 2026-02-03
	The proposed proprietary name / brand name	**METHISOL 1000MG INJECTION**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....1gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-Controlled
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Solu Medrol Injection (Pfizer)
	Pharmacotherapeutic Group of (API)	glucocorticoid)
	Name, address of Manufacturing site:	M/s WENOVO PHARMACEUTICALS, -PLOT # 31,32, PUNJAB SMALL INDUSTRIAL

		ESTATE, TAXILA, RAWALPINDI, PUNJAB -
	The status in reference regulatory authorities	EMC/FDA Approved
	Detail of previous approval	DRAP , Meeting 339th Page # 1505
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
132	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**
	Application Form Dy. No / Tracking ID & date of submission	(XZH-54Q-18WV, 2026-02-13)
	Detail of Fee Submitted	38700, 58500 2025-12-24, 2026-02-03
	The proposed proprietary name / brand name	**MEDOPIUM 18MCG Rota Capsule**
	Label Claim	Each capsule contains: tiotropium bromide monohydrate equivalent to 18 microgram tiotropium
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	TIOGET CAPSULE (GETZ PHARMA)
	Pharmacotherapeutic Group of (API)	TIotropium is classified as a long-acting muscarinic antagonist (LAMA) or anticholinergic agent.
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot #69/1, Block B, Phase I&II, Industrial Estate, Hattar, Haripur, KPK -
	The status in reference regulatory authorities	EMC/FDA Approved
	Detail of previous approval	DRAP 339th Meeting 1764-1771
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
133	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Mediate Pharmaceutical Pvt Ltd** Plot # 150-151 Sector 24, Korangi Industrial Area **(000167)**

	Application Form Dy. No / Tracking ID & date of submission	(X8G-GZH-AWHA, 2026-03-02)
	Detail of Fee Submitted	38700, 58500 2025-12-26, 2026-01-28
	The proposed proprietary name / brand name	**METHISOL 500MG INJECTION**
	Label Claim	Each vial contains:- or Each 4 mL (when mixed) contains: methylprednisolone sodium succinate equivalent to 500 mg methylprednisolone
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 Year25
	For generic drugs (me-too Status)	Solu Medrol Injection (Pfizer)
	Pharmacotherapeutic Group of (API)	synthetic glucocorticoid
	Name, address of Manufacturing site:	M/s WENOVO PHARMACEUTICALS, -PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI, PUNJAB -
	The status in reference regulatory authorities	EMC/FDA Approved
	Detail of previous approval	DRAP 339th Meeting 1457-1458
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
134	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(HPV-GMN-MPQL, 2026-03-03)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**POSAFIL DR Tablet 100 mg**
	Label Claim	Each Tablet Contains: Posaconazole 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's Bottle Pack-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	NA- New Drug Product
	Pharmacotherapeutic Group of (API)	Antifungal, ATC Code: J02AC04
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study (In-vitro) & Bioequivalence (BE, In-vivo) performed by Comparison of Innovator's product (NOXAFIL Tablet 100mg) with QILU's Posaconazole delayed release tablet 100mg.

	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical (Hainan) Co., Ltd., No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Spanish GMP: Certificate No: ES/106HV/24/1
	Details of Authorization Letter :	Imported product- Not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three batches B# SPO-I-190501, SPO-I-190502 & SPO-I-190503, of Posaconazole substance on accelerated (6M) & long-term (36M) conditions. Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	Posaconazole 100 mg, delayed release tablet, ANDA # 217720 by Qilu Pharmaceutical (Hainan) Co., Ltd. USFDA Approved
	Evaluation Remarks	
	The application fulfills other codal formalities. The product is approved in US FDA by the same manufacturer and GMP of agencia espanola is attached.	
	Decision	
	Approved Approved as per import policy	
135	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(29L-H7Z-71BV, 2026-03-03)
	Detail of Fee Submitted	, ,
	The proposed proprietary name / brand name	**VIREVA Tablet 300 mg**
	Label Claim	Each film coated tablet contains: Tenofovir Disoproxil Fumarate ..... 300 mg (eq. to 245 mg Tenofovir Disoproxil)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Bottle Pack-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30 degree centigrade
	For generic drugs (me-too Status)	Viread Tablet 300 mg, Registration No. 072522
	Pharmacotherapeutic Group of (API)	Nucleoside and nucleotide reverse transcriptase inhibitor , ATC Code: J05AF07
	Name, address of Manufacturing site:	Qilu Pharmaceutical Co., Ltd.-No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong 250101, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator's product (VIREAD Tablet 300mg) with QILU's Tenofovir Disoproxil Fumarate Tablet 300mg.
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical Co., Ltd., No. 317, Xinluo Road, High-tech Zone, Jinan, Shandong 250101, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Eudra GMP: Certificate No: ES/009HV/25
	Details of Authorization Letter :	Imported product- Not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three batches B# 5001GP61T, 5002GP61T& 5003GP61T, of

		Tenofovir Disoproxil Fumarate substance on accelerated (6M) & long-term (24M) conditions. Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	Tenofovir Disoproxil Fumarate Tablet 300mg, By Qilu Pharmaceutical Co., Ltd. ANDA#209498 USFDA Approved
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved Approved as per import policy	
136	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**REVIVE HEALTH CARE** 503, 5TH FLOOR EDEN HEIGHTS 6 MAIN GULBERG JAIL ROAD **(05-352-0065-031159D)**
	Application Form Dy. No / Tracking ID & date of submission	(EDN-P4P-D12B, 2026-03-03)
	Detail of Fee Submitted	313500, 2025-12-18,
	The proposed proprietary name / brand name	**DAPYCIN Injection 500 mg**
	Label Claim	Each Vial Contains: Daptomycin ..... 500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's Vial-As per SRO
	Shelf Life (Unit)	24 MonthStore between 2.0-8.0 degree centigrade
	For generic drugs (me-too Status)	NA- New Drug Product
	Pharmacotherapeutic Group of (API)	Cyclic Lipopeptide, antibiotic, ATC Code: J01XX09
	Name, address of Manufacturing site:	Qilu Pharmaceutical (Hainan) Co., Ltd.-No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study performed by Comparison of Innovator's product (CUBICIN Injection 500mg) with QILU's Daptomycin lyophilized powder for injection 500 mg
	Name, address of Marketing Authorization Holder:	Qilu Pharmaceutical (Hainan) Co., Ltd., No.273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan, 570314, China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Spanish GMP: Certificate No: ES/106HV/24/1
	Details of Authorization Letter :	Imported product- Not applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies performed on three batches B# DT1910001, DT1911001 & DT1911002, of Daptomycin substance on accelerated (6M) & long-term (24M) conditions. Stability data provided in 3.2.S.7.3
	The status in reference regulatory authorities	DAPTOMYCIN Injection 500 mg ANDA # 215316 by Qilu Pharmaceutical (Hainan) Co., Ltd. USFDA Approved
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	

	Approved Approved as per import policy	
137	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**STARWAYS PHARMACEUTICALS** Plot No. (Private Land), Near China Glassware, Nowshera Economic Zone, Risalpur, Nowshera, K.P.K, Pakistan **(000999)**
	Application Form Dy. No / Tracking ID & date of submission	(B1E-8BR-J41Z, 2026-02-11)
	Detail of Fee Submitted	38700, 2025-12-16,
	The proposed proprietary name / brand name	**Flunzo 50mg/5ml Suspension**
	Label Claim	Each 5 ml of reconstituted suspension contains Fluconazole.....50mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Fonaz Powder for Oral Suspension (50mg/5ml) BY ATCO
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Raj Pioneer Laboratories (India) Pvt. Ltd. Responsibility Manufacturing, 94-A,95-B & 96 A, Industrial Area No.1, A.B, Road Dewas (M.P), India(India).
	Detail of stability batches of drug product	SUS-001 , SUS-002, SUS-003, 1000 Bottles each batch at long term and accelerated conditions according to zone IV A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Genesis Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fonaz of Atco Batch No. PX007L
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated conditions according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Section Approval letter 01st August 2025
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Deferred	
138	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Kohinoor Industries** 159-160/B Small Industrial Estate, Sahiwal **(000197)**
	Application Form Dy. No / Tracking ID & date of submission	(HG6-3X9-UEXQ, 2025-09-03)
	Detail of Fee Submitted	37000.0, 2025-04-16,

	The proposed proprietary name / brand name	**Desla**
	Label Claim	Each ml contain Desloratadine 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 CG
	For generic drugs (me-too Status)	Jardin-D
	Pharmacotherapeutic Group of (API)	Amsal Chem private Limited India
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Amsal Chem private Limited India
	Detail of stability batches of drug product	03 batches at long term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan form DeMont
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated conditions
	The status in reference regulatory authorities	Clarinex Syrup
	GMP status of the firm	GMP certificate 27.03.2025
	Evidence of approval of manufacturing facility	Renewal of DML dated 24 June 2022 mentions Oral liquid (New) Section
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
139	Case Category	New Molecule/Formulation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(RL9-BS8-E1VQ, 2026-02-26)
	Detail of Fee Submitted	75000, 2026-01-16,
	The proposed proprietary name / brand name	**Ubro 50mg Tablets**
	Label Claim	Ubrogepant 50mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	ATC: N02CD04; Ubrogepant: CGRP antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP	Attached in Module 3 in section 3.2.P.8

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed with UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg, Initial U.S. Approval: 2019, Distributed by: Allergan USA, Inc. Madison, NJ 07940
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg, Initial U.S. Approval: 2019, Distributed by: Allergan USA, Inc. Madison, NJ 07940
	GMP status of the firm	GMP certificate dated 09.05.2024
	Evidence of approval of manufacturing facility	DS: GANSU HAOTIAN PHARMACEUTICAL CO., LTD, China; License and GMP DP: MEDIZAN LABORATORIES (PVT.) LTD, Islamabad, Pakistan; DML 000572
	Evaluation Remarks	
	The application fulfills codal formalities	
	Decision	
	Approved AApproved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
140	Case Category	New Molecule/Formulation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(DN3-1TV-UHNR, 2026-02-26)
	Detail of Fee Submitted	75000, 2026-01-16,
	The proposed proprietary name / brand name	**Ubro 100mg Tablets**
	Label Claim	Ubrogepant 100mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	ATC: N02CD04; Ubrogepant: CGRP antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	03 batches at long-term and accelerated conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Module 3 in section 3.2.P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP performed with UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg, Initial U.S. Approval: 2019, Distributed by: Allergan USA, Inc. Madison, NJ 07940
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long-term and accelerated conditions
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg, Initial U.S. Approval: 2019, Distributed by: Allergan USA, Inc. Madison, NJ 07940
	GMP status of the firm	GMP certificate dated 09.05.2024
	Evidence of approval of manufacturing facility	DS: GANSU HAOTIAN PHARMACEUTICAL CO., LTD, China; License and GMP DP: MEDIZAN LABORATORIES (PVT.) LTD, Islamabad, Pakistan; DML 000572
	Evaluation Remarks	
	The application fulfills codal formalities	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
141	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**
	Application Form Dy. No / Tracking ID & date of submission	(A5D-AZ1-4J1P, 2025-09-17)
	Detail of Fee Submitted	37000.0, 2025-01-27,
	The proposed proprietary name / brand name	**Fluterol 200+25mcg DPI Capsule**
	Label Claim	Each capsule contains: Fluticasone furoate.....200mcg Vilanterol (as trifenatate).....25mcg Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10’s, 14’s, 20’s, 28’s, 30’s, 56’s, 84’s, 10-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Relvar Ellipta DPI

	Pharmacotherapeutic Group of (API)	Fluticasone furoate: Corticosteroids. Vilanterol: LABAs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Pharmalabs Limited,INKE, S.A.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP cleared invoice for Fluticasone furoate dated 19/01/2024 and for Vilanterol dated 4-12-2023 along with the import documents is atttached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Breo Ellipta is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	FDA Approved Breo Ellipta
	GMP status of the firm	Valid till January 2027
	Evidence of approval of manufacturing facility	DPI Capsule Section dated 29th April 2022
	Evaluation Remarks	
	The applicaiton fulfills codal formalities.	
	Decision	
	Approved Approved subject to verification of Dosage Unit Sampling Apparatus (DUSA)	
142	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**
	Application Form Dy. No / Tracking ID & date of submission	(MD7-RPR-Z21L, 2026-02-19)
	Detail of Fee Submitted	37000.0, 1700 2025-01-27, 2025-10-01
	The proposed proprietary name / brand name	**Fluterol 100+25mcg DPI Capsule**
	Label Claim	Each capsule contains: Fluticasone furoate.....100mcg Vilanterol (as trifenatate).....25mcg Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 92 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10’s, 14’s, 20’s, 28’s, 30’s, 56’s, 84’s, 10-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Relvar Ellipta DPI
	Pharmacotherapeutic Group of (API)	Fluticasone furoate: Corticosteroids. Vilanterol: LABAs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Pharmalabs Limited,INKE, S.A.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP	DRAP cleared invoice for Fluticasone furoate dated 19/01/2024 and for Vilanterol dated 4-12-

	(in case of Import)	2023 along with the import documents is atttached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Breo Ellipta is attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	FDA Approved Breo Ellipta
	GMP status of the firm	Valid till January 2027
	Evidence of approval of manufacturing facility	DPI Capsule Section
	Evaluation Remarks	
	The application fulfills codal formalities	
	Decision	
	Approved Approved subject to verification of Dosage Unit Sampling Apparatus (DUSA)	
143	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)**
	Application Form Dy. No / Tracking ID & date of submission	(VQS-JEQ-S8BP, 2026-01-15)
	Detail of Fee Submitted	38700, 2025-08-26,
	The proposed proprietary name / brand name	**Becloforge 100+6+10mcg DPI Capsule**
	Label Claim	Each Capsule contains: Beclomethasone Dipropionate.....100mcg Formoterol Fumarate Dihydrate.....6mcg Glycopyrronium (as glycopyrronium bromide 12.5mcg) .....10mcg Each delivered dose (the dose leaving the mouthpiece) contains 88 micrograms of beclometasone dipropionate, 5 micrograms of formoterol fumarate dihydrate and 9 micrograms of glycopyrronium (as 11 micrograms glycopyrronium bromide).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's , 10’s, 14’s, 20’s, 28’s, 30’s-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Trimbow by Chiesi Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Beclomethasone Dipropionate Corticosteroid , Formeterol Fumarate Dihydrate Selective beta 2 adrenergic agonist, Glycopyrronium Anticholinergic agent / Muscarinic antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AVIK PHARMACEUTICAL LTD.,MELODY HEALTHCARE PVT. LTD,Vamsi Labs Ltd.
	Detail of stability batches of drug product	Stability data of 3 batches attached in section 3.2.P.8.3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence against the innovator product Trimbow is attached

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches is attached in section 3.2.S.7.3
	The status in reference regulatory authorities	EMA Approved Trimbow
	GMP status of the firm	Valid till January 2027
	Evidence of approval of manufacturing facility	DPI Capsule Section
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved Approved subject to verification of Dosage Unit Sampling Apparatus (DUSA)	
144	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(9A3-EES-AT6S, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Metirom 100mg**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Resmet 100mg Tablet (Solaris Life Sciences Private Limited)
	Pharmacotherapeutic Group of (API)	thyroid hormone receptor beta (THR-β) agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 100mg (Madrigal Pharmaceutical,Inc. West Conshohocken, PA)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
145	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(VRM-J6M-NHXU, 2025-05-15)

	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Metirom 80mg**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Resmet 80mg Tablet (Solaris Life Sciences Private Limited)
	Pharmacotherapeutic Group of (API)	thyroid hormone receptor beta (THR-β) agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 80mg (Madrigal Pharmaceutical,Inc. West Conshohocken, PA)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
146	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(Y62-NZ7-4214, 2025-05-15)
	Detail of Fee Submitted	93000.0, 2025-04-16,
	The proposed proprietary name / brand name	**Metirom 60mg**
	Label Claim	Each Film Coated Tablet contains: Resmetirom 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x6's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Resmet 60mg Tablet (Solaris Life Sciences Private Limited)
	Pharmacotherapeutic Group of (API)	thyroid hormone receptor beta (THR-β) agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Rezdiffra (Resmetirom) tablets 60mg (Madrigal Pharmaceutical,Inc. West Conshohocken, PA)
	Detail of previous approval	
	Evaluation Remarks	

	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
147	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(RJX-11R-NST8, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-04-24,
	The proposed proprietary name / brand name	**FOSFAC 500mg Capsule**
	Label Claim	Each Capsule contains: Fosfomycin Calcium equivalent to Fosfomycin.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x6's, 2x6's, 2x7's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Focin 500mg Capsules (Tabros pharma Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	phosphonic antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	FOSFOCINA 500 MG CAPSULAS (Ern Laboratories SA.)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
148	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(WWL-AEY-EPPD, 2025-06-05)

	Detail of Fee Submitted	93000.0, 2025-04-24,
	The proposed proprietary name / brand name	**FOSFAC 250MG/5ML DRY POWDER SUSPENSION**
	Label Claim	Each 5ml contains: Fosfomycin Calcium equivalent to Fosfomycin.....250mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1x30ml, 1x60ml, 1x9-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Focin Suspension 250mg/5ml (Tabros pharma Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	phosphonic antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	FOSFOCINA 250 MG/5 ML POWDER FOR ORAL SUSPENSION (Ern Laboratories SA)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(YUY-6WW-1ZAA, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-04-24,
	The proposed proprietary name / brand name	**FOSFAC SACHET**
	Label Claim	Each Sachet contains: Fosfomycin Trometamol equivalent to Fosfomycin 3g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x1's, 1x14's, 1x28'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Focin Ultra Sachet (Tabros pharma Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	phosphonic antibiotics
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Monurol 3000mg Granulat (Zambon Switzerland Ltd. Division of Zambon Group, SpA Via Industria 13 6814 Cadempino, Switzerland)

	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(SLQ-8D4-PTGP, 2025-06-05)
	Detail of Fee Submitted	93000.0, 2025-04-24,
	The proposed proprietary name / brand name	**CARBOXY 500MG/10ML INJECTION**
	Label Claim	Each ml contains: Ferric carboxymaltose Equivalent to Elemental Iron 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10ml, 1x2ml, 1x20m-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	IZER (Ferric carboxymaltose) 500mg/10ml Injection (M/s Pharmasol (Pvt) Ltd.)
	Pharmacotherapeutic Group of (API)	Iron replacement product
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	IZER (Ferric carboxymaltose) 500mg/10ml Injection (M/s Pharmasol (Pvt) Ltd)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
151	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**

	Application Form Dy. No / Tracking ID & date of submission	(S88-PP8-8BWN, 2025-06-16)
	Detail of Fee Submitted	93000.0, 2025-04-18,
	The proposed proprietary name / brand name	**NOTERONE 5MG TABLET**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 x 10's, 2 x 10's, -As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet (OBS Pharma (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	progestin, specifically a synthetic progestational hormone
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Primolut N Tablet 5mg Bayer plc 400 South Oak Way, Reading, Berkshire, RG2 6AD
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted a General Request TID (88D-PNP-1R7A) wherein they have provided the reference of approval for their cross-referred product.In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
152	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**MSA PHARMA** 1st floor, 793-D Block C Faisal Town **(05-352-0066-112591D)**
	Application Form Dy. No / Tracking ID & date of submission	(ZEM-ZYS-T4M3, 2025-10-27)
	Detail of Fee Submitted	313500, 2025-10-20,
	The proposed proprietary name / brand name	**Capivast 200mg Tablet**
	Label Claim	Each film coated tablet contains..... Capivasertib 200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	(1x64's)-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Henan Jin Huaitang Biological Engineering Co.,Ltd
	Name, address of Manufacturing site:	Everest Pharmaceuticals Limited.-Rahman's Regnum Centre (11th) Floor) 191/1, Tejgaon C/A, Dhaka-1208,-Bangladesh

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Everest Pharmaceuticals Limited., Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	01.10.20267 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 Months
	The status in reference regulatory authorities	TRUQAP 200mg Film-coated Tablets (Sweden)
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of i. Submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
153	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **(01-374-0006-118530D)**
	Application Form Dy. No / Tracking ID & date of submission	(G27-LYB-8M2Y, 2025-10-01)
	Detail of Fee Submitted	300000.0, 2025-06-25,
	The proposed proprietary name / brand name	**ALKUREST**
	Label Claim	Each vial Contains: Melphalan Hydrochloride..... 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 2°C to 8°C (36°F to 46°F). protect from light.
	For generic drugs (me-too Status)	Alkeran® Injection Strength: 50 mg per vial Dosage Form: Sterile, nonpyrogenic, freeze-dried powder for reconstitution MAH In Pakistan : GlaxoSmithKline (GSK) Packaging: Single-use vial containin
	Pharmacotherapeutic Group of (API)	Anti-Cancer
	Name, address of Manufacturing site:	Kindos Pharmaceuticals Co., Ltd. -No.8-9 Kexin Road. Chengdu Hi-Tech Comprehensive Bonded

		Zone.Chengdu, Sichuan, 611731, P. R. China - China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Melphalan Hydrochloride for Injection, 50 mg/vial is the approved reference listed drug (RLD) ALKERAN® Melphalan Hydrochloride for Injection, 50 mg/vial, the subject of an approved NDA 020207, held by APOTEX INC and approved on Nov. 18, 1992, as listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as Orange Book.
	Name, address of Marketing Authorization Holder:	Meitheal Pharmaceuticals Inc., , 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631 United States of America , United States of America
	Details of Certificates (CoPP/FSC/cGMP):	Valid
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Melphalan Hydrochloride are carried out by drug substance manufacturer, under long term conditions, (-20 °C ± 5 °C for 36 months) and accelerated conditions, (5 °C ± 3 °C for 6 months) as per ICH guidelines
	The status in reference regulatory authorities	Alkeran® Injection (Intravenous Formulation) Strength: 50 mg per vial Dosage Form: Sterile, nonpyrogenic, freeze-dried powder for reconstitution Manufacturer: GlaxoSmithKline Packaging: Single-use vial containing melphalan hydrochloride equivalent to 50 mg melphalan and 20 mg povidone, with a separate vial of sterile diluent Route of Administration: Intravenous infusion USFDA Approved
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved Approved subject to submission of i. Submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
154	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **(01-374-0006-118530D)**
	Application Form Dy. No / Tracking ID & date of submission	(Y4P-MRM-NN5B, 2025-09-23)

Detail of Fee Submitted	300000.0, 2025-06-25,
The proposed proprietary name / brand name	**MYLEZAN 60mg/10ml**
Label Claim	Each ml contains: Busalphan..... 6mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 MonthUnopened vials of Busulfan Injection must be stored under refrigerated conditions between 2° to 8°C (36° to 46°F). Discard unused portion.
For generic drugs (me-too Status)	BUSULFEX 60mg/10ml Manufacturer: Otsuka America Container Type: Single Dose Strength: 60mg/10ml (USFDA Approved)
Pharmacotherapeutic Group of (API)	Anti-Cancer
Name, address of Manufacturing site:	Kindos Pharmaceuticals Co., Ltd. -No.8-9 Kexin Road. Chengdu Hi-Tech Comprehensive Bonded Zone.Chengdu, Sichuan, 611731, P. R. China - China
Pharmaceutical Equivalence and Comparative Dissolution Profile	The aim of the formulation development was to produce finished products equivalent to the RLD, the subject of approved NDA 020954, held by OTSUKA and approved on Feb 4, 1999, as listed in the Orange Book. The drug product contains Busulfan the active ingredient, N,N-dimethylacetamide (DMAC) and Super Refined Polyethylene Glycol 400-LQ-(MH), NF (PEG400) the solvent.
Name, address of Marketing Authorization Holder:	Meitheal Pharmaceuticals Inc.,, 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631 United States of America , United States of America
Details of Certificates (CoPP/FSC/cGMP):	Valid
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Busulfan are carried out by drug substance manufacturer, under long term conditions, (25°C±2°C, 60%±5% RH for 60 months) and accelerated conditions, (40°C±2°C and 75%±5% RH for 6 months) as per ICH guidelines.
The status in reference regulatory authorities	BUSULFEX 60mg/10ml Manufacturer: Otsuka America Container Type: Single Dose Strength: 60mg/10ml (USFDA Approved)
Evaluation Remarks	
the application is complete as per codal formalities for consideration by the Registration Board	
Decision	
Approved Approved subject to submission of i. Submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. ii. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026.	

	iii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
155	Case Category	Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**ATCO LIFE SCIENCES (PRIVATE) LIMITED** B-18 S.I.T.E. Karachi **(051)**
	Application Form Dy. No / Tracking ID & date of submission	(39E-X6S-VXXD, 2025-10-06)
	Detail of Fee Submitted	313500.0, 2025-08-07,
	The proposed proprietary name / brand name	**PAZOTAB 200mg Tablet**
	Label Claim	Each film coated tablet contains: Pazopanib Hydrochloride equivalent to Pazopanib 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7×4's-De-Controlled
	Shelf Life (Unit)	24 MonthNot Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Pazorene 200mg film-coated tablets manufactured by Oncogen Pharma Karachi City, Sindh 75190 Pakistan.
	Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile are Attached under Module 3.
	Name, address of Marketing Authorization Holder:	Atco Life Sciences (Private) Limited., B-18 S.I.T.E., Karachi-75700., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP attached
	Details of Authorization Letter :	API Procurement Document is attached in module 3.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 60 Months Data of Long-Term Stability is attached in Module 3.
	The status in reference regulatory authorities	Votrient 200mg film-coated tablets manufactured by Novartis Pharmaceuticals UK Limited.
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved **Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy**	
156	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road **(000455)**
	Application Form Dy. No / Tracking ID & date of submission	(8LV-UV5-S2WH, 2026-02-04)

	Detail of Fee Submitted	38700, 2025-09-01,
	The proposed proprietary name / brand name	**Ezolite 40mg Capsule**
	Label Claim	Each capsule contains: Esomeprazole Mg EC pellets equivalent to Esomeprazole .... 40 mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nexum 40mg Capsule by M/s Getz Pharma, Karachi
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Detail of stability batches of drug product	Three batches of 1500 Capsules each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, local purchase from Ms Vision pharmaceuticals pvt Ltd
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Nexum 40 capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	USFDA approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.
	Evaluation Remarks	
	Decision	
	Approved	
157	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(NB4-BS6-945N, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-11-13,
	The proposed proprietary name / brand name	**Optinac 0.1% Ophthalmic Suspension**
	Label Claim	Each ml of Suspension Contains: Nepafenac 1.0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nevanac 0.1% Ophthalmic Suspension (Eye Drops) BY Novartis
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	SHANGHAI ORGANOPHARM CHEMICAL Co. Ltd. 3 rd floor middle B,No. 88,Beijing East Road, Taicang City Jiangsu P.R. China.
	Detail of stability batches of drug product	Three batches of 600 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Medicaids without timely intimation to DRAP, hence may be verified.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Optinac 0.1% Ophthalmic Suspension of Ms Winthrox Pvt.Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	FDA approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observation	Firm's response
1	Justification shall be submitted for trial batch manufacturing prior to issuance of DML.	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

Since the firm has not timely intimated DRAP regarding borrowing of API, hence loan may be verified, accordingly.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

158	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)**
	Application Form Dy. No / Tracking ID & date of submission	(ETZ-VZH-5ASW, 2026-01-30)
	Detail of Fee Submitted	38700, 9400 2025-11-12, 2026-02-27
	The proposed proprietary name / brand name	**Optinac 0.3% Ophthalmic Suspension**
	Label Claim	Each ml of Suspension Contains: Nepafenac 3.0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Nepatek TS 0.3% Ophthalmic Suspension 3ml by Innvotek Pharmaceuticals
	Pharmacotherapeutic Group of (API)	NSAIDs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANGHAI ORGANOPHARM CHEMICAL Co. Ltd. 3 rd floor middle B,No. 88,Beijing East Road, Taicang City Jiangsu P.R. China
	Detail of stability batches of drug product	600 bottles of each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms Medicaids without timely intimation to DRAP
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Nepac forte 0.3 of Ms Sante Pvt. Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	MHRA Approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Attached.

Evaluation Remarks

Sr. No.	Observation	Firm's response
1	Justification shall be submitted for trial batch manufacturing prior to issuance of DML.	The inspection was conducted on 22-04-2025, and the inspection report is dated the same. Based on the panel's recommendation, we initiated the trial batches to adhere to the advised timelines and to ensure operational readiness. Accordingly, Optimus Pharmaceuticals commenced trial batch manufacturing activities prior to the formal issuance of the DML. This step was taken in line with the panel's guidance to ensure process validation, preparedness, and continuity of operations while awaiting the official documentation.

Since the firm has not timely intimated DRAP regarding borrowing of API, hence loan may be verified, accordingly.

Decision

Approved

Registration letter will be issued after verification of loan letter of API.

159	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**

	Application Form Dy. No / Tracking ID & date of submission	(L9X-7TG-A7YH, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**ACUZITH 500MG TABLET**
	Label Claim	Each film coated tablet contains: Azithromycin as Dihydrate.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Zetro 500mg Tablet, M/s Getz Pharmaceuticals, Reg No. 053120
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CITI PHARMA LTD.
	Detail of stability batches of drug product	3 batches (1000 tablets each)
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, local purchase from Ms Citi Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Zyto 500mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved (ZITHROMAX® Tablet, M/s Pfizer Labs, Division of Pfizer Inc, NY 10017, USA)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	The firm has not submitted audit trail report on product testing and informed that they have Waters HPLC system with Empower 2 software, the system is currently not 21CFR compliant.	
	Decision	
	Deferred Deferred for confirmation of availability of 21CFR complaint HPLC system.	
160	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**
	Application Form Dy. No / Tracking ID & date of submission	(QWD-9XT-T5ZP, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-10,
	The proposed proprietary name / brand name	**ACUZITH 250MG TABLET**
	Label Claim	Each film coated tablet contains: Azithromycin as Dihydrate.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Zetro 250mg Tablet (M/s Getz Pharmaceuticals Registration No: 066913)

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CITI PHARMA LTD
	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 Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Zyto 250mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV-A conditions
	The status in reference regulatory authorities	USFDA Approved (ZITHROMAX® Tablet, M/s Pfizer Labs, Division of Pfizer Inc, NY 10017, USA)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	Decision	
	Deferred Deferred for confirmation of availability of 21CFR complaint HPLC system.	
161	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**
	Application Form Dy. No / Tracking ID & date of submission	(1G1-8WD-DRYD, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Aglop 100mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as Trihydrate.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Trispan 100mg/5ml Dry powder for suspension (M/s Seraph Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Citi Pharma Ltd. (3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.)
	Detail of stability batches of drug product	Three batches of 300 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted PE and CDP data against Cefspan100mg/5ml dry suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	(FDA Approved) Suprax® (cefixime) for Oral Suspension USP, 100 mg/5 mL (Lupin

		Pharmaceuticals Inc. Baltimore, Maryland 21202 United States.)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter attached at 1.3.5
	Evaluation Remarks	
	The firm has informed that they have Waters 600 Quaternary Gradient HPLC with 2487 Detector for stability studies. Currently the system is not 21CFR compliance. Audit trail on product testing is also not submitted.	
	Decision	
	Deferred Deferred for confirmation of availability of 21CFR complaint HPLC system.	
162	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**
	Application Form Dy. No / Tracking ID & date of submission	(PPM-65V-PQXZ, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Aglop 200mg/5ml Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains: Cefixime as Trihydrate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Trispan 200mg/5ml Dry powder for suspension (M/s Seraph Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Citi Pharma Ltd. (3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan)
	Detail of stability batches of drug product	Three batches of 300 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Cefspan 200mg/5ml dry suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV conditions
	The status in reference regulatory authorities	FDA Approved (Suprax® (cefixime) for Oral Suspension USP, 200 mg/5 mL) Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States.
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter attached at 1.3.5
	Evaluation Remarks	
	The firm has informed that they have Waters 600 Quaternary Gradient HPLC with 2487 Detector for stability studies. Currently the system is not 21CFR compliance. Audit trail on product testing is also not submitted.	
	Decision	

	Deferred Deferred for confirmation of availability of 21CFR complaint HPLC system.	
163	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**
	Application Form Dy. No / Tracking ID & date of submission	(PGV-M8H-3L3M, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Aglop 400mg Capsules**
	Label Claim	Each capsule contains: Cefixime as Trihydrate.....400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Trispan 400mg Capsule (M/s Seraph Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Citi Pharma Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Detail of stability batches of drug product	3 batches, 1000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP against Cefspan 400mg capsules
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV conditions
	The status in reference regulatory authorities	(FDA Approved) Cefixime Capsule 400mg (ALKEM LABS LTD United States.)
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted
	Evaluation Remarks	
	The firm has Waters 600 Quaternary Gradient HPLC with 2487 Detector for stability studies. Currently the system is not 21CFR compliance. Audit trail on product testing is not submitted.	
	Decision	
	Deferred Deferred for confirmation of availability of 21CFR complaint HPLC system.	
164	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)**
	Application Form Dy. No / Tracking ID & date of submission	(UP4-G8L-Y9RQ, 2026-01-02)
	Detail of Fee Submitted	38700, 2025-11-10,

	The proposed proprietary name / brand name	**HIFERO 100MG TABLET**
	Label Claim	Each chewable tablet contains: Iron as iron (III) hydroxide polymaltose complex.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temprature
	For generic drugs (me-too Status)	Ferosoft 100mg tabs, (M/s Hilton Pharmaceuticals Pvt Ltd, Registration No: 023995)
	Pharmacotherapeutic Group of (API)	Anti-Anemic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. CHEMIWORLD PVT. LTD
	Detail of stability batches of drug product	Three batches of 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	N/A, local purchase from Ms Chemiworld Pvt Ltd., Peshawar
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Ferosoft 100mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	-
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Section approval letter submitted

Evaluation Remarks

Sr. No.	Observation	Firm's reply
1	valid copy of approval of API/ DML/GMP certificate of drug substance manufacturer, since the already submitted copy of GMP was issued based on inspection conducted on 29-11-2016 and the DML was valid till 18-07-2023.	We have purchased API (Iron Polymaltose) from Chemiworld Pharma Pakistan. According to the supplier their valid copy of approval of API/ DML/GMP certificate are under process in DRAP. The firm has submitted receipt dated 14-01-2020 for issuance of GMP certificate.

Decision

Approved

Registration letter will be issued after submission of valid copy of approval of API/ DML/GMP certificate of drug substance manufacturer.

165	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(2YY-UGR-TTUP, 2025-11-12)
	Detail of Fee Submitted	38700, 9400 2025-11-05, 2026-02-27
	The proposed proprietary name / brand name	**D MOX LA 15% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)BELOW 30°C
	For generic drugs (me-too Status)	AMOCILLIN 15% INJECTION (10ml) (113593) ETERNA PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
166	Case Category	New Section (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(4S8-VQT-WYM6, 2025-11-12)
	Detail of Fee Submitted	38700, 9400 2025-11-05, 2026-02-27
	The proposed proprietary name / brand name	**D MOX LA 20% INJECTION**
	Label Claim	Each ML contains: (As Per Innovator Spec.) Amoxicillin as Trihydrate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 YearBELOW 30°C
	For generic drugs (me-too Status)	NOVAMOX 20% LA INJECTION (10ml) (043145) SELMORE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommended renewal of DML and grant additional Section
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
167	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(T6A-1GD-7SE8, 2025-06-27)
	Detail of Fee Submitted	37000.0, 9400 2025-05-26, 2026-02-27
	The proposed proprietary name / brand name	**Dairy Gold Granules**

	Label Claim	Each 1 kg Contains: Vitamin A.....0.8 gm. Copper Sulphate (CU).....0.25 gm. Vitamin D3.....0.16 gm. Magnesium Sulphate.....25 gm. Vitamin E.....0.38 gm. Calcium Chloride (Ca).....0.023 gm Vitamin B1.....1.0 gm. Zinc Sulphate (Zn).....2.17mg Vitamin B2.....1.25 gm. Manganese Sulphate.....120 gm. Vitamin B3 .....4.0 gm. Potassium Iodide (I2) .....0.5 gm. VitaminB6.....4.0gm. Sodium Selenite (Se).....0.01 gm. Vitamin B12.....9000 mcg D.C.P (P) (Phosphorous).....150 gm. Sodium Chloride.....120 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,15kg-De-Controlled,20kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place below 30□c
	For generic drugs (me-too Status)	White Gold Powder
	Pharmacotherapeutic Group of (API)	Nutritional Supplement/Livestock Feed Supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size	
168	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(YVY-4VE-M8NP, 2025-11-12)
	Detail of Fee Submitted	75000, 2025-09-16,
	The proposed proprietary name / brand name	**Vadada 300mg Tablets**
	Label Claim	Vadadustat 300mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C

	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Vadadustat is an oral hypoxia-inducible factor prolyl-hydroxylase inhibitor used to treat symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Stability of three trial batches 2025-T82, 2025-T83,2025-T84 of 1000 tablet batch size each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the innovator product VAFSEO® (vadadustat) tablets.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data performed as per zone IV condition is submitted by the firm
	The status in reference regulatory authorities	VAFSEO® (Vadadustat) tablets, for oral use Tablets: 150 mg Initial U.S. Approval: 2024 Manufactured for: Akebia Therapeutics®, Inc., Cambridge, MA 02142 VAFSEO® is a registered trademark of Akebia Therapeutics, Inc.
	GMP status of the firm	GMP certificate issue dated 9th May,2024.
	Evidence of approval of manufacturing facility	GMP certificate issue dated 9th May,2024, mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
169	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)**
	Application Form Dy. No / Tracking ID & date of submission	(VT1-R8W-TVTN, 2025-11-11)
	Detail of Fee Submitted	75000, 2025-09-16,
	The proposed proprietary name / brand name	**Vadada 150mg Tablets**
	Label Claim	Vadadustat 150mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Vadadustat is an oral hypoxia-inducible factor prolyl-hydroxylase inhibitor used to treat symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Detail of stability batches of drug product	Stability of three trial batches 2025-T79, 2025-T80,2025-T81 of 1100 tablet batch size each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the innovator product VAFSEO® (vadadustat) tablets.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data performed as per zone IV condition is submitted by the firm
	The status in reference regulatory authorities	VAFSEO® (Vadadustat) tablets, for oral use Tablets: 150 mg Initial U.S. Approval: 2024 Manufactured for: Akebia Therapeutics®, Inc., Cambridge, MA 02142 VAFSEO® is a registered trademark of Akebia Therapeutics, Inc.
	GMP status of the firm	GMP certificate issue dated 9th May,2024.
	Evidence of approval of manufacturing facility	GMP certificate issue dated 9th May,2024, mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved Approved subject to the submission of:- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
170	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	**HIMMEL PHARMACEUTICALS (PVT.) LTD** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore **(05-352-0065-016174D)**
	Application Form Dy. No / Tracking ID & date of submission	(GRB-GJ2-42TL, 2026-02-09)
	Detail of Fee Submitted	, ,

	The proposed proprietary name / brand name	**Melphalan AqVida 90 mg/ml concentrate for solution for infusion**
	Label Claim	Each ml of concentrate contains 90 mg melphalan (as melphalan hydrochloride).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2–8 °C).
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Antineoplastic and immunomodulating agents, ATC code L01AA03
	Name, address of Manufacturing site:	AqVida GmbH -Wekstr.21 23942 Dassow-Germany
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical comparative data is submitted by the firm.
	Name, address of Marketing Authorization Holder:	AqVida GmbH, Kaiser-Wilhelm-Str. 89 20355 Hamburg Germany, Germany
	Details of Certificates (CoPP/FSC/cGMP):	Firm submitted the GMP certificate of product License holder dated 08-07-2024.
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance is submitted by the firm.
	The status in reference regulatory authorities	IVRA by APOTEX
	Evaluation Remarks	
	Firm submitted the CoPP certificate no. AQV/271125/71 Stamp and date: 27. November 2025 Address of certifying authority: Freie und Hansestadt HamburgBehörde für Justiz und Verbraucherschutz V2 Arzneimittel, Medizinprodukte, Chemikalienrecht und Produktssicherheit Postfach 30 28 22 20310 Hamburg,Germany Letter of Authorization: dated 19 September 2025 confirmed that Himmel Pharmaceutical (Pvt.) Ltd. having its registered office at Ground Floor, 6-Judicial Colony, Phase-1 (Ext.) Sharah Nazaria Pakistan, Lahore, 53700 Pakistan, is exclusive agent of AqVida GmbH Kaiser-Wilhelm-Str. 89 20355 Hamburg Germany, to register and market the following oncology product in the territory of Pakistan: Melphalan Aq Vida 90 mg/ml concentrate for solution for infusion.	
	Decision	
	Approved Approved subject to the import policy order and submission of :- i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.	
171	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	**ATCO LIFE SCIENCES (PRIVATE) LIMITED** B-18 S.I.T.E. Karachi **(051)**
	Application Form Dy. No / Tracking ID & date of submission	(SQZ-HY5-RZYW, 2025-09-16)
	Detail of Fee Submitted	313500.0, 2025-08-07,
	The proposed proprietary name / brand name	**IBRUTAB 140mg Tablet**

	Label Claim	Each film coated tablet contains: Ibrutinib 140mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4×7's-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	ANTINEOPLASTIC AGENTS
	Name, address of Manufacturing site:	Eskayef Pharmaceuticals Limited-Murapara, Rupganj, Narayanganj 1464, Bangladesh.-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile are Attached under Module 3.
	Name, address of Marketing Authorization Holder:	Atco Life Sciences (Private) Limited., B-18 S.I.T.E., Karachi-75700., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP attached
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 Months Data of Accelerated Stability and 12 Months Data of Long-Term Stability of Ibrutinib is attached in Module 3.
	The status in reference regulatory authorities	IMBRUVICA 140 mg film-coated tablets manufactured by Janssen-Cilag Limited 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG U.K.
	Evaluation Remarks	
	CoPP: Firm submitted CoPP certificate no. DGDA/ 6-214/15321 dated 28-08-2024 is submitted by the applicant, certificate remain valid for two years from date of issuance and certifying authority is Directorate General of Drug Administration Mohakhali, Dhaka- I 2 I 2, Bangladesh. Letter of Authorization: Letter of authorization dated 17 September,2024 M/s. ATCO Life Sciences (Private) Limited having registered office atB-18, S.I.T.E., Karachi-75700, Pakistan is the authorized agent of Eskayef Pharmaceuticals Limited situated at plot: 82, Road: 14, Block: B, Banani, Dhaka-1213, Bangladesh to register and sell the following products in the territory of Pakistan. IBRUTAB Film Coated tablet : 140mg/tablet	
	Decision	
	Deferred Deferred for submission of complete stability data of three commercial batches of the drug product performed as per zone-IV conditions. All batch-related manufacturing documents for these stability batches should be maintained and available. The stability data should be submitted along with the corresponding Batch Manufacturing Records (BMRs).	
172	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(Q3Z-G8T-AMTN, 2025-11-14)
	Detail of Fee Submitted	37000, 1700 2025-06-27, 2025-10-06
	The proposed proprietary name / brand name	**ICUMET 500mg/100ml IV INFUSION**
	Label Claim	Each 100ml contains: Metronidazole.....500mg (BP Specs.)

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Flagyl injection BY Hoechst Pakistan Limited
	Pharmacotherapeutic Group of (API)	Antibiotic /Antiprotozoal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED E120/105/106,MIDC,TARAPUR,VIA BOISAR, DIST:THANE.MAHARASHTRA.INDIA (India).
	Detail of stability batches of drug product	100 Bottles for each batch.
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan from ms fahmeir pharma clearance certificate attached.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Flagyl 500mg/100ml m/s snofi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies are according to zone IV A.
	The status in reference regulatory authorities	Metronidazole 500mg/100ml MHRA Approved
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	No F.1-24/15-Lic (Vol-V-II)dated 03-feb-2025 mentioning liq inj vial general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
173	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**ICU Pharmaceuticals (SMC-Private) Limited** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, **(000956)**
	Application Form Dy. No / Tracking ID & date of submission	(U97-N3P-3M4D, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-06-27,
	The proposed proprietary name / brand name	**K-flox 400mg/250ml Infusion**
	Label Claim	Each vial contains: Moxifloxacin (as Hydrochloride).....400mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)	Mofest 400mg Infusion by Sami pharmaceuticals
	Pharmacotherapeutic Group of (API)	Fluoroquinolone (Anti Biotic)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PHARMAGEN LIMITED Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore ,Pakistan
	Detail of stability batches of drug product	100 Vails is for each batch.

	Documents for the procurement of API with approval from DRAP (in case of Import)	pharmagen.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Against Mofest 400mg Infusion by Sami pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Attached.
	Evidence of approval of manufacturing facility	No F.1-24/15-Lic (Vol-V-II)dated 03-feb-2025 mentioning liq inj vial general section.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
174	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(46V-LDH-MPQT, 2025-09-29)
	Detail of Fee Submitted	37000, 1700 2025-07-14, 2025-09-12
	The proposed proprietary name / brand name	**Montewell 4mg Sachet**
	Label Claim	Each Sachet Contains: Montelukast Base...4mg (USP Specification
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	Montika 4mg sachet M/s. SAMI Pharmaceuticals Pvt. Ltd. 050744
	Pharmacotherapeutic Group of (API)	Anti-Asthamatic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API Private ltd. Plot No.: 75, Flat No. 302, Bhanu Enclave, Sunder Nagar Erragadda, Hyderabad – 500038 Telangana State, India. Tel: +91 - 40 -2370 0421 / 2381 3969 / 2381 2317 Web: contact@metroapi.com
	Detail of stability batches of drug product	3 batches 150 sachet each
	Documents for the procurement of API with approval from DRAP (in case of Import)	6334/21-DRAP in name of M/s friends pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Montika 4mg sachet M/s Sammi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	No. F.1-37/2020-LIC (Vol-1) dated 3 -02-2025 mentioning sachet general section.
	Evaluation Remarks	

	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
175	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(5R4-UUD-NZV1, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	**Momera**
	Label Claim	Each gram contains: Mometasone Furoate .....0.1% w/w
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	5gm,10gm,15gm and 30-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
	For generic drugs (me-too Status)	Mometasone Furoate 0.1% w/w Cream by Maxitech Pharmaceuticals (RN 83743)
	Pharmacotherapeutic Group of (API)	Corticosteroids, potent (group III)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ENVEE DRUGS PVT.LTD. N. H. No. 8,Dumral-387 355,Ta. Nadiad, Dist: heda, Gujarat,India.
	Detail of stability batches of drug product	3 batches; Batch size: 200 tubes of 5gm each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Madera Pharmaceuticals Pvt. Ltd. E-6776320489571 dated 28.9.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE submitted against Hivate Cream of M/s Saffron
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV-A
	The status in reference regulatory authorities	PL No. (MHRA Approved)
	GMP status of the firm	New DML; GMP certificate is not submitted.
	Evidence of approval of manufacturing facility	Letter No. 2-11/2017-Lic dated 27-10-2023 specifies the grant of DML with the following seven sections: Tablet (General), Capsule (general), Dry powder suspension (general), Sachet powder (general), Cream ointment (general), Lotion (general) & Liquid Syrup/suspension/solution (General).
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
176	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Skywin Pharmaceuticals** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**

	Application Form Dy. No / Tracking ID & date of submission	(A5X-Q2T-RAXV, 2025-09-08)
	Detail of Fee Submitted	38700.0, 2025-08-15,
	The proposed proprietary name / brand name	**Skycip 250mg Tablet**
	Label Claim	Each Film coated Tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Solocip Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Ciprofloxacin is an antibiotic agent in the fluoroquinolone class used to treat bacterial infections such as urinary tract infections and pneumonia.
	Name, address of Manufacturing site:	Self Manufacturing
	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
	Detail of stability batches of drug product	Took 3 trial batches of 1500 Tablets per batch and submitting stability
	Documents for the procurement of API with approval from DRAP (in case of Import)	Took Loan from M/s Wimits Pharmaceuticals Pvt. Ltd. Local purchase from M/s Zenith
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Solocip Tablet of M/s Wimits Pharmaceuticals Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data as per Zone IV-A for Accelerated at Temp:40±2˚C, Humidity:75±5% RH & Real Time at Temp:30±2˚C, Humidity:65±5% RH
	The status in reference regulatory authorities	Ciprofloxacin 250 mg film-coated tablets of M/s SUN PHARMA UK LIMITED 6-9 The Square, Stockley Park, Uxbridge, UB11 1FW United Kingdom (EMA & HPRA Approved)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	1-14/2020 issued on 18-09-2023 mentioned tablet section general
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
177	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(ETQ-QS5-XBXT, 2025-07-16)
	Detail of Fee Submitted	37000.0, 2025-03-11,

The proposed proprietary name / brand name	**Tacro**
Label Claim	Each gram contains: Tarolimus..... 0.1% w/w
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	10gm-As per SRO
Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30oC
For generic drugs (me-too Status)	Tacrus 0.1% w/w by sharooq pharma
Pharmacotherapeutic Group of (API)	D11AH01: Agents for dermatitis, excluding corticosteroids.
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Manufacturer: Sumar BioTech LLP BY Plot No: 12,113,114,GIDC Estate Gozariya, Dist: Mehsana,382825,Gujarat, India Phone: +91-2763-264939,Email: nfo@sumarbiotech.com,inquiry@sumarbiotech.co
Detail of stability batches of drug product	
Documents for the procurement of API with approval from DRAP (in case of Import)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
The status in reference regulatory authorities	TACROLIMUS by FDA
GMP status of the firm	
Evidence of approval of manufacturing facility	
Evaluation Remarks	
"The application is complete as per codal formalities for consideration by the Registration Board"	
Decision	
Approved	

Division of Biological Evaluation and Research Division

Case No. 1: Imported Veterinary Biologicals applied by M/s Better Traders International, Faisalabad deferred in 351st meeting of Registration Board.

Following products of M/s Better Traders International, Faisalabad were approved in 313th, 316th & 344th meetings of Registration Board as per following details:

Sr. NO.	Name of MAH & Manufacturer	Brand Name & Composition	Decision of RB
1.	M/s AVAC Vietnam Co., Ltd., Highway A, Ngoc Lick, Trung Tac Province, Hung Yen City Vietnam	AVAC IB- H120 Infectious Bronchitis Vaccine, Live Each dose contains: Attenuated IB Virus strain H120……Not less than 10^2 EID^{50} Manufacturer's Specifications	*Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized FSC indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter.* **(M-313)**
2.		AVAC ND- Lasota Newcastle Disease Vaccine, Live Each 0.1ml contains: Each dose contains: Newcastle Virus strain Lasota…. Not less than 10^6EID_{50} Manufacturer's Specifications	*Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized FSC indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter.* **(M-313)**
3.		Avac ND -IB Live Newcastle and Infectious Bronchitis Vaccine, Live Each dose contains: Newcastle Disease Virus, Hitchner B1 strain……. not less than 10^6EID_{50} infectious Bronchitis Virus, H120 strain…… not less than 10^2EID_{50} BP Specifications	*Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.* *The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC.* **(M-316)**
4.		Avac ND -IB K Newcastle and Infectious Bronchitis Vaccine, Inactivated Each dose contains: Newcastle Disease Virus, LaSota strain……. not less than 10^6EID_{50} infectious Bronchitis Virus, H120 strain…… not less than 10^2EID_{50} BP Specifications	*Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.* *The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC.* **(M-316)**

5.		Avac Gumboro INT Infectious Bursal Disease Vaccine, Live Each dose contains: attenuated Infectious Bursal (IBD) Disease Virus, strain W2512……not less than 10^3TCID_{50} BP Specifications	*Keeping in view legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.* *The firm shall submit valid legalized Free Sale Certificate indicating diluent in combopack before issuance of registration letter. Chairman Registration Board is authorized for issuance of letter after submission of said FSC.* **(M-316)**
6.	M/s Avac Vietnam Joint Stock Company, Highway 5A, Ngoc Lich Village, Trung Trac Commune, Van Lam District, Hung Yen Province, Vietnam.	Avac LSD Lumpy Skin Disease Vaccine, Live Each dose contains: Attenuated LSD Virus (Neethling Strain)……NLT $10^{3.5}TCID_{50}$ Manufacturer's Specifications	*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.* **(M-344)**

During processing of Registration Letter, it was observed that in Free Sale Certificate submitted by the firm, following statement was mentioned:

"Can be freely sold in Viet Nam and overseas market".

As the clear statement was not mentioned, hence, it was decided to ask regulatory authority of country of origin to confirm the status of Free Sale of above products in country of import. Accordingly, email was forwarded twice once on 19-08-2025 & then on 02-09-2025 to the email address mentioned on one of the FSCs. However, no response was received. Accordingly, the case was placed in 351st meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the applications for submission of valid Free Sale Certificate of each product indicating actual status of availability of product in country of origin."

Accordingly, letter was issued on 06-10-2025. The firm has now submitted legalized FSCs for above products. Following are the observations in FSCs:

i. The submitted FSCs are same as were previously submitted and indicating the same statement i.e.
"Can be freely sold in Viet Nam and overseas market".
ii. The firm submitted notarized translation of theses FSCs which are indicating following statement:
"freely sold in Viet Nam and overseas market".

The FSCs issued by Regulatory Authority are already translated in English and the firm also submitted translation.

Decision:

Keeping in view the ambiguous status of availability of above products in country of origin and multiple opportunities given to the firm to clarify the status; Registration Board rejected the registration applications of following products applied by M/s Better Traders International, Faisalabad:

i. AVAC IB- H120

ii. **AVAC ND- Lasota**
iii. **Avac ND -IB Live**
iv. **Avac ND -IB K**
v. **Avac Gumboro INT**
vi. **Avac LSD**

Case No. 2: Correction in strength of API in already registered Veterinary Vaccine.

Following product of M/s Hilton Pharma (Pvt.) Limited, Karachi was approved in 347th meeting of Registration Board and registration letter was issued as per following details:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Conditions
131631	M/s PT Medion Farma Jaya, JI. Raya Batujajar No.29, Cimareme, Ngamprah, Bandung Barat, Indonesia	Medivac ND G7-AI H9N2 Subtype (Inactivated Vaccine for Poultry) Each dose contains: Inactivated Newcastle Disease virus of MDI5 strain (MD15 strain identical to Genotype VII.2 group) at least 10^7EID_{50} Inactivated Avian Influenza H9N2 Subtype virus of H9N2 strain at least $10^{3.5}$ EID_{50} (Manufacturer's Specification)	500ml Vial/De-controlled 18 Months (2^0C-8^0C)

The firm now submitted an application for correction in registration letter regarding strength of Avian Influenza Virus H9N2 as per following details:

Approved Composition	Proposed Composition
Each dose contains: Inactivated Newcastle Disease virus of MDI5 strain (MD15 strain identical to Genotype VII.2 group) at least…….10^7EID_{50} Inactivated Avian Influenza H9N2 Subtype virus of H9N2 strain at least……..$10^{3.5}$ EID_{50}	Each dose contains: Inactivated Newcastle Disease virus of MDI5 strain (MD15 strain identical to Genotype VII.2 group) at least…….10^7EID_{50} Inactivated Avian Influenza H9N2 Subtype virus of H9N2 strain at least……..**10^7EID_{50}**

The firm has submitted the CoPP No. 19018/PI.500/F/08/2025 dated 19-08-2025 in support of their claim. It is pertinent to mention that the firm submitted another CoPP No. 04154/PI.500/ F /07/2024 dated 30-07-2024 with initial application and registration letter was issued as per that CoPP. Now, firm submitted another CoPP with this application and requested to correct the strength as indicated in above table. Hence, in light of above, this application may be considered as change in strength instead of correction in strength.

As per Post-Registration Variation Guidelines for Pharmaceutical and Biological Products, variations like change in strength of one or more API, require new application. The firm has submitted full fee of registration with the application.

Decision:

Keeping in view the revised CoPP issued by regulatory authority of country of origin; Registration Board approved the correction in strength of Inactivated Avian Influenza H9N2 Subtype virus of H9N2 from $10^{3.5}$ EID_{50} to $10^{7}EID_{50}$.

Case No. 3: Application for issuance of duplicate registration letters of already registered drugs applied by M/s National Institute of Health, Islamabad.

Biological Production Division, National Institute of Health Islamabad informed that original registration certificates of below mentioned vaccines registered in 1970s cannot be traced despite their best efforts.

Sr. No.	Product Name	Reg. No.
1.	Anti-Rabies Serum	003847
2.	Tetanus Toxoid Adsorbed	003842
3.	Typhoid Cholera Mixed Vaccine	003838
4.	Typhoid Vaccine	003838
5.	Allergen Extract Vaccine	016742
6.	Measles Virus Vaccine (basic)	014404
7.	Measles Virus Vaccine (formulation)	018172

The firm has submitted copy of FIR and public notice regarding the lost registration certificate. The firm has requested to issue duplicate registration certificate of above products.

It is submitted that duplicate registration certificate may be issued in accordance with Rule 26(5) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Accordingly, the applicant was advised to submit the prescribed fee along with the renewal trail of the above-mentioned products vide letter dated 12-02-2026. The firm has submitted following response on 02-03-2026 only for Tetanus Toxoid (Adsorbed) (Reg. No. 00842):

"Reference letter No. 3-90/2015-DDC(Bio) dated 12-02-2026 regarding the duplicate registration and renewal certificates, it is submitted that the original registration certificate of the Tetanus Toxoid (Adsorbed), Registration No. 003842 have unfortunately been misplaced/ lost from our record.

2. In this regard, a FIR has already been lodged with the concerned police station. A copy of FIR is attached herewith along-with the supporting documents and deposited fee in favor of DRAP as per procedure.

- *06 November 2013- Challan No. 0030510*
- *19 January 2017- Challan No. 0565487*
- *09 March 2022- Reference for the renewal of Tetanus Toxoid (Adsorbed)*
- *07 August 2025- Challan No. 62092948432 (Tracking Id GPQ-748-24L3)*
- *Duplicate license Receiving- Tracking Id 7J7-SBB-VN95*

3. Furthermore, the Batch Production record (BPR) of the above-mentioned product along with supporting document of formulation is attached herewith.

4. In view of above, it is therefore requested that the case may kindly be processed at the earliest."

The mentioned BPR is not attached with the response.

Decision:

Registration Board directed to advise the firm to provide complete renewal trail of all the products including Tetanus Toxoid OR to submit Application for re-registration of above products in light of decision of 180th meeting of DRAP Authority.

Case No. 4: Change of Source of API (Human Insulin Recombinant) for Ferulin-R Injection (Reg# 060432) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.---Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: 9MG-X1U-W79P:

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060432	Ferulin-R Injection Each ml contains: Insulin Human…..100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required;
"Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology".

Decision:

Registration Board decided to ask the firm to submit complete quality comparison of finished product with Innovator product along with data in light of requirements of 278th meeting for rDNA Bio Therapeutic Proteins. The requirement of Safety and Efficacy data for such cases shall be discussed in forthcoming meeting of Registration Board and same shall be applicable to the firm.

Case No. 5: Change of Source of API (Human Insulin Recombinant) for Ferulin-N Injection (Reg# 060433) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.---Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: 93U-H5N-HE8J.

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060433	Ferulin-N Injection Each ml contains: Insulin Human…..100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required;

"Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology".

Decision:

Registration Board decided to ask the firm to submit complete quality comparison of finished product with Innovator product along with data in light of requirements of 278th meeting for rDNA Bio Therapeutic Proteins. The requirement of Safety and Efficacy data for such cases shall be discussed in forth coming meeting of Registration Board and same shall be applicable to the firm.

Case No. 6: Change of Source of API (Human Insulin Recombinant) for Ferulin 70/30 Injection (Reg# 060434) applied by M/s BF Biosciences Limited, 5-KM Sundar Raiwind Road, Raiwind, Lahore.

The firm M/s BF Biosciences Limited has applied for change of source of API from M/s MJ Biopharm Private Limited INDIA to M/s Tonghua Dongbao Pharmaceutical Co., Ltd.--- Dongbao New Village, Tonghua County, Tonghua, Jilin, China for their following product in PRV on e-app vide tracking ID: ZH6-ZSH-63JJ:

Reg. No.	Brand Name & Composition	Pack Size	Approved shelf life
060434	Ferulin 70/30 Injection Each ml contains: Insulin (Biphasic Isophane 70/30)…..100IU (BP Specifications)	10ml	2 years

As Insulin is rDNA protein, so complete data as per following WHO guidelines is required:
"Guidelines on the quality, safety and efficacy of bio therapeutic protein products prepared by recombinant DNA technology".

Decision:

Registration Board decided to ask the firm to submit complete quality comparison of finished product with Innovator product along with data in light of requirements of 278th meeting for rDNA Bio Therapeutic Proteins. The requirement of Safety and Efficacy data for such cases shall be discussed in forth coming meeting of Registration Board and same shall be applicable to the firm.

Case No. 7: Miscellaneous Matters.

Registration Board further decided the following:

i. Risk Management Plan in line with the decision of Registration Board taken in its 353rd meeting and notified vide F.No.14-1/2022-PEC dated 19th February, 2026. This decision will be implemented in a phased manner, initially for vaccines and subsequently for other Biological Drugs.

ii. Establishment of pharmacovigilance unit by the manufacturer/marketing authorization holder and notification of pharmacovigilance officer to the Pharmacy Services Division.

iii. GMP or product-specific inspections of locally manufactured vaccine facilities shall be conducted after approval by the Board and prior to the issuance of the registration letter by a panel constituted by the Director, Biological Drugs.

iv. Virtual GMP or product-specific inspections of bulk concentrate or ready-to-fill bulk manufacturers of locally produced vaccines shall be conducted after approval by the Board and before issuance of the registration letter by a panel constituted by the Director, Biological Drugs.

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

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Registration Board 354 Meeting Additional/Supplementary Minutes:

Sr. No	Title	Description
1	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(5SD-LM5-7Q3M, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yeflu NGH9**
	Label Claim	Each dose (0.5ml) contains: Newcastle Disease Virus LaSota strain, inactivated.....$\geq 10^{8.2}EID_{50}$ Avian Influenza Virus subtype H9 YBF003 strain, inactivated ... $\geq 10^{7.2}EID_{50}$ Infectious Bursal Disease Virus, VP2 protein.....AGP titer $\geq$ 1:16
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)75 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The product was initially approved in name of M/s Gallimune International, Lahore in 293rd meeting of Registration Board with brand name "Yemune NGH9". However, letter was not issued due to inspection of manufacturer abroad. Now, M/s Agriprom has applied for its registration and submitted termination letter of previous agent. Following are the deficiencies in application: 1. Free Sale is showing status as "can be freely sold" instead of showing actual availability. 2. Quantitative composition is not mentioned in FSC. 2. Strains of influenza and IBD viruses are not already registered in Pakistan. 3. Details of N Subtype of influenza virus are required.	

	Decision	
	Approved Keeping in view the recommendation of veterinary expert and GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Registration Board further directed DBE&R to write a letter to previous authorized importer i.e. M/s Gallimune International, Lahore to clarify the status of their authorization by manufacturer abroad. The registration letter shall be issued after clarification from previously authorized importer and submission of following by the firm: 1. Revised Free Sale Certificate indicating quantitative composition and actual availability of product in country of origin. 2. Details of N Subtype of influenza.	
2	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(WXD-52J-VWUB, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yemune NBG**
	Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated.....$\geq 10^{8.1}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... $\geq 10^{6.1}EID_{50}$ before inactivation Infectious Bursal Disease virus, VP2 protein ... AGP titer $\geq$ 1:16
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Medivac ND IB IBD
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)81 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The product was initially approved in name of M/s Gallimune International, Lahore in 293rd meeting of Registration Board with brand name "Yemune NGH9". However, letter was not issued due to inspection of manufacturer abroad. Now, M/s Agriprom has applied for its registration and	

	submitted termination letter of previous agent. Following are the deficiencies in application: 1. Free Sale is showing status as "can be freely sold" instead of showing actual availability. 2. Quantitative composition is not mentioned in FSC. 3. Strain of IBD virus is not already registered in Pakistan. 4. NOC from previous importer is not provided.	
	Decision	
	Approved Keeping in view the recommendation of veterinary expert and GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Registration Board further directed DBE&R to write a letter to previous authorized importer i.e. M/s Gallimune International, Lahore to clarify the status of their authorization by manufacturer abroad. The registration letter shall be issued after clarification from previously authorized importer and submission of following by the firm: 1. Revised Free Sale Certificate indicating quantitative composition and actual availability of product in country of origin.	
3	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(1A7-9DM-GZY1, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yevac NBE**
	Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated ... $\geq 10^{8.1}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... $\geq 10^{6.6}EID_{50}$ before inactivation Egg Drop Syndrome virus NE4 strain, inactivated ... $\geq 10^{6.6}EID_{50}$ before inactivation
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	Medivac ND EDS IB
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)77 dated 30-06-2025. Scanned Apostille FSC No. (2025) GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	

	The product was initially approved in name of M/s Gallimune International, Lahore in 293rd meeting of Registration Board. However, letter was not issued due to inspection of manufacturer abroad. Now, M/s Agriprom has applied for its registration and submitted termination letter of previous agent. Following are the deficiencies in application: 1. Free Sale is showing status as "can be freely sold" instead of showing actual availability. 2. Quantitative composition is not mentioned in FSC. 3. Strain of EDS virus is not already registered in Pakistan. 4. Newcastle Disease virus strain is different in FSC (N79) and in Form-5A (LaSota). 5. NOC from previous importer is not provided.	
	Decision	
	Approved Keeping in view the recommendation of veterinary expert and GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Registration Board further directed DBE&R to write a letter to previous authorized importer i.e. M/s Gallimune International, Lahore to clarify the status of their authorization by manufacturer abroad. The registration letter shall be issued after clarification from previously authorized importer and submission of following by the firm: 1. Revised Free Sale Certificate indicating quantitative composition and actual availability of product in country of origin. 2. Revised Form-5A indicating Newcastle Disease virus strain as per FSC along with fee for revision of Form-5A.	
4	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Agriprom Pakistan (Pvt) Ltd.** 1st Floor, Plot no. 19-B Off Abdul Sattar Eidhi Road near Qazalbash Chowk, Lahore **(05-352-0066-074116D)**
	Application Form Dy. No / Tracking ID & date of submission	(HBB-JPN-2ZMX, 2026-01-15)
	Detail of Fee Submitted	313500, 2026-01-14,
	The proposed proprietary name / brand name	**Yemune Reo 4 Plus**
	Label Claim	Each dose (0.5ml) of vaccine contains: Newcastle Disease virus LaSota strain, inactivated ... ≥ $10^{8.7}EID_{50}$ before inactivation Infectious Bronchitis virus M41 strain, inactivated ... ≥ $10^{6.2}EID_{50}$ before inactivation Infectious Bursal Disease virus, VP2 protein, ... AGP titer ≥ 1:16 Avian Viral Arthritis Virus AV2311 strain, ... ≥ $10^{6.7}ELD_{50}$ before inactivation
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	IZOVAC ND-IB-IBD-REO
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Yebio Bioengineering Co., Ltd.-No. 260 Heyuan Road, Hongdao, Qingdao-China
	Name, address of Marketing Authorization Holder:	Yebio Bioengineering Co., Ltd. of Qingdao, No. 21 Aodong Nan Road, Hongdao, Qingdao, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille FSC No. (2025)100 dated 23-07-2025. Scanned Apostille FSC No. (2025)

		GMP 15005 dated 07-05-2025.
	Details of Authorization Letter :	Scanned Apostille Distribution agreement dated 22-01-2025 and supplementary agreement dated 17-06-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The product was initially approved in name of M/s Gallimune International, Lahore in 293rd meeting of Registration Board. However, letter was not issued due to inspection of manufacturer abroad. Now, M/s Agriprom has applied for its registration and submitted termination letter of previous agent. Following are the deficiencies in application: 1. Free Sale is showing status as "can be freely sold" instead of showing actual availability. 2. Quantitative composition is not mentioned in FSC. 3. Strains of IBD and Avian Viral Arthritis are not already registered in Pakistan. 4. NOC from previous importer is not provided.	
	Decision	
	Approved Keeping in view the recommendation of veterinary expert and GMP & FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Registration Board further directed DBE&R to write a letter to previous authorized importer i.e. M/s Gallimune International, Lahore to clarify the status of their authorization by manufacturer abroad. The registration letter shall be issued after clarification from previously authorized importer and submission of following by the firm: 1. Revised Free Sale Certificate indicating quantitative composition and actual availability of product in country of origin.	
5	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Mustafa Brothers** 186-D, Peoples Colony No. 1, Faisalabad **(06-331-0168-031770D)**
	Application Form Dy. No / Tracking ID & date of submission	(UDY-TG8-879J, 2026-01-12)
	Detail of Fee Submitted	313500, 2026-01-12,
	The proposed proprietary name / brand name	**ARRIAH FMD QUAD "Foot and Mouth Disease Vaccine Sorbed Tetravalent Serotypes A, O, Asia-1, SAT-1, Liquid Inactivated with Gel of Aluminum Hydroxide and Saponin**
	Label Claim	Each 2 ml dose contains: Not less than 6PD50 for each serotype of A, O, Asia-1, SAT-1
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	18 Year(s)2c-8C
	For generic drugs (me-too Status)	Foot and Mouth Disease Vaccine - Pak Reg. No. 052400 - Manufactured By: FGBI ARRIAH Russian and Imported by Mustafa Brothers Faisalabad
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Federal Governmental Budgetary Institution “Federa-600901 Yur’evets, Vladimir-Russia
	Name, address of Marketing Authorization Holder:	Federal Governmental Budgetary Institution “Federa, 600901 Yur’evets, Vladimir, Russia
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP Certificate No. GMP-150/2024 dated 29-07-2024. Scanned FSC dated

		12-10-2025.
	Details of Authorization Letter :	Scanned Power of Attorney dated 23-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The product is containing Sat-1 serotype of Foot and Mouth Disease virus. The matter of requirement of SAT-1 containing vaccine was referred to Ministry of National Food Security and following response was received from them: "The Disease Alert issued by this Ministry explicitly indicated that Pakistan is endemic with FMD A, O and Asia-1 serotypes whereas FMD SAT-1, SAT-2 and SAT-3 serotypes are not present and the country is officially free from these serotypes (Annex-I). A meeting of the Provincial Livestock Departments and a range of stakeholders including DCFA was convened under the chair of Animal Husbandry Commissioner on 22nd January 2026 to discuss the preparedness of the Provincial Livestock Departments and to deliberate on the need for vaccines. The minutes of the meeting along with the decisions taken are hyperlinked as Annex-II. Expert consensus during the meeting clearly concluded that prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. The meeting highlighted that import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. It was emphasized that WOAH guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain. The participants agreed that priority should be given to strengthening surveillance, diagnostics, and early detection, including procurement of SAT-1 diagnostic kits and confirmation of any suspected cases through the National Veterinary Laboratory. However, the meeting allowed that limited import of monovalent FMDV SAT-1 vaccine may be considered only for emergency outbreak response, under strict control of competent veterinary authorities (On the request of Provincial Livestock Departments) and not for commercial or general use." Submitted for consideration of Board please.	
	Decision	
	Rejected Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. 2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. 3. WOAH guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain.	
6	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Mustafa Brothers** 186-D, Peoples Colony No. 1, Faisalabad **(06-331-0168-031770D)**
	Application Form Dy. No / Tracking ID & date of submission	(889-S9T-1TEM, 2026-01-13)

Detail of Fee Submitted	313500, 2026-01-12,
The proposed proprietary name / brand name	**ARRIAH-VAC QUAD "Foot And Mouth Disease Vaccine Inactivated Oil Adjuvant Tetravalent Containing Serotypes A, O, Asia-1, SAT-1"**
Label Claim	Each 2 ml dose contains: Not less than 6PD50 for each serotype of A, O, Asia-1, SAT-1.
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	50ml-De-Controlled
Shelf Life (Unit)	18 Year(s)2c-8C
For generic drugs (me-too Status)	Pak Reg. No. 08822 :: ARRIAH-VAC (Foot and Mouth Disease Vaccine Inactivated Oil Adjuvant Containing Serotypes A, O, Asia-1). By Mustafa Brothers -
Pharmacotherapeutic Group of (API)	Veterinary Vaccine
Name, address of Manufacturing site:	Federal Governmental Budgetary Institution “Federa-600901 Yur’evets, Vladimir-Russia
Name, address of Marketing Authorization Holder:	Federal Governmental Budgetary Institution “Federa, 600901 Yur’evets, Vladimir, Russia
Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP Certificate No. GMP-150/2024 dated 29-07-2024. Scanned FSC dated 12-10-2025.
Details of Authorization Letter :	Scanned Power of Attorney dated 23-10-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A

Evaluation Remarks

1. Only Potency test is being performed during stability studies. 2. Safety and Efficacy data of field trials is not submitted. 3. FSC and GMP are issued by two different authorities. 4. The product is containing Sat-1 serotype of Foot and Mouth Disease virus. The matter of requirement of SAT-1 containing vaccine was referred to Ministry of National Food Security and following response was received from them: "The Disease Alert issued by this Ministry explicitly indicated that Pakistan is endemic with FMD A, O and Asia-1 serotypes whereas FMD SAT-1, SAT-2 and SAT-3 serotypes are not present and the country is officially free from these serotypes (Annex-I). A meeting of the Provincial Livestock Departments and a range of stakeholders including DCFA was convened under the chair of Animal Husbandry Commissioner on 22nd January 2026 to discuss the preparedness of the Provincial Livestock Departments and to deliberate on the need for vaccines. The minutes of the meeting along with the decisions taken are hyperlinked as Annex-II. Expert consensus during the meeting clearly concluded that prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. The meeting highlighted that import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan’s international trade and export certification. It was emphasized that WOAH guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain. The participants agreed that priority should be given to strengthening surveillance, diagnostics, and early detection, including procurement of SAT-1 diagnostic kits and confirmation of any suspected cases through the National Veterinary Laboratory. However, the meeting allowed that limited import of monovalent FMDV SAT-1 vaccine may be considered only for emergency outbreak response, under strict control of competent veterinary authorities (On the request of Provincial Livestock Departments) and not for commercial or general use." Submitted for consideration of Board please.

	Decision	
	Rejected Keeping in view the following recommendations of meeting of Provincial Livestock Departments and a range of stakeholders including DCFA convened under the chair of Animal Husbandry Commissioner on 22nd January 2026; Registration Board rejected the application: 1. Prophylactic vaccination against FMDV SAT-1 is not required at this stage, as there is no laboratory-confirmed incursion of SAT-1 in Pakistan and uncertainty exists regarding the circulating topotypes in the region as it is challenging to determine which subtype (topotype I or topotype III) of SAT-1 may be introduced into the country. 2. Import of SAT-1 vaccines carries inherent risks, including potential introduction of new virus strains, complications in disease surveillance due to vaccine-induced antibodies, and adverse implications for Pakistan's international trade and export certification. 3. WOAH guidelines do not support routine vaccination against a serotype not currently circulating in the country and that vaccination decisions must be preceded by a formal risk assessment and antigenic matching with the circulating strain.	
7	Case Category	New Section (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(DN9-1ZU-MN1U, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	**MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen**
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability was conducted on 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	

Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.

Evaluation Remarks

Sr. No.	Queries (Deferred in 353)	Response by applicant
1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.	The Certificate of Analysis (CoA) for the API been provided by the Drug Substance Manufac M/s Hangzhou Patience Chemical Co., Ltd., C for batch number P20250302, manufactured o 20.09.2024 and with an expiry date of 19.09.2 for a quantity of 1 kg of Tirzepatide.
2.	Analytical procedures of products attached. The query was to provide analytical procedures of API and its validation.	Specifications of API by the finished product manufacturer, analytical procedure analytical verification report in terms of specificity, accu and precision with respective chromatograms.
3.	A letter was issued to the Incharge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.	The applicant submitted that API was importe two parts, 100gm & 300gm and they forgot to Intimate Evaluation cell regarding Import of 3 Materials, which was imported in the same dat when 100gm was imported. The firm undertak importing any further material without acquiri DRAP Clearance Certificate, it was imported p to the given undertaking. As reference the firm submitted Goods Declaration Certificate, Invo and Packing List.
4.	Accelerated summary is provided but High molecular weight species, dose accuracy; phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.	Accelerated stability study summary is provide including evaluation of high molecular weight species, dose accuracy, phenol content, particu matter, and impurity testing and respective res of those tests.
5.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi- dose prefilled pen is still required.	The Stability Studies of Multi Dose Pen and S Dose pen are separately performed. The chromatograms and related documents for the multi-dose presentation differ from those of th single-dose presentation. For Example, In the single-dose strength, 5 mg/0.5 mL represents t complete dose. However, in the multi-dose presentation, the total content is 20 mg/2.4 mL which delivers four individual doses of 5 mg/0 mL each. Furthermore, in the Pre-Filled Pen (P formulation, phenol is present at a very low concentration (0.012 mg), which remains belo Limit of Detection (LOD) of the validated HPL method. Though the phenol was observed in s of the chromatographic analysis, which have b attached for your reference. The complete data including chromatograms and supporting documentation, is attached in Annexure-4.
6.	Impurity testing at 9 months' time interval is mentioned in real time stability1 only. Raw data and chromatograms of all strengths is required.	The firm submitted that Complete Data includ Raw data and chromatograms of 9 months of a strengths is provided
7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.	Comparative testing along with raw data and chromatograms with innovator Attached in Annexure-6
8.	Summary of product characteristics is not provided.	Summary of product characteristics attached i Annexure-7

	Decision
	Approved The Registration Board approved the product with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

PARTIAL MINUTES OF 354TH MEETING OF REGISTRATION BOARD HELD ON 4TH MARCH 2026

Item No. 1: Applications for registration of Meningococcal Vaccines.

Deputy Director (P-1) M/o NHSR&C has referred to letter which is received to them form from Prime Minister Office pertaining to a request forwarded by the Manpower Exporters Welfare Association (MEWA) regarding the recent directive of GCC health authorities mandating Meningococcal Meningitis (Nimenrix) vaccination for all workers travelling to GCC countries, along with compulsory uploading of vaccination certificates with medical fitness reports. It has been reported that the Nimenrix vaccine is currently in short supply in Pakistan, with its price increased from PKR 6,400 to approximately PKR 11,000 due to high demand and limited availability. Around 50,000 workers travel to GCC countries each month and already incur medical examination expenses of about PKR 24,000 per person. MEWA has requested the Prime Minister's intervention to ensure immediate availability of the vaccine and its provision free of cost to outbound workers.

The Ministry further informed that BHS and FDI are hereby directed to take immediate necessary measure to ensure the provision of the above-mentioned vaccine on immediate basis and further advised to establish an appropriate and sustainable mechanism for the provision of the vaccine in the future. In aforesaid letter the Ministry has also DRAP is also requested to furnish the availability status of the vaccine for the month of March along with the agreed prices and market availability at the earliest, enabling FDI and BHS to proceed accordingly, while keeping NHSR&C in loop.

Therefore, keeping in view, the shortage of Meningococcal Vaccine as reported above, the Division of Biological Evaluation and Research has processed all applications pending in the division before the Registration Board for consideration.

Case No.1: <u>SOLE AGENCY TERMINATION LETTER BY M/S YUXI WALVAX BIOTECHNOLOGY CO CHINA IN NAME OF M/S AMSON VACCINES & PHARMA (PVT.) LTD., ISLAMABAD</u>

M/s HealthBee Projects Private Limited Bahria Town, Islamabad, had submitted an online application vide TID: DYV-T4Z-7RZV for change of registration of status for following vaccine registered in name of M/s Amson Vaccines & Pharma (Pvt.) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Details are as under:

Reg. No.	Brand Name & Composition & Pack Size	Product License Holder & Manufacturer	Date of Registration
115101	Group ACYW135Meningococcal Polysaccharide Vaccine (freeze-dried) for injection Each dose (0.5ml) contains: 50mcg of meningococcal group A, C, Y & W135 polysaccharide respectively **Diluent:**	M/s Yuxi Walvax Biotechnology Co., Ltd., No. 83 South Dongfeng Road, High & New Technology Industries	7th March 2023

	Each vial contains: Water for Injection…0.5ml	Development Zone, Yuxi City, Yunnan Province China	

2. Along with the aforementioned application, M/s HealthBee Projects Private Limited Bahria Town, Islamabad submitted a termination letter dated 31 August 2024 issued by M/s Yuxi Walvax Biotechnology Co., Ltd., China, pertaining to the above-mentioned vaccine. In this regard, M/s Amson Vaccines & Pharma (Pvt.) Ltd., Islamabad was directed to provide clarification vide DRAP letter dated 26 August 2025; however, no response received to date.

3. Accordingly the matter was placed before the Registration Board in its 352nd meeting held on 19-20 November 2025 wherein the Board decided to issue a final show cause notice to M/s Amson Vaccines and Pharma Pvt Limited Islamabad under provisions of Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976, in light of their termination of sole agency agreement of Group ACYW135Meningococcal Polysaccharide Vaccine (freeze-dried) for injection by the manufacture abroad i.e., M/s Yuxi Walvax Biotechnology Co., Ltd China.

4. Accordingly, as per decision of Registration Board, M/s Amson Vaccines and Pharma Pvt Limited Islamabad was again advised vide letter No. F.No.3-22/2014-DDC (BD) dated 21st January 2026 to submit their response. Response has been submitted vide TID: XRP-8J1-M7DZ dated 26th January 2026 which is as under:

"That Amson entered in to agreement contract with M/s Yuxi Walvax Biotechnology Co., Ltd. China after fulfilling all legal requirement and condition and fulfil legal formality as per law of Pakistan. At The time of registration of the product the manufacturer provided us the Authorization letter for distribution of the product in Pakistan and a registration of the product was granted to us. That Amson never violated the terms and conditions and adopted all the legal requirement and follow all laws and regulation related to drugs. Negotiation with Manufacturer: We are actively engaged in negotiations with M/s Yuxi Walvax Biotechnology Co., Ltd. China to address the concerns raised and resolve any contractual issues. Registration of Product: Amson Vaccines & Pharma (Pvt.) Ltd has allocated significant resources towards the registration & marketing of this product. The registration of this product was a lengthy and rigorous process, spanning over two years, we have incurred expenses associated with the registration process with the requirements set forth by the Drug Regulatory Authority Pakistan (DRAP). The Registration of the product is valid till 6th march 2028, & We are also under final negotiation with M/s Yuxi Walvax Biotechnology Co., Ltd. China, we will try to retain the Sole agency agreement soon with the manufacturer, We believe that the aforementioned points demonstrate our genuine commitment to working with M/s Yuxi Walvax Biotechnology Co., Ltd. China and our dedication to providing high-quality vaccines to meet the healthcare needs of our nation. We kindly request your careful consideration of these factors and the positive contributions & provide us sufficient time for the resolution of this matter. We will also provide you the latest feedback after completion of the final negotiation with the manufacturer. Therefore, we kindly requested to retain the registration of the product with Amson Vaccines &

Pharma (Pvt.) Ltd and also hold the transfer of Registration process of our registered product to the M/s HealthBee Projects private limited Islamabad till final negotiation with manufacturer".

A personal hearing notice has also been issued to the firm vide DRAP letter 3-22/2014-DDC(BD) dated 23.2.2026. However, no one appeared on behalf of the M/s Amson Vaccines and Pharma Pvt Limited Islamabad before Registration Board.

Decision of Registration Board:

Keeping in view discussions mentioned above, Registration Board made the following decisions:

1. **Cancelled the registration of Group ACYW135 Meningococcal Polysaccharide Vaccine (freeze-dried) for injection vide Reg. No: 115101 under Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976 in name of M/s Amson Vaccines & Pharma (Pvt.) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad manufactured by M/s Yuxi Walvax Biotechnology Co., Ltd., No. 83 South Dongfeng Road, High & New Technology Industries Development Zone, Yuxi City, Yunnan Province China in light of termination of sole agency agreement dated 31.08.2024.**
2. **Granted the registration of Group ACYW135 Meningococcal Polysaccharide Vaccine (freeze-dried) for injection manufactured by M/s Yuxi Walvax Biotechnology Co., Ltd., No. 83 South Dongfeng Road, High & New Technology Industries Development Zone, Yuxi City, Yunnan Province China in name of M/s HealthBee Projects Private Limited Bahria Town, Islamabad in light of sole agency authorization dated 01.03.2025 subject to the compliance of Import Policy for Finished Drugs.**
3. **Registration Board further directed the Division of Biological Evaluation & Research to issue registration letter with following additional condition based on WHO recommendations for Meningococcal Polysaccharide Vaccine:**

   "The vaccine shall be used only for travelers to countries where there are epidemics of meningococcal disease (e.g., sub-Saharan Africa and people travelling to perform Umrah & Hajj in Saudi Arabia)"

Case No. 2: MenQuadfi Solution for Injection (Meningococcal Conjugate Vaccine) approved by Registration Board in its 312nd Meeting

The below mentioned Meningococcal Conjugate Vaccine was approved in name of M/s Sanofi Aventis Pakistan Limited, Plot No 23, Sector-22, Korangi Industrial Area, Karachi in 312nd meeting of Registration Board as per details below:

Brand Name & Composition	**MA Holder & Manufacturer**	**Pack size & shelf life**
MenQuadfi (Solution for Injection)	M/s Sanofi Pasteur Inc., 1 Discovery	1's Vial

Each dose of 0.5mL contains: Meningococcal (Serogroup A) Polysaccharide (Monovalent Conjugate) ……10µg Meningococcal (Serogroup C) Polysaccharide (Monovalent Conjugate) ……10µg Meningococcal (Serogroup Y) Polysaccharide (Monovalent Conjugate) ……10µg Meningococcal (Serogroup W135) Polysaccharide (Monovalent Conjugate) ……10µg Tetanus Toxoid, Filtered Concentrate…….55 µg* *Tetanus toxoid quantity is approximate and dependent on the polysaccharide to protein ratio for the conjugates used in each formulation. (Manufacturer Specifications)	Drive, Swiftwater, PA 18370, USA.	48 months 2ºC-8ºC
Decision in 312nd meeting of Registration Board: Keeping in view legalized CoPP indicating product availability in country of origin and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Moreover, Registration Board acceded to the request of the firm for import of above product after registration in Standard Export Packs. The Board advised the firm to locally print MRP, Registration Number, Urdu Text and other parameters as per Drugs (Labelling & Packing) Rules, 1978 before sale of drug at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial area, Karachi (DML No. 000007) to comply the requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) years only. The firm shall maintain the cold chain during local printing and shall be responsible for final QC release.		

The title of applicant i.e., M/s Sanofi Aventis Pakistan Limited has been changed to M/s Hoechst Pakistan Limited vide DRAP letter No. 2-4/2000-Lic (Vol-II) dated 26.08.2024 and vide DSL No. DHOKK(Drugs)/-107/24 dated 28.8.2024.

Now M/s Hoechst Pakistan Limited, Plot No 23, Sector-22, Korangi Industrial Area, Karachi vide TID: WZP-B73-EV1G dated 12.12.2025 has submitted a request along with prescribed fee for change of name of applicant in their name as per approval of 312nd meeting of Registration Board. Notarized Sole Agency Agreement dated 02.12.2025 in name of M/s Hoechst Pakistan Limited, Plot No 23, Sector-22, Korangi Industrial Area Karachi from M/s Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370, USA is attached with the request.

Decision of Registration Board:

Keeping in view the approval granted by DRAP through letter No. 2-4/2000-Lic (Vol-II) dated 26.08.2024, the Drug Sale License issued vide License No. DSL No. DHOKK(Drugs)/-107/24 dated 28.08.2024, and the authorization letter from the manufacturer, M/s Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370, USA, Registration Board approved the change in the applicant's title from M/s Sanofi Aventis Pakistan Limited, Plot No. 23, Sector-22, Korangi Industrial Area, Karachi, to M/s Hoechst Pakistan Limited, Plot No. 23,

Sector-22, Korangi Industrial Area, Karachi subject to the compliance of Import Policy for Finished Drugs.

Case No.3: **Ingovax ACWY Vaccine (Single Dose Vaccine) applied by M/s Lab Diagnostic Systems (SMC) Pvt. Ltd., Rawalpindi.**

	Name, address of Applicant / Importer	**Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot 36-A, PSIC SIE, Taxila Rawalpindi.**
	Details of Drug Sale License of importer	License No: 01-374-0006-118530D **Address:** 36-A, PSIC, SIE,Taxila Rawalpindi Validity: 15/08/2029
	Name and address of marketing authorization holder (abroad)	Incepta Pharmaceuticals Ltd., Vaccine Division Plant address: Bara Rangamtia, Zirabo, Ashulia, Savar, Dhaka, Bangladesh. Office address: 40, Shahid Tajuddin Ahmed Sarani; Tejgaon I/A, Dhaka-1208; Bangladesh
	Name, address of manufacturer(s)	Incepta Pharmaceuticals Ltd., Vaccine Division Plant address: Bara Rangamtia, Zirabo, Ashulia, Savar, Dhaka, Bangladesh. Office address: 40, Shahid Tajuddin Ahmed Sarani; Tejgaon I/A, Dhaka-1208; Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted original CoPP having certificate no. NO. DA/6-148/2011/4103 issued by Government of Peoples Republic of Bangladesh The COPP specifies that the product is licensed for sale in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of Sole Agency Letter from **Incepta Pharmaceuticals Ltd., Vaccine Division** According to the letter, the firm **Incepta Pharmaceuticals Ltd., Vaccine Division** exclusively authorizes "**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.** for the purpose of registration, distribution and marketing of the product."
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Form -5F Dy. No.: Dated: 23rd June,2023
	Details of fee submitted	Rs: 150,000/- Dated: 21st June,2023 Deposit Slip No. 4122605352
	The proposed proprietary name / brand name	Ingovax ACWY Vaccine (Single Dose Vaccine)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each single dose vial contains: Meningococcal Polysaccharide Vaccine (Purified Polysaccharide from Neisseria meningitidis of serogroups A, C, W135 and Y) greater than equal to 50mcg/0.5ml.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Meningococcal Polysaccharide Vaccine
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Conditions	Store at 2-8°C.
	The status in reference regulatory authorities	Menomune-A/C/Y/W-135 Manufacturer: Sanofi Pasteur USFDA
	For generic drugs (me-too status)	Brand Name: MEVAC A Manufacturer: Hospital Services & Sales Pharmaceuticals Pvt. Ltd.
	Module-II (Quality Overall Summary	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	**Name:** Incepta Pharmaceuticals Ltd., Vaccine Division **Plant address:** Bara Rangamtia, Zirabo, Ashulia, Savar, Dhaka, Bangladesh.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches at accelerated conditions 25°C±2°C for 6 months. And long -term stability studies of three batches at 5±3 ℃ 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.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	Glass Vial (Type I, 1 ml clear), Rubber Stopper (13 mm, slotted, Type I), Gray Flip Off Seal 13 mm (Blue-3769)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of three batches (19003, 20001, 20002) at accelerated conditions 25°C±2°C for 6 months. And long -term stability studies of three batches (19003, 20001, 20002) at 5±3°C for 24 months. Depicting shelf life of 24 Months.
	Module-IV Non-Clinical	Firm has provided Module IV not as per CTD format
	Module-V Clinical	Firm has provided Module V not as per CTD format
Sr. No.	**Queries as per decision of 347th meeting of Registration Board**	**Reply by the firm**
1.	Certificate of Pharmaceutical Product (COPP) and Form 5F reflecting the combo pack of the vaccine product.	The firm has submitted copy of CoPP vide Memo No. DA/6-148/2011/8457 dated 23.01.2025 which reflects the combo pack of the vaccine product with revised Form-5F.
2.	Evidence for validated shipping conditions and cold chain management for the finished product.	Data logger record and soft box validation documents provided.
3.	Quality Overall Summary (QOS) – separate and complete drug substance sections for each purified polysaccharide and diluent.	QOS for each purified polysaccharide antigen is provided

4.	General properties with data on biological activity and impurity profile.	Tests pertaining to impurities like calcium, nucleic acid and protein content is submitted.
5.	Documentation provided to demonstrate that the Neisseria meningitidis strains used are among those recommended by WHO and have established safety and efficacy.	WHO recommends following strains: *The following strains have been shown to be suitable: for Group A polysaccharide-A 1, M1027; for Group C polysaccharide C11, C2241; for group Y polysaccharide-Y (Slaterus), 6306Y, IM2261; for Group W135-W135 6308, S. 4383, IM2263."* However the manufacturer informed that their interpretation of the above WHO guidance is that the WHO mentions these strains as examples, not as mandatory requirement. The guideline allows the use of other strains as long as they are approved by the country 's national control authority and have been shown to produce polysaccharide that is safe and effective in humans. Moreover, as per British Pharmacopoeia (BP), suitable strain of *Neisseria meningilidis* Group A, Group C, Group Y, and Group WI35 can be used if it is capable to produce polysaccharides consistently. All four strains used in Ingovax ACWY Vaccine were obtained from CCUG (Culture Collection University of GOteborg, Sweden), a globally recognized source. These strains were approved by the Directorate General of Drug Administration (DGDA) of Bangladesh. In addition, Ingovax ACWY Vaccine was shown to be both safe and effective in their clinical trial. It produced good immune response against all four serogroups and no major adverse events were reported. The trial results clearly support the safety and effectiveness of the vaccine. Eventually, the vaccine was approved for use in Bangladesh by DGDA.
6.	Process validation for aseptic processing and sterilization	Aseptic Process Validation report by Medial fill is submitted.
7.	Impurity information (related to substance, process, container closure system conforming to ICH guidelines (Q3A, Q3C, Q5C, Q6A, Q6B).	Tests pertaining to calcium, nucleic acid and protein content is submitted.
8.	Complete and signed analytical methods and method validation reports.	Analytical Method and validation report is submitted
9.	Submission of KD values or justification for molecular size distribution as per	The firm submitted that Quality control Section of Incepta Pharmaceuticals Ltd., Vaccine Division set the acceptance criteria of Molecular size distribution by

	WHO guidance.	size exclusion chromatography method of each polysaccharide bulk Neisseria meningitidis (Group A, C, Y, W135) according to BP, at least 65% of recovery for Neisseria meningitidis Group A, 75% of recovery for Neisseria meningitidis Group C, 80% of recovery for Neisseria meningitidis Group Y and Neisseria meningitidis Group W135 Purified Polysaccharide. This molecular size determined by measuring the recovery of the polysaccharide eluted before a K_D of 0.50 is reached.
10.	Stability data including forced degradation studies and stress testing.	The manufacturer has provided declaration against this point that they will conduct in March 2026.
11.	Diluent-specific sections of drug product (P.1–P.8) to be submitted separately.	Diluent details have been submitted.
12.	Scientific justification for use of mannitol (14 mg) and sucrose (35 mg) as stabilizers deviates from WHO recommendations.	Sucrose is used as a stabilizer in lyophilized vaccines formulation because it protects antigen during freezing and drying. Mannitol functions as a lyoprotectant (protecting against drying-related damage) to preserve the activity and efficacy of the vaccine. It serves as a stabilizer by preventing antigen damage during freeze-drying, preserving the vaccine's efficacy. Reason is elegance cake appearance, stability. Sucrose and mannitol help to preserve the refined cake structure of the Ingovax ACWY vaccine while improving stability and preventing potency degradation. The vaccine safety and efficacy with the formulation using sucrose and mannitol was found satisfactory in clinical and post-marketing pharmacovigilance study.
13.	In-house excipient (Tris base) with validated analytical method.	In Current BP, the name of raw material Tris Base is as Trometamol; We set the specification of this Raw Material as the Manufacturer CoA and write the reference ‘in- house’. As per management decision, Quality Control Section will change the Document and update this specification as per BP. The Quality Control Section of Incepta Pharmaceuticals Ltd., Vaccine Division will be revised the specification of Tris base as per BP within May’26.
14.	Specifications for identification and molecular size distribution compliant with European Pharmacopoeia and WHO standards.	Molecular Size or molecular mass distribution is determined by size-exclusion chromatography combined with an appropriate detection system. An acceptable value is established for each purified polysaccharide and Final Lot. Each batch must be shown to comply with this limit’.
15.	Tabulated summary of nonclinical studies and numerical data.	Non-clinical studies (Pharmacology: Primary Pharmacodynamics (Immunogenicity Testing),

		Toxicology: Single-Dose Toxicity & Repeat-Dose Toxicity (28-Day Study), Immunogenicity (Pharmacodynamics) and their respective results submitted. WHO TRS 594, 1975 states that the evidence suggests that the antibody responses of animals to the purified polysaccharides differ from those observed in man. This factor necessitates an approach different from that applied to the biological standardization of other bacterial vaccines in common use. With meningococcal vaccines it is important that the initial batches a new manufacturer and even batches prepared by an existing manufacturer using a new process be evaluated in man for immunogenicity by monitoring antibody responses.
16.	Justification for marking critical nonclinical sections as "Not Applicable" without reference to supporting guidelines.	In the nonclinical evaluation of vaccines, some sections related to long-term toxicity testing may be deemed irrelevant or not applicable, especially when the vaccine in question is intended for short-term use and contains well-characterized components. The decision to mark certain sections as 'Not Applicable' is made based on the following reasons, which are aligned with established regulatory guidelines and the nature of the product. 1. Irrelevance to the Study Type**: Certain sections such as **carcinogenicity**, **chronic toxicity**, and **reproductive toxicity** may be excluded because the **Ingovax ACWY Vaccine** is intended for **short-term prophylaxis** and does not involve prolonged or repeated exposure, making these studies unnecessary. 2. **Study Design**: The study design involves **28-day repeated-dose toxicity studies**, which sufficient to evaluate the **acute and sub-acute toxicity** of the vaccine. Long-term studies, such **carcinogenicity** and **chronic toxicity**, are not required for vaccines intended for short-term use. 3. **Regulatory Guidelines**: According to **WHO**, **EMA**, and **FDA** guidelines for vaccine development, **carcinogenicity** and **genotoxicity** studies are not routinely required for vaccines unless specific risk factors are identified, such as novel adjuvants or genetic material that could potentially lead to long-term exposure-related risks.

<table>
<tr><td>17.</td><td>Justification in the light of reference guidelines for study population limited to healthy adults (18–45 years), whereas the claimed indication includes children ≥2 years; no age-specific studies submitted.</td><td>According to WHO guideline: Guidelines on clinical evaluation of vaccines: regulatory expectations- the trial population for phases II and III vaccine clinical trial should be chosen to represent the group that will be the target for the vaccination in an immunization program. Generally, vaccines are given to healthy individuals as prevention of a specific disease. Ingovax ACWY (Meningococcal Polysaccharide Vaccine) manufactured by Incepta Pharmaceuticals Ltd. Vaccine division is indicated for the active immunization of children from 2 years of age, adolescents and adults against meningococcal disease caused by meningococci of serogroups A, C, W135and Y. So, as the target population of this vaccine is healthy population, so the clinical trial was conducted on healthy adults (18-45years) to evaluate the immunogenicity of the vaccine.</td></tr>
<tr><td>18.</td><td>Justification for Small sample size (n=44), as per correct calculation comes to be 50-55.</td><td>In this study we are going to test if the Ingovax ACWY vaccine is non-inferior to the Quadri MeningoTM vaccine. We assume the non-inferiority margin as 10% (i.e. δ= -0.10). With SBA titers seroconversion rate of the comparator vaccine as 97%, 5% level of significance and 80%:
<table><tr><th>Study Arm</th><th>Total</th><th></th></tr><tr><td>Ingovax ACWY (Test)</td><td>Quadri MeningoTM (Comparator)</td><td>Total No. of Participants</td></tr><tr><td>44</td><td>44</td><td>88</td></tr></table>
Protocol No. 17068 Version No.5.0, June 4, 2018 Clinical study report power we come up with 35 subject to be recruited in each group. Therefore, considering 20% attrition rate, total number of individuals to be recruited in each group is 44. The following formula was used to calculate the sample size</td></tr>
<tr><td>19.</td><td>Data on vaccine efficacy or effectiveness or justification in the light of reference guidelines of reference regulatory authorities.</td><td>The applicant has submitted Clinical Study Report PR 17068 with study following study objectives:
Primary Objective:
To evaluate and compare the immunogenicity of Ingovax ACWY’ with Quadri Meningo in healthy adults in Bangladesh.
Secondary Objective:
To evaluate and compare the safety of locally produced Ingovax ACWY with Quadri Meningo.</td></tr>
<tr><td>20.</td><td>Sampling schedule and immunogenicity timelines.</td><td>The sampling schedule for the study is outlined as follows:
Screening (Day -7 to -2): Informed consent is obtained, demographic and medical history are</td></tr>
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		recorded, vital signs are taken, and blood samples for lab tests are collected. **Vaccination (Day 0)**: Participants receive the vaccine and are observed for 30 minutes for any immediate reactions. **Follow-up Visits**: o **Day 30**: Participants return for a follow-up visit for immunogenicity testing, including blood samples. o **Day 60 & 90**: Additional follow-up visits to monitor long-term safety and immunogenicity. **Details are mentioned in** Appendix -1 of Clinical Study Protocol in Annexure-XVI.
21.	Risk Management Plan (RMP).	The firm has attached RMP.
22.	Periodic Safety Update Reports (PSUR) or PBRER.	Periodic safety update report form February 2021 to January 2026 is provided.
23.	AEFI reports (from country of origin or other NRAs).	An Observational, Adverse Event Following Immunization (AEFI) study to monitor the safety of Meningococcal Polysaccharide Vaccine (Ingovax ACWY), of Incepta Vaccine Ltd administered according to the prescribing information to healthy subjects in Bangladesh. Starting from 16.2.2020 to 20.3.2020.
24.	List of countries where the product is licensed or approved, including dates of approval.	Only registered in Bangladesh.

WHO mentions that Polysaccharide Meningococcal Vaccine is recommended for some specific risk groups and for the control of meningococcal outbreaks, and is available in different forms.
https://www.emro.who.int/health-topics/meningococcal-disease/vaccine-vaccination.html

Bivalent: protects against groups A and C. This form is administered as a single dose to persons ≥ 2 years old, which provides protection for 2–3 years. A second single dose is administered for school children and adults, which provides protection for at least 3 years. After 3–5 years, one booster dose may be given to persons considered to be at continued risk of exposure including health workers.

Trivalent: protects against groups A, C and W-135

Tetravalent: protects against groups A, C, Y and W-135. This form is recommended for travelers to countries where there are epidemics of meningococcal disease (e.g., sub-Saharan Africa and people travelling to perform Hajj in Saudi Arabia).

These vaccines do not protect against meningococcal groups B and X. Serogroup B vaccines have been extracted from selected outbreak strains and are currently used in some countries to limit outbreaks.

The available vaccines are safe and effective. The vaccines may cause mild and infrequent side effects, such as redness and pain at the injection site lasting up to two days. WHO in its position paper on the use of multivalent meningococcal conjugate vaccines in countries of the African meningitis belt dated 12.01.2024 mentions that Meningococcal polysaccharide vaccines should be

used only as a last resource, such as in the event of a large outbreak that exceeds the meningococcal conjugate vaccines stockpile. WHO emphasizes the critical need to secure the availability of MMCVs effectively for outbreak response and to take appropriate measures to ensure flexibility and availability of a large quantity of vaccine doses in case of need, while avoiding vaccine wastage. https://iris.who.int/server/api/core/bitstreams/91e9994c-7d65-4b8d-b64b-8be3a6ea8909/content.

Decision of Registration Board:

Registration Board approved the Ingovax ACWY Vaccine (Meningococcal Polysaccharide Vaccine) Single Dose Vaccine manufactured by Incepta Pharmaceuticals Ltd., Vaccine Division, Bara Rangamtia, Zirabo, Ashulia, Savar, Dhaka, Bangladesh subject to import Policy for Finished Drugs and subject to submission of valid Legalized CoPP mentioning the diluent of Vaccine.

Registration Board further directed the Division of Biological Evaluation & Research to issue registration letter with following additional condition based on WHO recommendations for Meningococcal Polysaccharide Vaccine and clinical trial data submitted for applied vaccine:

> ***"The vaccine shall be used only for travelers to countries where there are epidemics of meningococcal disease (e.g., sub-Saharan Africa and people travelling to perform Umrah & Hajj in Saudi Arabia). The use of this vaccine is restricted to adults aged between 18 and 45 years only".***

Registration Board further directed the Division that an advisory be issued to all registration holders to ensure the adequate availability of Meningococcal Vaccine across the country.

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