MINUTES OF 358TH MEETING OF REGISTRATION BOARD HELD ON 12TH MAY, 2026

Item No.	Detail of Item	Page No
I.	Confirmation of Minutes of 357th meeting of Registration Board	03
II.	Division of Pharmaceutical Evaluation & Registration	
	Registration-I Section ----------	04 – 17
	Registration-II Section ----------	17 – 19
	Post Registration Variation-II Section ----------	20 – 31
	RRR Section ----------	32 – 43
	Import & Vet Section ----------	44 – 61
	Pharmaceutical Evaluation Cell (PEC) ----------	62 – 453
III	Division of Quality Assurance & Laboratory Testing ----------	454 – 456
IV.	Division of Biological Evaluation & Research ----------	457 – 502
V.	Additional / Supplementary Minutes	
	Pharmaceutical Evaluation Cell (PEC) ----------	503 – 515
	Division of Biological Evaluation & Research ----------	516 – 538

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

358th meeting of Registration Board was held on 12th May, 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.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan, Rawalpindi.	Member
2.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore.	Member (Virtual)
3.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member (Virtual)
4.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member (Virtual)
5.	Mr. Asad Abrar, Director, Drugs Testing Laboratory, Govt. of Punjab, Bahawalpur.	Member (Virtual)
6.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member (Virtual)
7.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
8.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
9.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
10.	Miss Sadia Mahwish, Deputy Director, Representative of Quality Assurance & Lab Testing Division, DRAP.	Member
11.	Mr. Ahsan-Ul-Haq Athar, Deputy Director, Representative of Medical Device and Medicated Cosmetics Division, DRAP.	Member
12.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
13.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary

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

Item No. I Confirmation of minutes of 357th meeting of Registration Board.

357th meetings of Registration Board were held on 21st April, 2026. Accordingly, draft minutes of the 357th 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 357th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 357th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 357th meeting.

Item No. II Division of Pharmaceutical Evaluation & Registration

Registration-I Section

Case No. 01: Application for Registration of Nac Tablet of M/s Convell Laboratories, Swat.

Registration Board in its 312th meeting (held on 14th-16th Sep, 2021) approved the request of M/s Convell Laboratories, Swat regarding registration of "Nac Tablet 100mg". Detail is reproduced as under:

468	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Nac Tablets 100mg
	Composition	Each film coated Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11459 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0807635)
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg film-coated Tablets by M/s Accord Healthcare, MHRA Approved.
	Me-too status	Gratis Tablets 100mg BP by M/s Navegal, Reg. No. 43900
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	Firm revised its formulation from uncoated to film coated without providing fee
	Previous Decision (M297)	Deferred for submission of requisite fee for revision of formulation as per the reference product.
	Remarks of Evaluator VII	The firm has submitted fee challan of Rs. 7500/- (Deposit slip # 23584807517) dated 3-08-2021 for change of formulation from uncoated to: Each film coated Tablet Contains: Aceclofenac…100mg
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications.	

However, registration letter of above-mentioned product could not be issued due to brand name resemblance and requirement of fee for revision of specifications.

Proceedings of 352nd Meeting of RB:

The case was placed before the Board in its 352nd meeting (held on 19th-20th Nov, 2025) wherein the Board was apprised that the firm was inspected on 29.07.2022 and it was reported that the manufacturing facilities for the following sections had been **completely demolished and are not existing**:

- Tablet (General)

- Capsule (General)
- Dry Powder (General)
- Liquid
- Tablet (Psychotropic)
- Warehouse
- Finished Goods Store
- H & OTC Sections (e.No.00121)

In view of the above, it is evident that the firm presently **does not have the requisite facility** for manufacturing of "Nac (Aceclofenac) Tablet 100mg". Accordingly, the case is placed before the Registration Board for deciding the fate of "Nac Tablet 100mg" approved in 312th meeting.

Decision of 352nd meeting of RB:

Registration Board decided to refer the case to Licensing Division, DRAP for confirmation regarding current status of below mentioned manufacturing facilities of M/s Convell Laboratories, Swat.

- *Tablet (General)*
- *Capsule (General)*
- *Dry Powder (General)*
- *Liquid*
- *Tablet (Psychotropic)*
- *Warehouse*
- *Finished Goods Store*
- *H & OTC Sections (e.No.00121)*

In compliance with the above-mentioned decision, the case was referred to Licensing Division, DRAP. The said division has responded (vide e-office document No.F.3-10/2025-Reg-I(M-352)(Misc) dated 13.04.2026) as follows:

"It is informed that M/s Convell Laboratories, Saidu Sharif, Khyber Pakhtunkhwa, Swat has following sections:

i. Capsule Section (Cephalosporin)
ii. Dry Powder Suspension Section (Cephalosporin)

Their DML (No.000509-By way of Formulation) for the period 26.02.2023 to 25.02.2028 was renewed with above sections only. Other sections were suspended by the CLB in its 292nd meeting held on 4th Oct, 2023 due to collapse of the building which are still suspended. The applicant request vide TID: L8R-8PW-MQGW has been received for conduct of inspection which is under process."

Foregoing in view, the case has been placed before the Registration Board for deciding the fate of under-process applications and products already registered under following sections of M/s Convell Laboratories, Swat:

- Tablet (General)
- Capsule (General)
- Dry Powder (General)
- Liquid
- Tablet (Psychotropic)

Decision: Registration Board decided as under:

i. **Under section 7(11)(b) of the Drugs Act, 1976, suspended all products registered under below-mentioned sections (w.e.f. 04.10.2023) till reinstatement of these sections by the Central Licensing Board.**

- **Tablet (General)**
- **Capsule (General)**
- **Dry Powder Suspension (General)**
- **Liquid Syrup (General)**
- **Tablet (Psychotropic)**

ii. **Revoked the decision regarding approval of 'Nac (Aceclofenac) Tablet 100mg' taken in its 312th meeting. Accordingly, all approved applications with awaited registration letters (if any) shall stand deferred till reinstatement of requisite manufacturing facilities by the Central Licensing Board.**

Case No. 02: Request of M/s Martin Dow Limited, Karachi for Withdrawal of Registration Application of Viridio Tablet 50mg & 100mg.

M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi (DML No. 000267) filed two applications vide e-Application TID 944-W7U-1MYA and TWP-BS8-A745 for registration of "Viridio (Sildenafil) Tablet 50mg & 100mg" by way of contract manufacturing at M/s Wimits Pharmaceuticals, Lahore. The applications were approved by the Registration Board in its 353rd meeting (held on 14th – 15th Jan, 2026).

However, while processing for issuance of registration letters, it was identified that the applicant has also filed separate applications of same products on self-manufacturing basis. Accordingly, clarification was sought from the applicant which has been responded as under:

"Please note that M/s Martin Dow Limited initially submitted the application on Contract basis from Wimits & intended to market the same. Meanwhile, we initiated the development at our own facility, considering that we will transfer the manufacturing site from contract to self-manufacturing after successful development of the product.

Unfortunately, the product of Wimits faced some major queries in DRB meeting which raised concerns over its certain approval. Hence, we decided to submit the application of self-manufacturing for this product & proceeded accordingly.

Thereupon, the Wimits product got approval in DRB meeting and our contract product which was applied from Wimits was cross referenced in the subsequent meeting.

However, we hereby opt to ***withdraw*** *this application from Wimits on Contract Manufacturing basis as we will be proceeding with self-manufacturing for the complete range of Sildenafil. We also assure the esteemed authority of being vigilant & avoid such cases in future."*

Foregoing in view, request of M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi (DML No. 000267) for withdrawal of two e-Application TID 944-W7U-1MYA and TWP-BS8-A745 is submitted for consideration by the Registration Board, please.

Decision: **Registration Board acceded to the request of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi (DML No. 000267) for withdrawal of registration applications of "Viridio (Sildenafil) Tablet 50mg & 100mg", submitted vide e-Application TID 944-W7U-1MYA and TWP-BS8-A745, respectively.**

Case No.03. Approval of Cephalosporin Containing Products Issued to M/s Hicon Pharmaceuticals, Peshawar

Registration Board in its 349th meeting (held on 14th July, 2025) approved the following products of M/s Hicon Pharmaceuticals, Hayatabad by way of contract manufacturing at Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi.

1.	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hicon Pharmaceuticals** 131- Industrial estate Hayatabad **(000583)**
	Application Form Dy. No / Tracking ID & date ofsubmission	(DHE-VYM-RGMU, 2025-01-13)
	Detail of Fee Submitted	93000.0,2024-10-25,
	The proposed proprietary name / brand name	**DUXIMA 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)	3 Year Room Temperature
	For generic drugs (me-too Status)	Cefim suspension by Hilton
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Cefixime suspension (USFDA Approved)
	Detail of previous approval	CARECEF 100mg/5ml Dry Suspension Minutes of297th Meeting of Registration Board (12-15thJanuary, 20
	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	
2.	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hicon Pharmaceuticals** 131- Industrial estate Hayatabad **(000583)**
	Application Form Dy. No / Tracking ID & date ofsubmission	(P8X-QN4-HB8W, 2025-01-13)
	Detail of Fee Submitted	93000.0,2024-10-25,
	The proposed proprietary name / brand name	**DUXIMA 400mg Capsules**
	Label Claim	Each capsule Contains: Cefixime as trihydrate.....400mg (JP Specs)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	28's/14's,-As per SRO

	Shelf Life (Unit)	3 Year Room Temperature
	For generic drugs (me-too Status)	Brand Name: Cefim capsules Registration holder: Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Brand Name: Cefixime capsules Regulatory Authority: USFDA Approved
	Detail of previous approval	Minutes of 297th meeting of Registration Board, with brand name of CARECEF 400mg 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	

Proceedings of 353rd Meeting of RB:

Registration Board in its 353rd meeting (held on 14th-15th Jan, 2026) was apprised that during processing for issuance of registration letters, it was identified that M/s Hicon, Peshawar previously held registration of above-mentioned products. However, the firm requested for suspension of registrations stating that they are in process of developing dedicated cephalosporin facility. Accordingly, registrations of below-mentioned products were suspended on 06.04.2021 subject to following conditions in compliance with the decision taken by the Registration Board in its 297th meeting (held on 12th -15th January, 2021):

Sr. No.	Reg. No.	Product Name and Composition
1.	041504	Podomax Tablets Each Tablet contains: Cefpodoxime Proxetil Eq. to Cefpodoxime……..100mg
2.	041507	Podomax Dry Suspension Each 5ml contains: Cefpodoxime Proxetil Eq. to Cefpodoxime….40mg
3.	041508	Duxima Dry Suspension Each 5ml contains: Cefixime ……100mg
4.	041509	Duxima Capsules Each capsules contains: Cefixime Axitel ……... 400mg
5.	041510	Concef Dry Suspension Each 5ml contains: Cephradine ……...125mg
6.	041511	Concef Dry Suspension Each 5ml contains: Cephradine …….…...250mg

7.	041512	Concef Capsules Each Capsule contains: Cephradine …….. 250mg
8.	041513	Concef Capsules Each Capsule contains: Cephradine ……..500mg
9.	041514	Foxil Dry Suspension Each 5ml contains: Cefadroxil ……..……..125mg
10.	041515	Foxil Dry Suspension Each 5ml contains: Cefadroxil ……..…….250mg
11.	041516	Foxil Capsules Each Capsule contains: Cefadroxil …….……..……500mg

i. The firm shall submit timelines for completion of dedicated cephalosporin facility.

ii. The firm shall continue to submit renewal applications of above-mentioned products throughout the duration of suspension.

Foregoing in view, the firm was asked to justify. In response, the firm has informed that they are in the process of designing a new layout for a standalone cephalosporin manufacturing building. The updated plan is being developed to ensure full compliance with the latest requirements related to segregation, GMP standards, and safety protocols. Once the layout design is finalized, they will move forward with the next stages, including approval, construction, installation, and qualification activities. A detailed and structured timeline will be submitted to the Board at that stage.

Furthermore, the firm has also requested (vide e-Application TID: PLX-8B1-1VEJ) to process the above-mentioned approvals in PRV capacity (i.e., change the manufacturing site from our own facility to a contract manufacturing facility by M/s Biogen, Rawat), maintaining the same product names and current registration numbers.

Decision of 353rd Meeting of RB:

Registration Board noted that despite the lapse of almost 5 years, M/s Hicon, Peshawar has neither established dedicated cephalosporin facility nor submitted any timeline for completion.

Therefore, the Board decided to issue show cause notice to the firm under section 7(11)(b)&(c) of the Drugs Act, 1976 read with section 42 thereof that why the registrations of their cephalosporin containing products may not be cancelled.

In compliance with the above-mentioned decision, the applicant was issued show-cause notice on 20.02.2026 vide e-Application TID PLX-8B1-1VEJ.

In response, the applicant has stated as under:

"We humbly submit that due to financial and operational constraints, it has not been feasible for us to establish a separate building for cephalosporin manufacturing facility.

After due consideration, the management has decided not to establish a separate cephalosporin facility and intends to change the manufacturing status of the already registered products (cephalosporins) from own manufacturing to contract manufacturing at a DRAP-licensed facility.

Necessary applications and documents for approval shall be submitted accordingly.

We respectfully request the honorable Registration Board to kindly consider our submission and allow us to proceed under contract manufacturing."

Decision: **Registration Board decided as under:**

i. **PRV approval for change in manufacturing site shall be issued to M/s Hicon Pharmaceuticals, Peshawar for 'Duxima 100mg/5ml Dry Suspension' and 'Duxima 400mg Capsule' in line with the approval granted by the Registration Board in its 349th meeting.**

ii. **Furthermore, under section 42 of the Drugs Act, 1976, M/s Hicon Pharmaceuticals, Peshawar shall be called for personal hearing with respect to following products which were suspended on 06.04.2021.**

Sr. No.	Reg. No.	Product Name and Composition
1.	041504	Podomax Tablets Each Tablet contains: Cefpodoxime Proxetil Eq. to Cefpodoxime……..100mg
2.	041507	Podomax Dry Suspension Each 5ml contains: Cefpodoxime Proxetil Eq. to Cefpodoxime….40mg
3.	041510	Concef Dry Suspension Each 5ml contains: Cephradine ……...125mg
4.	041511	Concef Dry Suspension Each 5ml contains: Cephradine ……....250mg
5.	041512	Concef Capsules Each Capsule contains: Cephradine …….. 250mg
6.	041513	Concef Capsules Each Capsule contains: Cephradine ……..500mg
7.	041514	Foxil Dry Suspension Each 5ml contains: Cefadroxil ……..……..125mg
8.	041515	Foxil Dry Suspension Each 5ml contains: Cefadroxil ……..….250mg
9.	041516	Foxil Capsules Each Capsule contains: Cefadroxil …….……..…500mg

Case No.04. **Correction in Minutes of 353rd Meeting of Registration Board.**

Registration Board in its 353rd meeting (held on 14th-15th Jan, 2026) considered following 03 registration applications of 'Avanafil Tablets' received from M/s Platinum Pharmaceuticals (Pvt) Ltd, A-20, North Western Industrial Zone, Bin Qasim. Karachi (DML No.000415) and decided as under:

S/N	Product Detail	e-App TID	Decision of RB-353rd

1.	Avanafil 100mg tablet Each tablet contains Avanafil 100mg	QRT-5P7-GH35	Approved
2.	Avanafil 50mg tablet Each tablet contains Avanafil 50mg	V95-N4B-81QJ	Approved The Registration Board approved the product subject to verification of submitted data by a panel constituted by the Chairman, Registration Board.
3.	Avanafil 200mg Tablet Each tablet contains Avanafil 200mg	XUL-1P8-MSQR	Approved The Registration Board approved the product subject to verification of submitted data by a panel constituted by the Chairman, Registration Board

Decision regarding **"verification of submitted data by a panel"** (mentioned against products at S.No. 02 & 03) appears to be a typo/ cut-paste error as there were no evaluation remarks mentioned in the minutes referring to the need for verification of data. Furthermore, unconditional approval of 'Avanafil Tablet 100mg' in same meeting also suggests the same. Registration letters have been issued accordingly, and case is placed before the Registration Board for correction in minutes of 353rd meeting.

Decision: **Registration Board noted the correction in minutes of 353rd meeting with respect to decisions recorded against registration applications of "Avanafil 50mg Tablet & Avanafil 200mg Tablet" of M/s Platinum Pharmaceuticals (Pvt) Ltd, A-20, North Western Industrial Zone, Bin Qasim, Karachi (DML No.000415).**

Case No.05. Conditionally Approved Registration Applications of M/s City Pharmaceutical Laboratories, Karachi

Registration Board in its 316th meeting (held on 15th-18th March, 2022) approved the following registration applications of M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi:

S/N	Product Detail	Dy. No. & Date of Application	Decision of 316th Meeting of RB/ Remarks of Reg-I Section (if any)
1.	Claronil 500mg Tablet Clarithromycin…..500mg/tab USP	**Dy.No 10793 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Clarithromycin……..…500mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** In line with the decision of RB, the firm has submitted fee of Rs. 7500/-(S#4929712164 dated 27.10.2023) **without undertaking.**
2.	Amoxi 500mg IV Injection Each Vial contains:	**Dy. No. 32568- dated 13-12-2021**	**Approved with BP specification.** • **Manufacturer will place first three commercial batches on long term stability studies throughout proposed shelf life and**

	Amoxicillin Sodium sterile powder for solution for injection eq. to Amoxicillin … 500mg BP		**on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three commercial batches as per the commitment submitted in the registration application.** • **Firm shall submit following before issuance of registration letter:** ➢ **Performance of accuracy parameter in the analytical method verification studies of drug substance.** **Compatibility studies of finished product with diluent.**
3.	Asrovit 20mg Tablet Atorvastatin Calcium……..…20mg/tab USP	**Dy.No 10791 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Atorvastatin as calcium trihydrate…..…20mg** **Registration Board further decided that registration letter will be issued after submission of:** **Revised master formulation adjusting the weight of API considering the salt factor** **Undertaking the end of Form 5** **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
4.	Asrovit 10mg Tablet Atorvastatin Calcium……..10mg/tab USP	**Dy.No 10790 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Atorvastatin as calcium trihydrate…..…10mg** **Registration Board futher decided that registration letter will be issued after submission of:** **Revised master formulation adjusting the weight of API considering the salt factor** **Undertaking at the end of form 5** **Firm shall submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
5.	Ibistan DS 300/25mg Tablet Each Tablet Contains: Irbesartan…….300mg Hydrochlorothiazide...25mg USP	**Dy.No 10789 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….300mg** **Hydrochlorothiazide…….25mg** **Registration Board futher decided that registration letter will be issued after**

			submission of Undertaking at the end of form 5. **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
6.	Ibistan 150/12.5mg Tablet Each Tablet Contains: Irbesartan…….150mg Hydrochlorothiazide.12.5mg USP	**Dy.No 10788 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….150mg** **Hydrochlorothiazide…...12.5mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5** **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
7.	Ibistan plus 300/12.5mg Tablet Each Tablet Contains: Irbesartan…….300mg Hydrochlorothiazide..12.5mg USP	**Dy.No 10792 dated 05-03-2019**	**Approved with following label claim:** **Each Film Coated Tablet Contains:** **Irbesartan…….300mg** **Hydrochlorothiazide…...12.5mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
8.	Peridoline DS Tablet 8/10mg Each Tablet Contains: Perindopril……8mg Amlodipine (as Besylate)...……10mg Manufacturer's specifications	**Dy.No 10795 dated 05-03-2019**	**Approved with innovator's specifications and following label claim:** **Each Film Coated Tablet Contains:** **Perindopril Erbumine……..8mg** **Amlodipine (as Besylate)……..10mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), and correction/change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

9.	Peridoline plus Tablet 4/10mg Each Tablet Contains: Perindopril……..…4mg Amlodipine (as Besylate)..……...10mg Manufacturer's specifications	**Dy.No 10796 dated 05-03-2019**	**Approved with innovator's specifications and following label claim:** **Each Film Coated Tablet Contains:** **Perindopril Erbumine……..4mg** **Amlodipine (as Besylate)……..10mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), and correction/change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
10.	Peridoline Tablet 4/5mg Each Tablet Contains: Perindopril…….4mg Amlodipine (as Besylate)..……5mg Manufacturer's specifications	**Dy.No 10794 dated 05-03-2019**	**Approved with innovator's specifications and following label claim:** **Each Film Coated Tablet Contains:** **Perindopril Erbumine……..4mg** **Amlodipine (as Besylate)…….....5mg** **Registration Board further decided that registration letter will be issued after submission of Undertaking at the end of form 5.** **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), and correction/change of formulation from un-coated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

The applicant was communicated shortcomings vide letter dated 14.09.2022, reminder dated 16.10.2023 and finally vide e-Application TID PJ9-E4D-J9HX on 22.01.2026. **However, despite the lapse of more than 4 years the applicant has not complied with the decisions of Registration Board.** Accordingly, the case is placed before the Registration Board for deciding the fate of above-mentioned applications.

Decision: **Registration Board decided that M/s City Pharmaceutical Laboratories, Karachi shall be issued final reminder for submission of requisite information/ documents/ fee in compliance with the decision taken by the Board in its 316th meeting.**

Case No.06. Recommendations to Registration Board in the Light of Decisions of 6th Meeting of Pharmacovigilance Risk Assessment Expert Committee (PRAEC), Held on 31st December, 2025

Following recommendations have been received from Secretary, PRAEC:

I. DOMESTIC CASES

i. Request for Review of Drug Formulation and Comparative Clinical Assessment of Inj A-Care (Atracurium) 50mg/5ml.

Decision:

The PRAEC deliberated on the matter at length. The Pharmacovigilance (PV) Focal Person from Punjab and the Director General, Directorate of Drug Control, Punjab, Mr. Muhammad Sohail, attended the meeting via Zoom and provided a detailed presentation of the case.

The Committee was informed that the complaint pertained to a lack of efficacy of the product. However, the referred case lacked essential information, including detailed adverse event reports (lack of efficacy) of the affected patients, which is necessary to establish causality. It was noted that the Individual Case Safety Reports (ICSRs) associated with this matter may be obtained by the Punjab Pharmacovigilance Centre for a comprehensive assessment of the case series.

The Committee further decided to refer the matter to the Registration Board for appropriate regulatory action to ascertain the efficacy of A-Care manufactured by M/s Caraway Pharmaceuticals, and to prospectively consider similar issues related to other High Alert Medicines. Furthermore, the committee also recommended to the Registration Board to conduct Product Specific Inspection (PSI) of the firm, including its storage area.

II. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

i. Isotretinoin: Sacroiliitis

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022, registration holders of isotretinoin-containing medicines are required to include information on the risk of sacroiliitis in the Adverse Drug Reactions and Warnings and Precautions sections of the SmPC/label, in line with the Health Canada Product Monograph; and

b. The PRAEC, as per Rule 10(1)(e) recommended to the Registration Board to direct all registration holders of isotretinoin-containing medicines to update the prescribing information in light of the decisions of Health Canada and PRAEC- DRAP.

ii. Mesalazine: Risk of idiopathic intracranial hypertension

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1)(h) (iv) of the Pharmacovigilance Rules, 2022, registration holders are required to include information regarding the risk of idiopathic intracranial hypertension in the Warnings and Precautions section and also list this risk with a frequency of "not known" in the Adverse Drug Reactions (ADRs) section of the SmPC/label for all mesalazine-containing medicine in Pakistan in line with MHRA-UK decision; and

b. The PRAEC, as per Rule 10(1)(e) of the Pharmacovigilance Rules, 2022, recommended to the Registration Board to direct all registration holders of mesalazine-containing medicines to update the SmPC/label in light of the decisions of MHRA-UK and PRAEC-DRAP.

iii. Thiopurines: Intrahepatic cholestasis of pregnancy

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1) (h) (iv) of the Pharmacovigilance Rules, 2022, registration holders are required to include the risk of intrahepatic cholestasis of pregnancy, with a frequency of "not known", in the Adverse Drug Reactions and Warnings and Precautions sections of the SmPC/label of thiopurine-containing medicines registered in Pakistan, in line with the SmPC approved by MHRA; and

b. The PRAEC, as per Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022, recommended to the Registration Board to direct all registration holders of thiopurine-containing medicines to update the SmPC/label in light of the decisions of MHRA-UK and PRAEC-DRAP.

iv. Finasteride, Dutasteride: Potential risk of suicidal thoughts

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1)(h) (iv) of the Pharmacovigilance Rules, 2022, registration holders are required to include the risk of suicidal ideation (suicidal thoughts) in the Adverse Drug Reactions section, with a frequency of "unknown", for oral finasteride and dutasteride-containing medicines registered in Pakistan, in line with the decision of EMA-PRAC; and

b. The PRAEC as per Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022, recommended to the Registration Board to direct all registration holders of oral Finasteride and dutasteride-containing medicines to update the SmPC/label in light of the decisions of EMA-PRAC and PRAEC-DRAP.

v. Sulfamethoxazole, trimethoprim: Risk of circulatory shock

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1)(h) (iv) of the Pharmacovigilance Rules, 2022, registration holders are required to include the risk of "circulatory shock", with a frequency of "not- known", in the Adverse Drug Reactions (ADRs) section of the SmPC/label of the sulfamethoxazole–trimethoprim combination, in line with the decision of EMA-PRAC; and

b. The PRAEC, as per Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022, recommended to the Registration Board to direct all registration holders of drugs containing sulfamethoxazole and trimethoprim drug combination to update the SmPC/label in light of the decisions of EMA-PRAC and PRAEC-DRAP.

vi. Semaglutide: Risk of non-arteritic anterior ischemic optic neuropathy (NAION)

Decision:

The PRAEC decided as follows: -

a. As per Rule 10 (1)(h) (iv) of the Pharmacovigilance Rules, 2022, registration holders are required to include the risk of non-arteritic anterior ischemic optic neuropathy (NAION) in the Warnings and Precautions section and list it with a frequency of "very rare" in the Adverse Drug Reactions (ADRs) section of the SmPC/label of semaglutide-containing medicines registered in Pakistan, in line with the decisions of EMA-PRAC and WHO; and

b. The PRAEC as per Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022, recommended to the Registration Board to direct all registration holders of drugs containing Semaglutide to update the SmPC/label in light of the decisions of EMA-PRAC, WHO and PRAEC-DRAP.

Proceedings of 358th Meeting:

Mr. Abdul Mateen, Secretary PRAEC, DRAP attended the meeting and apprised the Board regarding background of the above-mentioned cases.

During deliberation on 'Domestic Cases', the Board noted that the referred case lacks essential information which is necessary to establish causality and linkage with "Inj A-Care (Atracurium) 50mg/5ml" of M/s Caraway, Rawat. However, Director DTL, Bahawalpur (Member RB) highlighted that DTL Bahawalpur has received and declared a few samples as sub-standard of M/s Caraway, Rawat including drugs used in critical care. Therefore, keeping in view the recommendation received from PRAEC, a detailed inspection shall be conducted, specifically for injectable products of M/s Caraway Pharmaceuticals, Rawat.

Decision: Registration Board decided as under:

i. **With respect to Item No. I (i.e., Domestic Cases), a detailed inspection to the extent of 'Injectable products' of Ms/ Caraway shall be conducted by a panel comprising of Director DTL, Bahawalpur and one member from, DRAP to be nominated by the Chairman, Registration Board.**
ii. **With respect to Item No. II (i.e., Reliance on International Safety Decisions), Registration Board noted the recommendations and agreed to direct the registration holders to include the updated information (in line with the RRAs) in SmPCs of the already registered products and submit it for approval in line with the DRAP's notification No. F.14-1/2022-PEC dated 19th February, 2026.**

Registration-II Section

Case No. 01: Change of contract Manufacturer from M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi before issuance of registration letter.

Following registration applications have been approved in 336th meeting *(Page # 3338-3339)* of Drug Registration Board (DRB) regarding applications of M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, on prescribed Form 5-F, for registration of Drug products by way of contract manufacturing, from M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi wherein Board approved the registration of the drug products by way of contract manufacturing.

2. Before issuance of registration letters, the applicant decided to change the contract manufacturer and submitted applications on prescribed Form 5F (CTD) Module – I only, before issuance of registration letter.

3. As per the requirement / guidelines in DRAP's Letter No. 1-2/2022-DMMC dated 13th June 2023, the applicants submitted applications on Form 5F Module I only for the formulations to be manufactured by proposed contract manufacturer i.e. M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi who already possess Previous Registration Approval of the Drug Registration Board (DRB) of same formulations with the product development and stability data.

4. Accordingly, cases have been evaluated and presented in the committee as under: -

S. #	Already registered Product Name with composition & details	Previous Contract Manufacturer	Proposed Contract Manufacturer	Details of Application & fee received	Products already Approved on CTD format for the proposed manufacturing site
1.	Biozole 30mg Capsule Each Capsule Contains: Dexlansoprazole Dual Delayed Release	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial	M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi	**Fee:** PKR 48600/- *Vide slip #* 5555103399	Bi-Dex 30mg Capsule Each capsule contains;

	Pellets Eq. to Dexlansoprazole…30 mg	Triangle, Kahuta Road, Islamabad		Tracking ID: V48-TV4-S27S **Dated** 20-02-2026	Dexlansoprazole dual delayed released pellets 22.5% eq. to Dexlansoprazole ……. 30mg (As per *Innovator's Specifications) **Reg. No.** 124507 **Meeting of RB: 339**
2.	Biozole 60mg Capsule Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole…60 mg	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad	M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi	**Fee:** PKR 48600/- *Vide slip #* 23354206275 Tracking ID: NYQ-EGH-ZM1J **Dated** 20-02-2026	Bi-Dex 60mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets) … 60mg (As per *Innovator's Specifications) **Reg. No.** 123586 **Meeting of RB: 335**

Decision: Registration Board acceded to the request of M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi for change of contract manufacturer of above mentioned products from M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi.

Case No. 02: Change of contract Manufacturer from M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi before issuance of registration letter.

Following registration applications have been approved in 324th meeting *(Page # 208-2014)* of Drug Registration Board (DRB) regarding applications of M/s Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad, on prescribed Form 5-F, for registration of Drug products by way of contract manufacturing, from M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi wherein Board approved the registration of the drug products by way of contract manufacturing.

2. Before issuance of registration letters, the applicant decided to change the contract manufacturer and submitted applications on prescribed Form 5F (CTD) Module – I only, before issuance of registration letter.

3. As per the requirement / guidelines in DRAP's Letter No. 1-2/2022-DMMC dated 13th June 2023, the applicants submitted applications on Form 5F Module I only for the formulations to be manufactured by proposed contract manufacturer i.e. M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi who already possess Previous Registration Approval of the Drug Registration Board (DRB) of same formulations with the product development and stability data.

4. Accordingly, cases have been evaluated and presented in the committee as under: -

S. #	Already registered Product Name with composition & details	Previous Contract Manufacturer	Proposed Contract Manufacturer	Details of Application & fee received	Products already Approved on CTD format for the proposed manufacturing site

1.	G-Perium Injection 500mg Each vial contains: Meropenem trihydrate eq to meropenem……500mg USP	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi	**Fee:** PKR 48600/- *Vide slip #* 5555103399 Tracking ID: W84-MZD-MTE5 **Dated** 04-09-2025	Fainum 500mg Injection Each vial contains: Meropenem trihydrate eq. to Meropenem…500mg (USP Specifications) **Reg. No.** 111766 **Meeting of RB: 312**
2.	G-Perium Injection 1g Each vial contains: Meropenem trihydrate eq to meropenem……1g USP	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi	**Fee:** PKR 48600/- *Vide slip #* 3206463078 Tracking DJ4-W1T-ZPET **Dated**04-09-2025	Fainum 1g Injection Each vial contains: Meropenem trihydrate eq to Meropenem … 1g (USP Specifications) **Reg. No.** 111767 **Meeting of RB: 312**

Decision: Registration Board acceded to the request of M/s Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat for change of contract manufacturer of above mentioned products from M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. to M/s. Biogen Life Sciences, 8-km, Chakbeli Road, Rawat, Rawalpindi.

Case No. 03: M/s. Werrick Pharmaceuticals, Plot No. 216 - 217, I-10/3, Industrial Area Islamabad.

Registration Board in its 155th meeting considered the following application of M/s. Werrick Pharmaceuticals, Plot No. 216 - 217, I-10/3, Industrial Area Islamabad. Detail is as under:

Sr. No.	Name of Drug(s)	Demanded Pack Size/Price	Decision of 155th DRB	Remarks
1.	F-M 15 Tablets Each tablet contains: Flupentixol HCl eq. to Flupentixol……..5mg Melitracen HCl eq. to Melitracen……..10mg (Anti-Depressant)	10's/ As Per SRO	Deferred	EMA approved formulation is as; "**Each film coated tablet contains:** **Flupentixol HCl eq. to Flupentixol … 0.5mg** **Melitracen HCl eq. to Melitracen … 10mg**" Product is also not available in any available addition of Pharmacopoeias.

Firm has submitted following documents;

i. Form 5
ii. Photocopy of fee challan of Rs.5000/- and fresh submission of Rs.38700/- dated 11-05-2026 vide challan No. 03011983655 vide tracking ID: 853-9W6-A7VL
iii. Copy of GMP Certificate issued based upon evaluation conducted dated 19-11-2025.
iv. Fee of Rs.9400/- for correction in formulation in line with RRA vide challan No. 7174389212.

Decision: Registration approved above mentioned product in the name of M/s. Werrick Pharmaceuticals, Plot No. 216 - 217, I-10/3, Industrial Area Islamabad as per following details;

"Each film coated tablet contains:
Flupentixol HCl eq. to Flupentixol … 0.5mg
Melitracen HCl eq. to Melitracen … 10mg
As per Innovator's Specifications"

Case No. 01: Report on Investigation of Authenticity / Genuineness of Product Development and Stability Data Submitted for transfer of manufacturing activities of Product Rictose 500mg/10ml Injection Reg No. 124919.

Background:

The firm M/s Winlet Pharmaceuticals (Pvt) Ltd had applied for post registration variation to transfer manufacturing activities of their product Rictose 50mg/10ml injection Registered vide No. 124919 from M/s Bio-Labs Islamabad to M/s Welwrd Pharmaceuticals Hattar. The application was submitted on eapp vide tracking ID ZRU-S8Q-DGQU.

M/s Welwrd pharmaceuticals Hattar holds registration of same product by name Irofec Injection (500mg/10ml) vide No.110275. The registration was issued on 10.12.2021. The firm M/s Winlet Pharma had submitted dossier that they had received from M/s Welwrd pharma for transfer of manufacturing activities. The dossier of M/s Welwrd pharma was submitted as per CTD guidance document.

Multiple typographic mistakes were observed in the submitted dossier. For example, the sample preparation referred to tablets, whereas the product under consideration was a concentrate for infusion. Additionally, in the initial submission, the iron content was stated to be assessed by a UV method, while the assay method described a titrimetric approach. The firm was asked to clarify these discrepancies and responded that they were typographical errors.

Based on above findings, the Chairman Registration Board constituted following panel of experts for onsite investigation to confirm genuineness / authenticity of product development data, stability data and associated documents, import of API, quality, specification, test analysis and facilities etc.

Composition of Panel:

1. Ms. Sana Kanwal, Deputy Director PRV, PE&R Division, DRAP Islamabad.
2. Mr. Adil Saeed, Deputy Director PEC, PE&R Division, DRAP Islamabad.

The firm M/s. Welwrd pharmaceuticals Hattar was inspected for the mentioned purpose on Thursday, 16th April, 2026. The report as per attached proforma/ questionnaire is being submitted for perusal and further necessary action.

Sr. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	Clearance certificate vide No. E-1952148409536 dated 15.07.2022 mentioning 10kg drug substance was submitted. The firm was involved in active production of Ferric Carboxymaltose injection as they already have registration of the same formulation. The material used in manufacturing of trial batches was imported in 2022 and was consumed. Resent import was of 10kg drug substance and it was also consumed in manufacturing of batches for market.
2.	What was the rationale behind selecting the particular manufacturer of API?	It was based on documentation.

3.	Do you have documents confirming the import reference standard and impurity standards?	Working standards were present and their invoices were not present.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	COA was available.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	GMP certificate and DML is submitted in dossier.
6.	Do you use API manufacturer method of testing?	Firm was using similar method for titration for assessment of Iron content as the one which was mentioned in DMF.
7.	Do you have stability studies reports on API?	Provided
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability was performed as per in-house method. Degradation products were not being tested.
9.	Do you have method for quantifying the impurities in the API?	Method from drug substance manufacturer was available and is also submitted with the dossier.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Only small quantity of working standard was present.
11.	Have you used pharmaceutical grade excipients?	Yes
12.	Do you have documents confirming the import of the used excipients?	Not Applicable
13.	Do you have test reports and other records on the excipients used?	Not Applicable
14.	Do you have written and authorized protocols for the development?	Yes
15.	Have you performed Drug-excipients compatibility studies?	No excipients are being used in this product. Product is manufactured by dissolving the drug substance in bulk water for injection. If pH adjustment is needed then HCl or Sodium hydroxide solution is used.
16.	Have you performed comparative dissolution studies?	NA
17.	Do you have product development (R&D) section	Separate R&D Department was not present.
18.	Do you have necessary equipment's available in product development section for development of new product?	NA
19.	Are the equipment in product development section qualified?	NA
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD Section?	NA

21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Production and QC technical persons were involved in active product development.
22.	Have you manufactured three stability batches for the stability studies of new product as required?	3 trial batches were manufactured. Each was of 400 vials. Batch No. W-01, W-02, W-03 Batches were manufactured in 08.2024. Samples were still placed on long term stability studies.
23.	Do you have any criteria for fixing the batch size of stability batches?	SOP was available.
24.	Do you have complete record of production of stability batches?	BMRs were available.
25.	Do you have protocols for stability testing of stability batches?	Protocols were present
26.	Do you have developed and validated the method for testing of stability batches?	Standard analytical procedure of the own product was used for testing stability batches.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any otherlab?	NA
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes
29.	Do your method of analysis stability indicating?	Yes
30.	Do your HPLC software is21CFR compliant?	Not Applicable The analytical method was not based on HPLC
31.	Can you show Audit Trail reports on New product testing?	N.A
32.	Do you have some remaining quantities of degradation products and stability batches?	N.A
33.	Do you have stability batches kept on stability testing?	Yes, some samples of stability batches were present in stability chamber. Retained samples of marketed batches were also present.
34.	Do you have valid calibration status for the equipments used for production and analysis of new product?	Available.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Yes.
36.	Are related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

Proceedings of Inspection:

The plant manager accompanied the panel during inspection. Plant manager was also working as QC incharge of the firm. The main focus of the inspection was on Quality testing of the product mainly the assay because firm has submitted variable methods for it.

2. On site method for assay of Iron content in Iron Carboxymaltose injection adopted by the firm was indirect titration method, based on Iodine-Sodium thiosulfate titration. The theory behind this method to assess the ferric content is that the ferric ions liberated after digestion of carboxymaltose complex reduce Iodide ions (from excess of potassium iodide) into elemental iodine. 2 moles of Ferric 3+ ions oxidize 2 moles of Iodide –ve ions resulting in formation of 1 mole of iodine (I_2). Then this generated iodine is measured by reducing it back to iodide by titrating it against 0.1N sodium thiosulphate solution. The firm was using 1ml of injection to assess the iron content. 1ml of the injection should contain 50mg elemental iron as per the approved label claim.

3. The indicator used to assess Iodine generated is freshly prepared starch solution. Iodine gives dark blue to black water insoluble complex with starch. As it converts back to iodide ion, it can no longer form the coloured complex with starch. This change of colour from blue-black to colourless is very instant and considered as the end point of the titration.

4. After titrating, following formula was used by the firm to calculate percent iron content;

$$Percentage\ of\ Iron\ Content\ = \frac{Volume\ of\ Titrant\ Used \times Iron\ Factor}{Equivalent\ weight\ of\ Iron} \times 100\%$$

Where;

- Volume of titrant = Amount of 0.1N/0.1M Sodium thiosulfate Solution consumed.
- Iron Factor = Firm was using 5.505 (literature suggests that 1ml of 0.1M sodium thiosulfate should be equal to 5.5845mg of Iron)
- Equivalent weight of Iron = 50mg (because 1ml of injection was used which should have 50mg Iron)

5. During onsite inspection 2 samples of trial batches placed on long term stability were checked and 1 sample of retained sample of Irofec marketed batch. In all 3 cases 7ml of 0.1M sodium thiosulfate solution caused the disappearance of blue-black colour of starch-iodine complex. If we calculate Iron content from formula used by the firm, it comes out to be less than 80% (around 78%). The technical persons of the firm kept insisting that we should keep running the titration upto 9ml as the solution was slightly yellow and end point is colourless instead of disappearance of blue-black precipitates.

6. The technical persons of the firm were also adding $KMnO_4$ in the titration mixture which was totally unnecessary and had no scientific justification. (it could potentially oxidize iodide to iodine, which would further affect the assay resulting in false higher results of total iron content.)

7. Further firm had a pack of FCM injection manufactured by M/s Genix pharma. We tested it too at the same time to verify if there was any issue with the reagents or otherwise. In its assay, blue-black precipitates completely disappeared when 9ml of 0.1M sodium thiosulfate solution was consumed, making its assay at 100.5%.

8. Above findings indicated that the trial batches manufactured by the firm M/s Welwrd Pharma were not of standard quality. Apart from this, their marketed batches also appeared to have an assay of 78.183%.

9. The technical persons of the firm did not agree with us on matter of colour change at end point of titration and they were of the opinion that disappearance of blue-black colour is not the end point, rather yellow colour vanishing from the titration flask should be considered as end point of the titration.

Conclusion and Recommendations;

Keeping in view the above findings of the product specific inspection for assay method of Ferric Carboxymaltose injection manufactured by M/s Welwrd Pharmaceuticals Hattar, the panel unanimously recommends following points for consideration of the Registration Board;

1. The ferric carboxymaltose injection manufactured by the firm M/s Welwrd pharmaceuticals appears to be substandard as its assay for iron content was found to be less than 90% at time of inspection.
2. There was a need for additional technical staff in the QC lab, as there was only one full-time QC analyst, supported by an undergraduate intern assisting with testing. Furthermore, the lab was congested and lacked sufficient space to effectively carry out both in-process and finished product release testing.
3. Iron content testing by titrimetric method requires technical expertise and interpretation of end point can be perceived differently by different persons based on their technical expertise. It also gives opportunities to achieve results of one's own choice by changing concentrations of reagents or by overshooting the titrants. Due to this reason, it is recommended to consider making use of atomic absorption spectrophotometric method mandatory for assessment of iron content in injectable iron preparations.
4. It is also recommended to issue an advisory to all testing laboratories (DTLs and CDL) to use their own developed method for assessment of Iron content in Iron containing injectables instead of relying on testing methods submitted by the manufacturers for assessment of iron content while their own products are being tested at government testing laboratories.

Decision: Registration Board deliberated the matter and decided to:-

1) Issue show cause under section 42 of the Drugs Act, 1976 to proposed manufacturer i.e M/s Welwrd pharmaceuticals:-

    a. As the retained sample of Ferric carboxymaltose injection (Irofec Injection 500 mg/10 ml, Reg. No. 110275) was found to be of substandard quality by a panel during course of inspection.
    b. There was only 1 technical staff in the QC lab supported by an undergraduate intern assisting him with testing.
2) The Board advised all testing laboratories (DTLs and CDL) to use validated methods for assessment of Iron content in Iron containing injectables instead of relying on testing methods submitted by the manufacturers for assessment of iron content.
3) Referred the case to the Licensing Division to check the qualified persons of M/s. Welwrd Pharmaceuticals, Hattar.

Case No.02: DELEGATION OF FUNCTIONS

The Registration Board delegated the following functions to the Chairman of the Registration Board on behalf of the Registration Board concerning pre- and post-registration variations:

Sr. No.	Functions

M-307	
1.	Relaxation / exemption in Urdu version only for drugs imported for critical ailments like AIDS, cancer, vaccines, sera etc. subject to the condition that same shall be printed at any licensed premises prior to marketing.
2.	Export Registration of finished drugs for following categories except Narcotic, Psychotropic drugs and precursor chemicals. • Generic version / me too drugs of already registered formulations. • Formulations which have already been registered for export purposes. • Formulations which are approved by reference regulatory authorities (as approved by Registration Board) and yet not registered for local sale.
3.	Change of name of the manufacturer of imported drug(s).
4.	Increase/ decrease in shelf life of registered drug.
5.	Grant of additional packing of already registered same drugs/medicines except injectables. (For Veterinary Drugs only)
6.	Action initiated on safety of drugs.
7.	Change of packing from: • PVC to Alu-Alu and vice-versa • strip to blister and vice-versa • strip/blister to bottle and vice-versa • glass bottle to PET/HDPE bottle and vice-versa • PET bottle to HDPE bottle and vice-versa • Vial to ampoule and vice-versa • Glass vial/ampoule to plastic ampoule and vice-versa • Glass vial/ampoule to pre-filled syringe and vice-versa
8.	Change in labeled storage conditions of imported product
9.	Change of source/grant of additional source of half-finished products like pellets, bulk liquid and granules etc. of registered drugs.
10.	Constitution of panel of inspector for product specific inspection, verification of stability data, GMP inspection and dosage form specific inspection of manufacturer abroad etc.
11.	Correction of typographic errors in recording minutes and registration letters like composition, brand names, demanded price, pack size, address (as per DML/DSL) etc. or other typing mistakes.
12.	Change in the packing design/packaging components/ change in label, carton/change in shape, colour of Capsule, Tablets and shape of blister/ aluminum foil.
13.	Change of brand names of registered drug(s).
14.	To grant approval of exemption from inspection of manufacturer abroad as per Import Policy for inspection of finished drugs.
15.	To grant approval for issuance of registration letter(s) on recommendation of inspection panel nominated for inspection of manufacturer abroad.
16.	Correction in formulation in accordance with standard formulations approved by reference regulatory authorities i.e. change from uncoated to film/ sugar/enteric coated tablet or vice versa and correction in base / salt / ester / form of API.
17.	Grant of registration of diluents as combo packs for already registered/approved drugs provided that such diluents shall be provided free of cost.
18.	Issuance of registration letters in approved cases of ciprofloxacin granules for oral suspension containing ciprofloxacin base where revision / correction of salt form and granules of the formulation is required after submission of requisite fee. All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product.

	• Soya lecithin • Medium chain triglycerides • Flavor • Sucrose • Purified water.
19.	Approval of change of registration status from old title/name of the firm to the new title/name of the firm (If site remains the same)
20.	Approval of change/correction of finished product specifications in different scenarios mentioned as under: i. Products registered with manufacturer specifications but formulation exist in official monograph (as decided by Registration Board in 267th meeting) ii. Products registered with any pharmacopoeial specification (e.g. USP) but formulation do not exist in that particular pharmacopeia but another pharmacopeia (e.g. BP). iii. Correction in specification while issuance of registration letters in accordance with decisions taken in 264th, 266th & 267th meetings of Registration Board. iv. Product approved/registered with any pharmacopoeial specification but formulation do not exist in any official monograph. v. Change of specifications from one official pharmacopeia to another official pharmacopeia. vi. Manufacturer/innovator specifications for a product are more stringent than official pharmacopoeial specifications.
21.	Grant of renewal of registration (locally Manufactured) which have been received within time as required under Rule 27 of Drug (LR&A) Rules 1976.
22.	Grant of extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.
23.	Change of contract manufacturer/ manufacturing site of already registered products.
24.	Issuance of show cause notice for cancellation of registration after termination of agency authorization by Manufacturer / Product License Holder.
25.	Issuance of show cause notice for cancellation of registration after cancellation of DML
M-316	
26.	Approval of product license holder/Market Authorization Holder including incorporation of exporter (if required) by the firm.
27.	Change of manufacturer from self to contract manufacturer Registration Board deliberated that as case pertains to contract manufacturing of already registered drug products thus authorized its Chairman for approval of contract manufacturing permission after rectification of identified shortcomings and product specific inspection.
M-323	
28.	Grant of approval/ recommendation for procurement of controlled drug substances/ innovator's drug product pack/ reference and impurity standards etc. for trial/ development & stability purposes
29.	Issuance of show cause notice for cancellation of registration in case of non-compliance of shortcoming letters
30.	Delegation 323rd RB, Export registration of Narcotic, Psychotropic drugs and precursor chemicals: Registration Board authorized its Chairman for export registration of Narcotic, Psychotropic drugs and precursor chemicals subject to availability of approved requisite manufacturing facility and NOC from Ministry of Narcotics Control.
M-336	
31.	Change of name & address of Product License Holder (Local)

32.	Change/Update in name & address of API/ Half-finished product manufacturer.
33.	Addition and or Replacement of manufacturing site of API.
34.	Change/ Update of Analytical Procedures of finished product in case of Pharmacopoeial methods.
35.	Change of Marketing Authorization Holder in Pakistan
M-343	
Import in international packs and local printing	
Change of importer (from one firm to another)	
Grant of additional pack size of drugs (non-essential medicines) except injectable	
M-345 1. To facilitate the export of drug products and to expedite the Export only registrations; Registration Board authorized its Chairman for grant of registration for Export Purpose only to formulations which are neither available in RRAs nor have Me-Too.	
M-346	
Regularization of Renewal for applications received after due date (within 1 year)	
M-347	
Registration Board authorized its Chairman for all such cases of change in registration status from finished import to local manufacturing (where source of drug substance remains the same).	

In addition to above mentioned functions following functions are hereby proposed to be delegated to Chairman as under:

1) Standardization/change of formulation in accordance with the innovator's product/ approvals of reference regulatory authorities/ pharmacopeias/WHO recommendation

   - Proposed change (qualitative/quantitative) is in line with RRA/innovator's product.
   - Existing formulation is not in accordance with the innovator's product/ approvals of reference regulatory authorities/ pharmacopeias/WHO recommendation

2) Changes/update in Labelling & Prescribing Information and/or SmPC as per RRA/Innovator.

3) Issuance of show cause notice for cancellation of registration in case of non-availability of manufacturing facility/ relevant section.

4) Issuance of renewal of the products.

Decision: The Registration Board has endorsed/approved the delegation of the following functions to the Chairman for disposal of matters:-

Sr. No.	**Functions**
M-307	
1.	Relaxation / exemption in Urdu version only for drugs imported for critical ailments like AIDS, cancer, vaccines, sera etc. subject to the condition that same shall be printed at any licensed premises prior to marketing.
2.	Export Registration of finished drugs for following categories except Narcotic, Psychotropic drugs and precursor chemicals. • Generic version / me too drugs of already registered formulations. • Formulations which have already been registered for export purposes.

	• Formulations which are approved by reference regulatory authorities (as approved by Registration Board) and yet not registered for local sale.
3.	Change of name of the manufacturer of imported drug(s).
4.	Increase/ decrease in shelf life of registered drug.
5.	Grant of additional packing of already registered same drugs/medicines except injectables. (For Veterinary Drugs only)
6.	Action initiated on safety of drugs.
7.	Change of packing from: • PVC to Alu-Alu and vice-versa • strip to blister and vice-versa • strip/blister to bottle and vice-versa • glass bottle to PET/HDPE bottle and vice-versa • PET bottle to HDPE bottle and vice-versa • Vial to ampoule and vice-versa • Glass vial/ampoule to plastic ampoule and vice-versa • Glass vial/ampoule to pre-filled syringe and vice-versa
8.	Change in labeled storage conditions of imported product
9.	Change of source/grant of additional source of half-finished products like pellets, bulk liquid and granules etc. of registered drugs.
10.	Constitution of panel of inspector for product specific inspection, verification of stability data, GMP inspection and dosage form specific inspection of manufacturer abroad etc.
11.	Correction of typographic errors in recording minutes and registration letters like composition, brand names, demanded price, pack size, address (as per DML/DSL) etc. or other typing mistakes.
12.	Change in the packing design/packaging components/ change in label, carton/change in shape, colour of Capsule, Tablets and shape of blister/ aluminum foil.
13.	Change of brand names of registered drug(s).
14.	To grant approval of exemption from inspection of manufacturer abroad as per Import Policy for inspection of finished drugs.
15.	To grant approval for issuance of registration letter(s) on recommendation of inspection panel nominated for inspection of manufacturer abroad.
16.	Correction in formulation in accordance with standard formulations approved by reference regulatory authorities i.e. change from uncoated to film/ sugar/enteric coated tablet or vice versa and correction in base / salt / ester / form of API.
17.	Grant of registration of diluents as combo packs for already registered/approved drugs provided that such diluents shall be provided free of cost.
18.	Issuance of registration letters in approved cases of ciprofloxacin granules for oral suspension containing ciprofloxacin base where revision / correction of salt form and granules of the formulation is required after submission of requisite fee. All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product. • Soya lecithin • Medium chain triglycerides • Flavor • Sucrose • Purified water.
19.	Approval of change of registration status from old title/name of the firm to the new title/name of the firm (If site remains the same)

20.	Approval of change/correction of finished product specifications in different scenarios mentioned as under: vii. Products registered with manufacturer specifications but formulation exist in official monograph (as decided by Registration Board in 267th meeting) viii. Products registered with any pharmacopoeial specification (e.g. USP) but formulation do not exist in that particular pharmacopeia but another pharmacopeia (e.g. BP). ix. Correction in specification while issuance of registration letters in accordance with decisions taken in 264th, 266th & 267th meetings of Registration Board. x. Product approved/registered with any pharmacopoeial specification but formulation do not exist in any official monograph. xi. Change of specifications from one official pharmacopeia to another official pharmacopeia. xii. Manufacturer/innovator specifications for a product are more stringent than official pharmacopoeial specifications.
21.	Grant of renewal of registration (locally Manufactured) which have been received within time as required under Rule 27 of Drug (LR&A) Rules 1976.
22.	Grant of extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.
23.	Change of contract manufacturer/ manufacturing site of already registered products.
24.	Issuance of show cause notice for cancellation of registration after termination of agency authorization by Manufacturer / Product License Holder.
25.	Issuance of show cause notice for cancellation of registration after cancellation of DML
26.	Approval of product license holder/Market Authorization Holder including incorporation of exporter (if required) by the firm.
27.	Change of manufacturer from self to contract manufacturer Registration Board deliberated that as case pertains to contract manufacturing of already registered drug products thus authorized its Chairman for approval of contract manufacturing permission after rectification of identified shortcomings and product specific inspection.
28.	Grant of approval/ recommendation for procurement of controlled drug substances/ innovator's drug product pack/ reference and impurity standards etc. for trial/ development & stability purposes
29.	Issuance of show cause notice for cancellation of registration in case of non-compliance of shortcoming letters
30.	Delegation 323rd RB, Export registration of Narcotic, Psychotropic drugs and precursor chemicals: Registration Board authorized its Chairman for export registration of Narcotic, Psychotropic drugs and precursor chemicals subject to availability of approved requisite manufacturing facility and NOC from Ministry of Narcotics Control.
31.	Change of name & address of Product License Holder (Local)
32.	Change/Update in name & address of API/ Half-finished product manufacturer.
33.	Addition and or Replacement of manufacturing site of API.
34.	Change/ Update of Analytical Procedures of finished product in case of Pharmacopoeial methods.
35.	Change of Marketing Authorization Holder in Pakistan
36.	Import in international packs and local printing
37.	Change of importer (from one firm to another)
38.	Grant of additional pack size of drugs (non-essential medicines) except injectable
39.	Registration Board authorized its Chairman for grant of registration for Export Purpose only to formulations which are neither available in RRAs nor have Me-Too.
40.	Issuance of Renewal for already registered products.

41.	Change in registration status from finished import to local manufacturing (where source of drug substance remains the same)
42.	Standardization/change of formulation in accordance with the innovator's product/ approvals of reference regulatory authorities/ pharmacopeias/WHO recommendation • Proposed change (qualitative/quantitative) is in line with RRA/innovator's product. • Existing formulation is not in accordance with the innovator's product/ approvals of reference regulatory authorities/ pharmacopeias/WHO recommendation
43.	Changes/update in Labelling & Prescribing Information and/or SmPC as per RRA/Innovator.
44.	Issuance of show cause notice for cancellation of registration in case of non-availability of manufacturing facility/ relevant section.

Case No. 0.3: <u>ISSUE REGARDING MECOBALAMIN INJECTION DOSAGE FORM: MANUFACTURER METHOD OF ANALYSIS</u>

A letter is received from Director DTL Punjab, Bahawlapur wherein a technical concern regarding the manufacturer methods' of **Mecobalamin Injection** products in Pakistan, is highlighted. The observations related to analytical techniques, identification methodologies, and potential implications for product quality and patient safety are presented.

The content of said letter is provided below:

*In recent years, the number of registered mecobalamin products has grown significantly. Due to the lack of an official compendial monograph, these products are commonly registered based solely on **Innovator Specs / Manufacturer Specifications (MS)**. A review of available dossiers and analytical methods indicates that **most of these manufacturer methods rely on UV spectrophotometric techniques** for both identification and assay determination without any method for impurity/ related substances analysis.*

*While UV spectrophotometry remains a widely accepted analytical tool, certain limitations have been observed in its application within these specifications. In many cases, the UV-based identification method relies exclusively on matching the **maximum absorbance (λmax)** without conducting a **full spectral scan**, as Mecobalamin Standard have specific spectral configuration with four maxima on specific characteristic wavelengths and the samples having **manufacturer methods with UV-Vis spectrophotometric techniques** do not correspond with standard hence need further analysis utilizing chromatographic methods (HPLC).*

*When of these products are analysed using the **Innovator's method** (copy attached) of analysis (which is similar to that of **USP / JP Compendial Monograph for "Mecobalamin Tablets"),** which encompasses HPLC method for identification and quantification, has revealed noteworthy findings. Chromatographic evaluation frequently demonstrated **multiple peaks**, in certain **mecobalamin injection samples**, rather than a singular principal peak. These additional peaks are further characterized as **hydroxocobalamin,** formulation-related excipients **or cyanocobalamin** (as adulteration).*

Recently, various samples of Mecobalamin injection (multiple brands) from field & government supply are reported/ declared as falsified (Substandard/Adulterated) on the basis of qualitative & quantitative analysis.

Drug Form	Brand Name	Batch No.	Manufacturer	Test Details
Injection	Cobamin	25BA04	Friends Pharma (Pvt) Ltd.	Adulterated

Injection	Benbala 500µg	25G022	Biogen Life Sciences	Sub Standard, Adulterated
Injection	Hicobal	HT13437	Himont Pharmaceuticals (Pvt.) Ltd.	Sub Standard, Adulterated
Injection	Hancobal	G-991	Hansel Pharmaceuticals (Pvt.) Ltd.	Sub Standard
Injection	Hancobal	G-991	Hansel Pharmaceuticals (Pvt.) Ltd.	Sub Standard
Injection	Neocobal	S-2825	Pulse Pharmaceuticals (Pvt.) Ltd.	Sub Standard, Adulterated
Injection	Remedy	R-2419	Pak Risen Pharmaceuticals	Sub Standard, Adulterated
Injection	Remedy	R-2411	Pak Risen Pharmaceuticals	Sub Standard, Adulterated
Injection	Benbala 500ug	24G001	Biogen Life Sciences	Sub Standard, Adulterated
Injection	Neocobal	S-2455	Pulse Pharmaceuticals (Pvt.) Ltd.	Sub Standard, Adulterated
Injection	Anacobin 500ug, 1ml	AF133	Epharm Laboratories	Sub Standard, Adulterated
Injection	Methimor Inj 500mcg	MMI003	English Pharmaceutical Industries, Lahore	Sub Standard
Injection	REMEDY 1ML	R-2406	PAK RISEN PHARMACEUTICALS	Sub Standard

Given the therapeutic importance of Mecobalamin and its widespread clinical use, it may be prudent to consider the following actions:

1. As there is no official/compendial (USP, BP, EP, IP and JP) monograph of Mecobalamin Injection Dosage Form, which highlights the concern regarding stability of such dosage form of Mecobalamin.
2. Development or adoption of a method for qualitative and quantitative analysis based on chromatographic techniques (considering reference monographs Mecobalamin Tablets USP / JP).
3. Encouragement of impurity profiling requirements and stability-indicating chromatographic methods.

These measures would contribute toward ensuring analytical consistency, regulatory uniformity, and sustained product quality.

This letter is intended solely as a constructive communication and improvement, aimed at strengthening quality assurance practices. I would welcome the opportunity to provide further data, analytical findings, or collaborative support if required.

Your urgent attention to this matter is required to improve the quality of the product for the health of general public.

Decision: The Registration Board, after deliberation, concluded that chromatographic evaluation (HPLC) can detect multiple impurity peaks, such as hydroxocobalamin and cyanocobalamin, in mecobalamin injection, in contrast to UV spectrophotometry, which reflects only a single principal peak. Accordingly, all manufacturers of mecobalamin injections are directed to adopt the HPLC method for analysis of the said formulation.

Case No. 1: Data requirements for registration granted in the light of 180th and 199th Authority meeting:

Registration Board has been considering applications for registration in various meetings For disposing of all such cases where registration has become invalid on administrative grounds in the light of following decision:

"*The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:*

i) Shall be considered out-of-queue and

ii) Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1)/2018 dated 08th June, 2018

It is hereby submitted that the firm may be required to furnish product development studies, stability data, process validation and analytical validation studies, as the subject products were initially registered on the basis of commitments to conduct process validation studies and generate stability data covering the approved shelf life period.

Moreover, firms should be advised not to use the decision for undue financial benefit. Only those applications should be submitted in cases where renewal applications were inadvertently overlooked and a lapse of one year has occurred, for which renewal cannot be regularized in the light of S.R.O. 1005(I)/2017.

Decision: The Registration Board deliberated the matter and resolved to propose recommendations to the DRAP Authority for either withdrawal of the exemption granted to Form 5F/CTD applications or, alternatively, for mandatory submission of product development and stability data**.**

Case No.02. M/s Wenovo Pharmaceuticals Plot No. 31 & 32 Punjab Small Industrial Estate, Taxila Rawalpindi

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**	Wencin 500mg Injection
	Composition	Each Vial Contains: Vancomycin as Hydrochloride……..…500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **W4W-39J-9PAH**)
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's As per SRO.
	Me-too status	Vencoben 500mg IV Injection Registration No: 111737
	RRA Status	VANCOMYCIN 500mg INJECTION USFDA APPROVED
	GMP Status	GMP certificate based on inspection conducted on 13-12-2024. Valid till 12-12-2027

		Dry Powder Injectable Vial Section (General) granted on 06th February 2025
	Remark of the Renewal section	Registration of **Wencin 500mg Injection** (085366) is cancelled due to non-submission of renewal application within prescribe time period
	Decision: Approved	
2.	**Brand Name + Dosage Form and Strength**	Wencin 1000mg Injection
	Composition	Each Vial Contains: Vancomycin as Hydrochloride……..…1000mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **W4W-39J-9PAH**)
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1's As per SRO.
	Me-too status	Vencoben 1000mg IV Injection Registration No: 111738
	RRA Status	VANCOMYCIN 1000mg INJECTION USFDA APPROVED
	GMP Status	GMP certificate based on inspection conducted on 13-12-2024. Valid till 12-12-2027 Dry Powder Injectable Vial Section (General) granted on 06th February 2025
	Remark of the Renewal section	Registration of **Wencin 1gm Injection** (085365) is cancelled due to non-submission of renewal application within prescribe time period
	Decision : Approved	

Case No.03. M/s. Weather Folds Pharmaceuticals Plot No. 62/2 Phase-II Industrial Estate Hattar

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**	ARTHAM 280mgTablet
	Composition	Each Tablet Contains: Artemether (USP)…….40 mg Lumefantrine (USP)……240 mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Altis DS 40mg/240mg Tablet (076680) of Ray Pharma.
	RRA Status	ARTEMETHER + LUMAFANTRINE 280MG TABLET (WHO Approved)
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of ARTHAM 280mgTablet (052937) is cancelled due to non-submission of renewal application within prescribed time period

		Applied formulation is available in International Pharmacopeia
	Decision: Approved. Firm will revise specifications along with fee (as per SRO) on account of pre-registration variation.	
2.	**Brand Name + Dosage Form and Strength**	ARTHAM 140mg Tablet
	Composition	Each Tablet Contains: Artemether…….20mg Lumefantrine ……120mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Artemate Plus 20/120 Tablet (058209) of SAFE PHARMACEUTICAL.
	RRA Status	ARTEMETHER + LUMAFANTRINE 140mg TABLET (WHO Approved)
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance.
	Remark of the Renewal section	Registration of ARTHAM 140mg Tablet (052936) is cancelled due to non-submission of renewal application within prescribe time period **Applied formulation is available in International Pharmacopeia**
	Decision: Approved. Firm will revise specifications along with fee (as per SRO) on account of pre-registration variation	
3.	**Brand Name + Dosage Form and Strength**	ARTHAM 560mg Tablet
	Composition	Each Tablet Contains: Artemether …….80mg Lumefantrine ……480mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: VBY-1VZ-9DTX)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Altis DS 80mg/480mg Tablet (076681) of Ray Pharma.
	RRA Status	ARTEMETHER + LUMAFANTRINE 560mg TABLET (WHO Approved)
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of ARTHAM 560mg Tablet (060149) is cancelled due to non-submission of renewal application within prescribed time period **Applied formulation is available in International Pharmacopeia**
	Decision: Approved. Firm will revise specifications along with fee (as per SRO) on account of pre-registration variation	
4.	**Brand Name + Dosage Form and Strength**	CIPROFOLD 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Ciprofloxacin as Hydrochloride (USP)……..…….250mg

	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Ciscap 250mg Tablet (029448) of Bloom Pharmaceuticals (Pvt) Ltd.
	RRA Status	CIPROFLOXACIN 250mg Tablet MHRA APPROVED
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of CIPROFOLD 250mg Tablet (052948) is cancelled due to non-submission of renewal application within prescribe time period
	Decision: Approved	
5.	**Brand Name + Dosage Form and Strength**	CIPROFOLD 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Ciprofloxacin as Hydrochloride (USP)……..…….500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Ciscap 500mg Tablet (029449) of Bloom Pharmaceuticals (Pvt) Ltd.
	RRA Status	CIPROFLOXACIN 500mg Tablet MHRA APPROVED
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of CIPROFOLD 500mg Tablet (052949) is cancelled due to non-submission of renewal application within prescribe time period
	Decision: Approved	
6.	**Brand Name + Dosage Form and Strength**	LEOFOLD 250mg Tablet
	Composition	Each Film Coated Tablet contains: Levofloxacin as Hemihydrate ….....250mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Julevo 250mg Tablet (081916) of Jupiter Pharma.
	RRA Status	LEVOFLOXACIN 250mg Tablet MHRA APPROVED
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of LEVOFOLD 250mg Tablet (052945) is cancelled due to non-submission of renewal application within prescribe time period
	Decision: Approved	
7.	**Brand Name + Dosage Form and Strength**	LEOFOLD 500mg Tablet
	Composition	Each Film Coated Tablet contains: Levofloxacin as Hemihydrate ….....500mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5

	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Julevo 500mg Tablet (081917) of Jupiter Pharma.
	RRA Status	LEVOFLOXACIN 500mg Tablet MHRA APPROVED
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of LEVOFOLD 500mg Tablet (052946) is cancelled due to non-submission of renewal application within prescribe time period
	Decision: Approved	
8.	**Brand Name + Dosage Form and Strength**	CHOOZ 100mg Tablet
	Composition	Each film coated tablet contains: Iron (III) Hydroxide Polymaltose Complex eq to Elemental Iron……..100mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Tyzofer 100mg Tablet (109394) of Jinnah Pharmaceuticals Pvt Ltd
	RRA Status	TGA APPROVED
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of CHOOZ 100mg Tablet (060135) is cancelled due to non-submission
	Decision: Approved	
9.	**Brand Name + Dosage Form and Strength**	P-DEXT 20mg Tablet
	Composition	Each Tablet contains: Piroxicam Beta Cyclodextrin 191.2mg eq. to Piroxicam…....20mg
	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **VBY-1VZ-9DTX**)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Piroxibet 20mg Tablet (054939) of Lawari international
	RRA Status	Approved by AIFA Italy
	GMP Status	GMP inspection conducted on 17-10-2023. Operating at satisfactory level of GMP compliance
	Remark of the Renewal section	Registration of P-DEXT 20mg Tablet (052943) is cancelled due to non-submission
	Decision: Approved	

Case No.04: M/s Wnsfield Pharmaceuticals Plot No. 122 Block-A Phase-V Industrial Estate Hattar

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**	Alwel Tablet 100mg
	Composition	Each film coated Tablet Contains: Aceclofenac……100mg

	Dairy No. date of R &I fee	Rs.38700/- (Tracking ID: **R92-TAY-6JMH**)
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO.
	Me-too status	Acefen 100mg Tablet (0558813) of-Semos Pharmaceuticals PVT LTD
	RRA Status	UK MHRA
	GMP Status	GMP certificate based on inspection conducted on 08-08-2025. Valid till 02-10-2028
	Remark of the Renewal section	Registration of **Alwel Tablet 100mg** (064161) is cancelled due to non-submission of renewal application within prescribed time period.
	Decision: Approved	

Deferred cases in 354th meeting:

Case No.05: 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-H IV Infusion
	Composition	Each 1000ml contains:- Sodium Chloride….....6.00gm Potassium Chloride.....0.400gm Sodium Lactate.....6.200gm Calcium Chloride 2H2O.....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	
	Firm has revised formulation **(TID: 43D-XJ7-467B)** in line with MHRA as under: Each 1000ml contains: Sodium Chloride …… 6.00gm Potassium Chloride …… 0.40gm Sodium Lactate ……. 3.20gm Calcium Chloride.2H2O ……. 0.27gm Also submitted fee of Rs 38,700/- vide challan 426118612695	
	Decision: Registration Board approved revised formulation in line with RRA as under: **Each 1000ml contains:** **Dextrose (as Monohydrate) …… 50.00gm** **Sodium Chloride …… 6.00gm** **Potassium Chloride …… 0.40gm** **Sodium Lactate ……. 3.20gm** **Calcium Chloride.2H2O ……. 0.27gm**	
2.	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	
	Firm has revised formulation **(TID: 8MW-JRB-ANN1)** in line with MHRA as under: Each 1000ml contains: **Dextrose (as Monohydrate) …… 50.00gm** Sodium Chloride …… 6.00gm Potassium Chloride …… 0.40gm **Sodium Lactate ……. 3.20gm** Calcium Chloride.2H2O ……. 0.27gm Also submitted fee of Rs 38,700/- vide challan 92364796467	
	Decision: Registration Board approved revised formulation in line with RRA as under: **Each 1000ml contains:** **Dextrose (as Monohydrate) …… 50.00gm** **Sodium Chloride …… 6.00gm** **Potassium Chloride …… 0.40gm** **Sodium Lactate ……. 3.20gm** **Calcium Chloride.2H2O ……. 0.27gm**	
3.	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.	
	Firm has revised formulation **(TID: 98497675734)** in line with MHRA as under: **Each 100ml contains:** **Mannitol BP …..…… 20.00gm** (BP Specifications) Also submitted fee of Rs 38,700/- vide challan **98497675734**	
	Decision: Registration Board approved revised formulation in line with RRA as under: **Each 100ml contains:** **Mannitol BP …..…… 20.00gm**	

Case No.06: M/s. Convell Laboratories pharmaceutical manufacturing Saidu sharif swat Pakistan

Following applications were considered in 354th meeting and deferred for confirmation of manufacturing facility:

1.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP.	
2.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP.	
3.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP.	
4.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP.	
5.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP.	
6.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP	
7.	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 in 354th meeting: Deferred for confirmation of manufacturing facility and updated GMP	

The Licensing division has confirmed approval (vide No.F.3-10/2025-Reg-I(M-352) (MISC) of following two sections till date:

a) Capsule section (Cephalosporin)
b) Dry Powder Suspension (Cephalosporin)

While rest of the sections were suspended by CLB in 292nd meeting held on 4th October 2025 due to collapse of building. However, inspection is under process.

Decision: Registration Board deferred the above-mentioned applications till approval of relevant manufacturing facility by the Central Licensing Board.

Recommendations of 10 Meeting of Sub-Committee on Veterinary Drugs

1. Formulations Containing Furazolidone in Veterinary Drug Products

Registration Board in its 291st meeting held on 2nd, 3rd & 4th September, 2019, while considering registration applications of various veterinary drugs containing Furazolidone, decided to issue show cause notices to all the registered veterinary formulations containing Furazolidone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects by *Furazolidone* and complete ban of the same by US-FDA and Euroepan Union, Registration Board decided to issue show cause notices to all firms having registered products containing Furazolidone under the provisions of Section 7(11) (b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976.

Accordingly show cause notice has not been issued as yet.

International status of furazolidone containing formulations from official website of USFDA accessed on dated 06-05-2026 Animal Drugs @ FDA

All listed product shows status: Prescription and Approved

Product Type **OTC ANIMAL DRUG**

Sr. #	Manufacturer	Brand Name & Composition	Indication	Target Animal
1.	Kinetic Technologies, LLC 961 Beasley St. suite 270 Lexington, Kentucky 40509 United States	**FUROX® AEROSOL POWDER** The product contains 10 percent furazolidone in inert dispersing agent and propellant.	Horses For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and following firing (heat or electrocautery). Dogs For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and pyogenic dermatitis.	Equids : Horse Dogs : Equids : Pony,
2.	Farnam Companies, Inc. 301 West Osborn Phoenix, Arizona 85013-3928 United States	Furall The product contains 4 percent furazolidone in inert dispersing agent and propellant.	Horses (and ponies) For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by Staphylococcus aureus, Streptococcus species and Proteus species sensitive to furazolidone	Equids : Horse, Equids : Pony

The Sub-Committee on Veterinary Drugs recommended furazolidone-containing topical preparations only for use in non-food-producing animals.

Decision:

The Registration Board deliberated upon the matter of furazolidone containing veterinary products and decided that only topical preparations intended exclusively for use in non-food producing animals may be considered for registration. The use of furazolidone in food-producing animals shall not be allowed in view of international regulatory practices and associated public health risks.

The Board further decided that the firms having already registered furazolidone containing formulations shall be granted a timeline of six (06) months to align their products in accordance with international practices for use only in non-food producing animals via Post Registration Variation

(PRV). In case of non-compliance within the stipulated timeline, the registration of such products shall be processed for cancellation.

2. **Formulations Containing Furaltadone in Veterinary Drug Products**

Registration Board in its 291st meeting held on 2nd, 3rd & 4th September, 2019, while considering registration applications of various veterinary drugs containing Furaltadone, decided to issue show cause notices to all the registered veterinary formulations containing Furaltadone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects by Furaltadone and complete ban of the same by US-FDA and Euroepan Union, Registration Board decided to issue show cause notices to all firms having registered products containing Furaltadone under the provisions of Section 7(11)(b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976.

Following products, containing ***Furaltadone,*** were approved in various meetings of Registration Board, but, registration letters of the said products were withheld till policy decision regarding the use of Furaltadone.

No data available from official website of reference regulatory authorities data base.

EU **Prohibited substances list**

Pharmacologically active substance	MRL
Aristolochia spp. and preparations thereof	MRL cannot be established
Chloramphenicol	MRL cannot be established
Chloroform	MRL cannot be established
Chlorpromazine	MRL cannot be established
Colchicine	MRL cannot be established
Dapsone	MRL cannot be established
Dimetridazole	MRL cannot be established
Metronidazole	MRL cannot be established
Nitrofurans (including furazolidone)	MRL cannot be established
Ronidazole	MRL cannot be established

The Sub-Committee on Veterinary Drugs recommended *Furaltadone* containing topical preparations only for use in non-food-producing animals.

Decision:

The Registration Board deliberated upon the matter of furaltadone containing veterinary products and decided that only topical preparations intended exclusively for use in non-food producing animals may be considered for registration. The use of furaltadone in food-producing animals shall not be allowed in view of international regulatory practices and associated public health risks.

The Board further decided that the firms having already registered furaltadone containing formulations shall be granted a timeline of six (06) months to align their products in accordance with international practices for use only in non-food producing animals via Post Registration Variation (PRV). In case of non-compliance within the stipulated timeline, the registration of such products shall be liable to cancellation.

3. **AMANTADINE CONTAINING FORMULATIONS**

Old registrations of amantadine veterinary products with larger pack sizes, The EWG recommended reduced pack size 100 g/100 mL through one-time variation or cancelled if not compliant, as per DRAP rules.

Decision:

The Registration Board decided that the firms having already registered amantadine-containing formulations shall be granted a timeline of six (06) months to align their products in accordance with international practices for use only in non-food producing animals and with pack sizes up to 100 gm/ml through the Post Registration Variation (PRV). In case of non-compliance within the stipulated timeline, the registration of such products shall processed for cancellation.

1.	Name and address of Applicant	M/s Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore
	Detail of Drug Sale License	Name: M/s Chakwal Pharma International Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity: 13/11/2028
		Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/S. Alfasan International B.V., Kuipersweg 9, 3449 JA Woerden The Netherland
	Name and address of marketing authorization holder	M/S. Alfasan Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland
	Name of exporting country	The Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 22591 Dated 14-09-2023
	Fee including differential fee	Rs : 150,000 Dated 01-09-2023 (Slip No. 849948788520)
	Brand Name +Dosage Form + Strength	Ceftiosan 50mg/ml Suspension for Injection
	Composition	Each ml contains: Ceftiofur as HCl…50mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Cephalosporin antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml vial
	International availability	Ceftiosan, 50 mg/ml, suspension for injection (Approved in Netherlands)
	Me-too status	Eficur Injectable Suspension 50mg/ml of M/s Hipra Pakistan (Private) Limited, Lahore. (Reg. No. 094466)
	Detail of certificates attached	➢ Original legalized COPP BD/2022/No. of Certificate 257952 dated 04-08-2022 certified by Medicines Evaluation Board Agency- Veterinary Medicinal Products Unit, Ministry of Agriculture, Nature and Food Quality, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of legalized letter of exclusive sole distributor/ authorization dated: 11-07-2022

	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. Target species: Cattle Shortcomings: • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid notarized original Letter of distribution/ sole distribution agreement since already submitted is copy.
	Decision of 340th meeting: Deferred for submission of following: • Clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid notarized original Letter of distribution/ sole distribution agreement since already submitted is copy.	
	Updated status: The firm has submitted the following: • Declaration letter that Alfasan would like to clarify that we follow international GMP guidelines, using dedicated facilities and equipment for manufacturing products containing penicillins (e.g. ampicillin, amoxicillin, etc.). The facilities and manufacturing protocols undergo regular inspections to ensure compliance with GMP guidelines. These inspections confirm that our measures to prevent cross-contamination are effective and in-line with the regulatory standards. In conclusion, Alfasan ensures compliance with GMP guidelines, minimizing cross-contamination risks across all veterinary medicinal products manufacturing processes. • Originally legalized letter of exclusive sole distributor/ authorization from Alfasan International BV in the name of Ms Chakwal pharma International.	
	Decision: (M-343) Deferred till decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. Firm reply: Firm requested for consideration via tracking id 3YR-YUN-421A as above manufacturer statement. **Decision:** **Deferred for submission of documents from concerned regulatory body showing that manufacturer have dedicated section for applied product.**	
02.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Flukacid CE Drench
	Composition	Each ml contains: Oxyclozanide …… 30mg Levamisole HCl …… 15mg Sodium Selenite ..... 0.50mg Cobalt Sulphate ……... 1.67mg
	Diary No. Date of R& I & fee	Dy. No. 23282 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 99125071)
	Pharmacological Group	Anthelmintic/ Minerals

	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	New DML
	Remarks of the Evaluator [X]	Shortcomings: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: (M-331) Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Already registered product is Lefozan Plus Oral Drench of M/s. Prix Pharma (Reg No. 075641)** **Decision: Approved**	
03.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Oxazon-Cs Oral Suspension
	Composition	Each ml contains: Oxfendazole …… 22.65mg Cobalt Sulphate ……. 0.75mg Sodium selenite ……. 0.30mg
	Diary No. Date of R& I & fee	Dy. No. 23302 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 203042981)
	Pharmacological Group	Anthelmintic, Minerals
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	New DML
	Remarks of the Evaluator [X]	Shortcomings: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: (M-331)Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Already registered product is Safen Suspension of M/s. Attabak Pharma (Reg. No. 058901)** **Decision: Approved**	

04.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Biodex Injection 50ml
	Composition	Each ml contains: Benzyl Penicillin Procaine … 125,000IU Benzathine Penicillin G … 125,000IU Dihydrostreptomycin Sulphate … 0.25g Dexamethasone Sodium Phosphate … 0.20mg Dexamethasone-21-Isonicotinate … 0.20mg
	Diary No. Date of R& I & fee	Dy. No. 23243 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 9946428151)
	Pharmacological Group	Penicillin Antibacterial/ Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	BDEX Liquid Injection of M/s. Selmore Pharmaceuticals (Reg. No. 080952)
	GMP status	New DML
	Remarks of the Evaluator [X]	Target species: Cattle, sheep
	Decision: (M-334) Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. Sub-committee on veterinary drugs recommended such formulations. **Decision: Approved**	
05.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Pen-S Vet Powder Injection
	Composition	Each vial contains: Penicillin G Procaine…30,00,000 IU Penicillin G Sodium…10,00,000 IU Dihydro Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 858 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	50ml vial (5gm); Decontrolled
	Me-too status	PG-Vet Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No.080957)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	Shortcomings: • Approval of Penicillin Injection (Veterinary) Section. • Provide conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams
	Decision of 329th meeting: Deferred for following: • Confirmation of Penicillin Injection (Veterinary) Section from Licensing Division. • conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
	Updated status: The firm has submitted the following: • Letter No. F.2-8/2011-Lic(Vol-I) dated 15-06-2021 for renewal of DML of the firm for following sections. ▪ Oral powder (Veterinary) Section ▪ Oral Liquid (Veterinary) Section ▪ Aerosol ▪ Sterile Liquid Vial Injection (Veterinary) Section ▪ Sterile Powder Vial Injection (Veterinary) Section ▪ Sterile Liquid Vial Injection Penicillin (Veterinary) Section ▪ Oral powder (Penicillin) (Veterinary) Section The firm has also submitted conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams	
	Remarks of the Evaluator: Evidence of approval of Dry Powder Penicillin Injection (Veterinary) Section is required. Shortcomings: Evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML	
	Decision of 340th meeting: Deferred for submission of evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML.	
	Updated status: The firm has submitted following as an evidence of section approval. • Grant of additional section approval letter No. F. 2-8/2011-Lic dated 11-04-2017 • GMP certificate dated 20-02-2023 (Oman) • GMP certificate dated 26-03-2024 (Myanmar) • Area FID last GMP inspection report dated 08-08-2024	
	Decision: (M-343) Deferred for submission of evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML. Reply: Firm has submitted DML renewal showing STERILE POWDER FOR INJECTABLE VIAL - Penicillin (Veterinary) dated 19th March, 2026. **Decision: Approved subject to fee for specification correction.**	
06.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (10ml)

	Composition	Each ml contains: Progestrone (USP)…25 mg
	Diary No. Date of R& I & fee	Dy.No 14577 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	PREGTONE INJECTION of M/s Star Labs. (Reg.#058711)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: (M-308) Deferred for discussion regarding requirement for steroidal manufacturing facility. Firm has submitted STERILE INJECTABLE - Hormone (Veterinary) section approval confirmation from DML renewal letter dated 19th March, 2026. **Decision: Approved**.	
07.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (50ml)
	Composition	Each ml contains: Progestrone (USP)…25 mg
	Diary No. Date of R& I & fee	Dy.No 14578 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	PROGESTONE INJECTION of M/s SYMANS Pharmaceuticals (Pvt) Ltd., Lahore Registration No 063695

	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: (M-308) Deferred for discussion regarding requirement for steroidal manufacturing facility. Firm has submitted STERILE INJECTABLE - Hormone (Veterinary) section approval confirmation from DML renewal letter dated 19th March, 2026. **Decision: Approved**	
08.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name + Dosage Form + Strength	Aspivetz-C Oral Powder
	Composition	Each Kg contains: Aspirin ……..……...67 gm Vitamin C……..……..200 gm Sodium citrate…… 0.7 gm Calcium carbonate…50 gm Sodium chloride…… 40 gm Magnesium Sulfate…40 gm
	Diary No. Date of R & I & fee	Dy No. 33030 : 04-10-2018 ; Rs. 20,000
	Pharmacological Group	Analgesic / minerals
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 gm, 150 gm, 250 gm, 500 gm, 1 Kg, 5 Kg, 25 Kg Decontrolled
	Me-too status	ACELYTE WATER SOLUBLE POWDER by M/s M/S. DECENT PHARMA, Reg No. 079821
	GMP status	Inspection report dated 26 & 27-7-2019 concludes, ”Based on the above observation their current GMP compliance level is rated as good”.
	Remarks of Evaluator	
	Decision: (M-293) Registration Board deferred the case as the formulation is under review. Sub-committee on veterinary drugs recommended such formulation. **Decision: Approved subject to fee for specification correction.**	

09.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceuticals (Private) Limited, Plot # Q-1, S.I.T.E. Kotri Sindh.
	Brand Name +Dosage Form + Strength	Vitavetz Oral Liquid
	Composition	Each 1000 ml contains:- Vitamin A……..200 mg Vitamin D…….200 mg Vitamin E……20 mg Vitamin K3…… Selenium……
	Diary No. Date of R& I & fee	Dy.No. 386, 19-6-2016, Rs.20,000/-
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	BP (Manufacturing)
	Pack size & Demanded Price	Decontrolled 100 ml, 250 ml, 500 ml, 1000 ml plastic bottle
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	NA
	GMP status	The inspection conducted on 24-10-2017 concluded as: "Maintenance of required quality of air and temperature as well as cleanliness of the facility, its design to facilitate cleaning was found nicely managed. The implementation of quality oversight and control over the manufacturing of drugs was found well attended by the entire team under their best capacity. The ability of management, enthusiasm to walk with scientific standards was visible and remarkable. The exercise to understand the entire status of compliance with emerging regulatory expectations is under way and will be recorded accordingly".
	Previous remarks of the Evaluator.	
	Previous decision	Deferred in 276th meeting for following: Clarification for strength of Vitamin K & Salanium in applied formulation. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	The firm has submitted revised Form-5 along with fee of Rs. 20,000/- (Deposit slip No. 0603127) dated 23-01-2018.

		Each 1000ml contains: Vitamin A……..30,000,000 IU Vitamin D…….1000,000 IU Vitamin E……5000mg Vitamin K3……..6000mg The submitted me-too reference "Adekbar Oral Liquid of Baariq Pharma (Reg # 073950)" has been verified.
	Decision: (M-279) Deferred for further deliberation upon revision of formulation. Sub-committee on veterinary drugs recommended such formulations. **Decision: Approved subject to fee for specification correction.**	
10.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dairytone-M Powder
	Composition	Each Kg contains: Calcium as Dicalcium Phosphate…155gm Phosphorous as Dicalcium Phosphate…135gm Magnesium as Magnesium Oxide…55gm Sodium as Sodium Chloride…45gm Iron as Ferrous Sulphate…1gm Zinc as Zinc Sulphate...3gm Manganese as Manganese Sulphate...2gm Copper as Copper Sulphate...0.6gm Cobalt as Cobalt Chloride...0.01gm Iodine as Potassium Iodide...0.04gm Selenium as Sodium Selenite...0.003gm
	Diary No. Date of R& I & fee	Dy.No 7379 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 36358257072)
	Pharmacological Group	Dietary supplement of essential macro and micro minerals
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 5Kg, 10Kg, 20Kg; Decontrolled
	Me-too status	HS-Minerals Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112272)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	Target species:

		Cattle, calves, sheep, goats Oral Powder (General) section confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal Shortcomings: The applied formulation contains different salt form of Sodium than the reference product. So, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: (M-339) Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Remarks: The composition of the me-too product is the same in all aspects except for sodium: the applied product contains sodium as sodium chloride (45 g), whereas the me-too product contains sodium as sodium sulphate anhydrous (45g). **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
11.	Name and address of manufacturer /Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Oxcel + Drench
	Composition	Each ml Contains: Oxfendazole…22.65mg Selenium…00.35mg Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 9450 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Ovizole SC Drench of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074008)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 18. Latest GMP inspection report conducted within the period of last three years. 19. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Liquid Section (General) (Veterinary)	

	Decision: Approved subject to fee for specification correction.	
12.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Alzole 10 Drench
	Composition	Each ml contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 9453 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Albamax 100 Drench of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074007)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Liquid Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
13.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Effinol Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…40mg Guaiphenesin…100mg
	Diary No. Date of R& I & fee	Dy.No 9452 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial, expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled

	Me-too status	EG Enro Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No.074099)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Liquid Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
14.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Nicilan 72 Oral Powder
	Composition	Each Gm contains: Neomycin Sulphate…720mg
	Diary No. Date of R& I & fee	Dy.No 9456 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	New-Mycin 72% Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 080133)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Powder Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
15.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad

	Brand Name +Dosage Form + Strength	Doxiro 500 W/S Powder
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 9460 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Soludox 50% W/S Powder of M/s Prix Pharmaceutica, Lahore (Reg. No. 032212)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: 3. confirmation of relevant manufacturing facility from Licensing Division. 4. latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Powder Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
16.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Broment Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg
		Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 9459 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No. 073917)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.

	Decision: Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Powder Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
17.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Linco 4.4 Oral Powder
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 9455 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Lincopri 44 Oral Powder of M/s Prix Pharmaceutica, Lahore (Reg. No. 063897)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: (M-329) Deferred for following: **0.** confirmation of relevant manufacturing facility from Licensing Division. **1.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Powder Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
18.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hepatage Oral Liquid
	Composition	Each ml contains: Vitamin E…200mg Choline Chloride…50mg
		Zinc…4mg Sorbitol…50mg Selenium…2.3mg
	Diary No. Date of R& I & fee	Dy.No 9451 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Immune booster

	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Supertone Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049629)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. 3. Solubility of formulation
	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. **3.** Solubility of formulation The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Liquid Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**	
19.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Oxyflon Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 9454 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Stenop Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089846)
	GMP status	
	Remarks of the Evaluator X	Shortcomings: 1. Latest GMP inspection report conducted within the period of last three years. 2. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.

	Decision: (M-329) Deferred for following: **1.** confirmation of relevant manufacturing facility from Licensing Division. **2.** latest GMP inspection report conducted within the period of last three years. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. Firm has submitted section approval confirmed from DML renewal letter dated 11-06-2025 (Oral Powder Section (General) (Veterinary) **Decision: Approved subject to fee for specification correction.**

Case.No.01: **REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCT.**

M/s Searle Pakistan Limited, One IBL Center, 2nd Floor, Plot No.1, Block 7&8, DMCHS, Tipu Sultan Road, Off Shahra-e-Faisal, 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.	Zerbaxa, Powder for concentrate for solution for infusion Each vial contains: Ceftolozane …1gm (eq. to 1.147g of ceftolozane sulfate) Tazobactam… 0.5g (eq. to 0.537g of tazobactam sodium) (Innovator Specification)*	115739	ZERBAXA® was never launched or commercially supplied neither marketed in Pakistan, and no ongoing patient dependency exists. Accordingly, MSD has formally requested SEARLE to initiate product registration withdrawal for ZERBAXA® in compliance with DRAP regulations.	Not alternate registered Adequate alternative antibacterial therapies are available in Pakistan within the same therapeutic spectrum as ZERBAXA®, including 3rd and 4th generation β-lactams and carbapenems, such as Ceftazidime/Avibactam, Meropenem, Imipenem/Cilastatin, and Piperacillin/Tazobactam.

Firm has submitted following supporting documents:

a. Copy of Registration letter issued on 17-01-2024.
b. Fee of Rs.12500/- for above product.
c. Justification as mentioned above.
d. 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.	Zerbaxa, Powder for concentrate for solution for infusion Each vial contains: Ceftolozane …1gm (eq. to 1.147g of ceftolozane sulfate) Tazobactam… 0.5g (eq. to 0.537g of tazobactam sodium) (Innovator Specification)*	115739

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(J49-S1S-L13M, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	**Preget CR 82.5mg Tablet**
	Label Claim	Each extended release film coated contains: Pregabalin.....82.5mg
	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 below 30 C.
	For generic drugs (me-too Status)	Brand Name: Gablin 82.5 CR Tablet Registration holder: CCL Pharmaceuticals (Pvt.) Ltd. Lahore Pakistan
	Pharmacotherapeutic Group of (API)	ATC code: N02BF02 (Gabapentinoids)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life Sciences. by CABIN NO. 3, GALA NO. D4, HOUSE NO.1414/4, GROUND FLOOR,, GLOBAL PARK COMPLEX CO. OP.SOC. LTD. ANJUR ROAD, RAHNAL VILLAGE ,BHIWANDI
	Detail of stability batches of drug product	Data of three batches of 1000 tablets each at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 25.01.2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica CR 82.5 mg Tablet batch 079983; manufacturer Upjohn Co, Kalamazoo, USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	FDA approved drug
	GMP status of the firm	GMP certificate dated 11.11.2022
	Evidence of approval of manufacturing facility	DML 00860 dated 12.06.2022
	Evaluation Remarks	
	Drug Substance Manufacturer GMP/license is on Form 25A issued by the regulatory authority of the country of origin, with the scope of API for export purpose.	
	Decision	
	Approved	

2	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(BHG-7E3-EH2W, 2024-07-23)
	Detail of Fee Submitted	30000.0, 2024-07-04,
	The proposed proprietary name / brand name	**Preget CR 165mg Tablet**
	Label Claim	Each extended release film coated contains: Pregabalin.....165mg
	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.
	For generic drugs (me-too Status)	Brand Name: Gablin 165mg CR Tablet Registration holder: CCL Pharmaceuticals (Pvt.) Ltd. Lahore Pakistan
	Pharmacotherapeutic Group of (API)	ATC code: N02BF02 (Gabapentinoids)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Progress Life Sciences. by CABIN NO. 3, GALA NO. D4, HOUSE NO.1414/4, GROUND FLOOR,, GLOBAL PARK COMPLEX CO. OP.SOC. LTD. ANJUR ROAD, RAHNAL VILLAGE ,BHIWANDI
	Detail of stability batches of drug product	Data of three batches of 1000 tablets each at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 25.01.2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Lyrica CR 165 mg Tablet batch 045214; manufacturer Upjohn Co, Kalamazoo, USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	FDA approved drug
	GMP status of the firm	GMP certificate dated 11.11.2022
	Evidence of approval of manufacturing facility	DML 00860 dated 12.06.2022
	Evaluation Remarks	
	Drug Substance Manufacturer GMP/license is on Form 25A issued by the regulatory authority of the country of origin, with the scope of API for export purpose.	
	Decision	
	Approved	
3	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(H16-UDN-GT4P, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-05-27,
	The proposed proprietary name / brand name	**Dologab Capsule 25mg**
	Label Claim	Each Capsule contains: Pregabalin.....25mg(BP Specification)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Zeegab Capsule 25mg
	Pharmacotherapeutic Group of (API)	ATC code: N02BF02 (Gabapentinoids)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Sciences, Gujarat, India
	Detail of stability batches of drug product	Data of three batches 5000 capsules at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 17.11.2022
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeegap by Hilton Pharma, Karachi batch no 151726
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Lyrica Capsule, USFDA
	GMP status of the firm	GMP certificate dated 18.03.2024
	Evidence of approval of manufacturing facility	DML No 000028 dated 28.04.2020
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
4	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Max Pharmaceuticals** Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 **(000671)**
	Application Form Dy. No / Tracking ID & date of submission	(PZ8-DE2-VMRQ, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-04-05, 2024-09-27
	The proposed proprietary name / brand name	**Prewell**
	Label Claim	Each Capsule Contains: Pregabalin BP..... 75mg The product complies BP specs.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centrigrade. Potect from light, heat and moisture.
	For generic drugs (me-too Status)	Gabica 75mg Capsules manufactured by Getz Pharma.
	Pharmacotherapeutic Group of (API)	ATC code: N02BF02 (Gabapentinoids)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Alka Laboratories Pvt. Ltd.
	Detail of stability batches of drug product	Data of three batches of 8400 capsules each at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10.01.2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gabica 75 mg by Getz Pharma, Karachi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions

	The status in reference regulatory authorities	Lyrica 75mg Capsules manufactured by Pfizer, USFDA.
	GMP status of the firm	GMP certificate dated 16.06.2023
	Evidence of approval of manufacturing facility	DML No 000671 dated 15.10.2019; Renewal 07.07.2021
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Board.	
	Decision	
	Approved	
5	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**Caraway Pharmaceuticals** PLOT NO.12, STREET NO.3 NATIONAL INDUSTRIAL ZONE RAWAT, PAKISTAN **(000629)**
	Application Form Dy. No / Tracking ID & date of submission	(U4L-JQ7-W9LT, 2025-04-25)
	Detail of Fee Submitted	37000.0, 2025-04-09,
	The proposed proprietary name / brand name	**Citograin 100mg/ml Oral Solution**
	Label Claim	Each ml contains: Citicoline Sodium Equivalent to Citicoline .....100mg (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30mL/60mL-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Between 15° to 30°C.
	For generic drugs (me-too Status)	Citolin (Citicoline Sodium) 100 mg/mL (30 mL), Registration No. 029540, By Global Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	ATC code N06BX06; psychostimulant and nootropic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Xinxiang Pharmaceuticals Co., Ltd No: 16, Jianwen Road, North District, Industrial Cluster zone, Yanjin country, Xinxiang city, Henan, China.
	Detail of stability batches of drug product	Three Stability Batches of Drug Product, Batch No.(s) 24CTL001, 24CTL002, 24CTL003 (Batch size 500 Bottles Each batch), are attached in section No. 3.2.P.8.3 in Module-3
	Documents for the procurement of API with approval from DRAP (in case of Import)	Document for Procurement of API
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence studies
	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	Somazine 100 mg/ml oral solution By Ferrer Internacional S.A. Gran Vía de Carlos III, 94 08028 – Barcelona Spain. (CIMA Spain Approved).
	GMP status of the firm	GMP Certificate dated 07th August 2024
	Evidence of approval of manufacturing facility	Section Approval Letter dated 04th July 2022
	Evaluation Remarks	

	The primary container closure system for referenced product is glass whereas the applicant is using PET bottles	
	Decision	
	Approved	
6	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)**
	Application Form Dy. No / Tracking ID & date of submission	(HQT-W4L-SR52, 1970-01-01)
	Detail of Fee Submitted	30000.0, 7000.0 2024-04-03, 2024-11-25
	The proposed proprietary name / brand name	**Onzon 4mg/5mL Syrup**
	Label Claim	Each 5mL contains: Ondansetron HCl eq. to Ondansetron....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per Zone-IVA
	For generic drugs (me-too Status)	Ubkino 4mg/5mL Syrup Reg# 114588
	Pharmacotherapeutic Group of (API)	A04AA01: serotonin (5HT3) antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifescencies Pvt. Ltd
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/scripts/cder/daf/index.event=overview.process&ApplNo=020605
	GMP status of the firm	GMP certificate dated 02 June 2023
	Evidence of approval of manufacturing facility	DML 20.09.2020; Renewal 20 Sept 2021 (Oral liquid section)
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
7	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(7MM-AVW-LH2V, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-05-27,
	The proposed proprietary name / brand name	**Dologab Capsule 300mg**
	Label Claim	Dologab capsule 300mg Each capsule contains: Pregabalin .....300mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Lyrica Capsule 300mg
	Pharmacotherapeutic Group of (API)	ATC code: N02BF02 (Gabapentinoids)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Sciences Block No. 251-252 Sachin-Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 17.11.2022
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xeegap by Hilton Pharma, Karachi
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	GMP certificate dated 18.03.2024
	Evidence of approval of manufacturing facility	DML No 000028 dated 28.04.2020
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
8	Case Category	New Section (Abdul Mughees)
	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	(143-XA1-WU51, 2025-01-30)
	Detail of Fee Submitted	37000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Colisin 3 MIU Injection**
	Label Claim	Each vial contains: Colistimethate sodium (3 MIU) eq. to Colisin base activity (approx)----- 102 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 centigrade
	For generic drugs (me-too Status)	Genthate 3 MIU Injection
	Pharmacotherapeutic Group of (API)	ATC code: J01XB01; Polymixins antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nill
	Detail of stability batches of drug product	Data of three batches of 500 vials at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10 September 2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Genthate 3MIU injection (Biogen Life Sciences)

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC MHRA Approved
	GMP status of the firm	GMP certificate dated 02.11.2023
	Evidence of approval of manufacturing facility	DML No. 000486 dated 12.04.2021 Additional Section (Lyophillized Powder for Injection (General) New) approval letter dated 26.01.2024
	Evaluation Remarks	
	Already lyophilized powder is filled.	
	Decision	
	Approved	
9	Case Category	New Section (Abdul Mughees)
	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	(BS9-7SY-W4QT, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Colisin 1MIU Injection**
	Label Claim	Each vial contains: Colistimethate sodium (1 MIU) eq. to Colisin base activity (approx)---34mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 centigrade
	For generic drugs (me-too Status)	Genthate 1 MIU Injection
	Pharmacotherapeutic Group of (API)	ATC code: J01XB01; Polymixins antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nill
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10 September 2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Genthate injection (Biogen Life Sciences)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Colistamethate sodium (2.M.I.U and 1.M.I.U)powder for solution for injection (IV)
	GMP status of the firm	GMP certificate dated 02.11.2023
	Evidence of approval of manufacturing facility	DML No. 000486 dated 12.04.2021 Additional Section (Lyophillized Powder for Injection (General) New) approval letter dated 26.01.2024
	Evaluation Remarks	
	Already lyophillized powder is filled.	
	Decision	

	Approved	
10	Case Category	New Section (Abdul Mughees)
	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	(HY3-TYQ-E4AM, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Colisin 4.5 MIU Injection**
	Label Claim	Each vial contains: Colistimethate sodium (4.5 MIU) eq. to Colistin base activity (approx)---150mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 centigrade
	For generic drugs (me-too Status)	Genthate 4 MIU Injection
	Pharmacotherapeutic Group of (API)	ATC code: J01XB01; Polymixins antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nill
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10 September 2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Genthate injection (Biogen Life Sciences)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	COLISTIN LINK colistimethate sodium (equivalent to colistin 150 mg, 4,500,000 IU) powder for injection vial
	GMP status of the firm	GMP certificate dated 02.11.2023
	Evidence of approval of manufacturing facility	DML No. 000486 dated 12.04.2021 Additional Section (Lyophillized Powder for Injection (General) New) approval letter dated 26.01.2024
	Evaluation Remarks	
	Already lyophillized powder is filled.	
	Decision	
	Approved	
11	Case Category	New Section (Abdul Mughees)
	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	(Z6Z-MD7-H15U, 2025-02-04)
	Detail of Fee Submitted	37000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Colisin 2 MIU Injection**
	Label Claim	Each vial contains: Colistimethate sodium (2 MIU) eq. to Colistin base activity (approx)---68

		mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25 centigrade
	For generic drugs (me-too Status)	Genthate 2 MIU Injection
	Pharmacotherapeutic Group of (API)	ATC code: J01XB01; Polymixins antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nill
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10 September 2024
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Genthate injection (Biogen Life Sciences)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Colistamethate sodium (2.M.I.U and 1.M.I.U)powder for solution for injection (IV)
	GMP status of the firm	GMP certificate dated 02.11.2023
	Evidence of approval of manufacturing facility	DML No. 000486 dated 12.04.2021 Additional Section (Lyophillized Powder for Injection (General) New) approval letter dated 26.01.2024
	Evaluation Remarks	
	Already lyophillized powder is filled.	
	Decision	
	Approved	
12	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(6WD-HYE-PVAM, 2026-03-05)
	Detail of Fee Submitted	38700, 2026-02-10,
	The proposed proprietary name / brand name	**Gabarol 75mg capsule**
	Label Claim	Each capsule contains: Pregabalin 75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's, 4x7's, 6x7's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	gabapentinoid drug class or gamma-aminobutyric acid (GABA) analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited.) LTD.
	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	on loan from Horizon
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm provided long term studies on 25C. Later provided same data on 30C.
	The status in reference regulatory authorities	Attached (Lyrica 75mg Capsule) US FDA
	GMP status of the firm	New DML dated 28.03.2025
	Evidence of approval of manufacturing facility	New DML dated 28.03.2025
	Evaluation Remarks	
	Long term Drug Substance studies were provided on 25C. In response to query, same data is provided on 30C.	
	Decision	
	Rejected Registraiton Board rejected the application due to falsification of temperature and humidity conditions of drug substance stability summary sheets	
13	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(EGH-RP3-LTH3, 2026-03-05)
	Detail of Fee Submitted	38700, 2026-02-10,
	The proposed proprietary name / brand name	**Gabarol 50mg capsule**
	Label Claim	Each capsule contains: Pregabalin 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's, 4x7's, 6x7's, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	gabapentinoid drug class or gamma-aminobutyric acid (GABA) analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited.) LTD.
	Detail of stability batches of drug product	Long-term and accelrated conditions of T01, To2, and T03 of 2000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Horizon
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gabica 50mg Capsule (Reference product) manufactured by Getz Pharma, Batch number 315C28
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term atudies on 25C. Later on provided same data on 30C.
	The status in reference regulatory authorities	Attached (Lyrica 50mg Capsule) US FDA
	GMP status of the firm	New license 28.03.2025
	Evidence of approval of manufacturing facility	DML dated 28.03.2025
	Evaluation Remarks	
	Long term Drug Substance studies were provided on 25C. In response to query, same data is provided on 30C.	
	Decision	
	Rejected	

	Registraiton Board rejected the application due to falsification of temperature and humidity conditions of drug substance stability summary sheets	
14	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(VED-N9D-PEHQ, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-09,
	The proposed proprietary name / brand name	**Gabarol 150mg capsule**
	Label Claim	Each capsule contains: Pregabalin .....150mg Product Spec´s .... BP
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	gabapentinoid drug class or gamma-aminobutyric acid (GABA) analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited.(1076, Parijat House, Dr. E. Moses Road, Worli, Mumbai- 400018, India)
	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	on loan from Horizon
	Pharmaceutical Equivalence and Comparative Dissolution Profile	New DML dated 28.03.2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm provided long term studies on 25C. Later provided same data on 30C.
	The status in reference regulatory authorities	Attached (Lyrica 150mg Capsule) US FDA
	GMP status of the firm	New DML dated 28.03.2025
	Evidence of approval of manufacturing facility	New DML dated 28.03.2025
	Evaluation Remarks	
	Long term Drug Substance studies were provided on 25C. In response to query, same data is provided on 30C.	
	Decision	
	Rejected Registraiton Board rejected the application due to falsification of temperature and humidity conditions of drug substance stability summary sheets	
15	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(WNP-UGE-GZ9X, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-09,
	The proposed proprietary name / brand name	**Gabarol 100mg capsule**

	Label Claim	Each capsule contains: Pregabalin .....100mg Product Spec´s .... BP
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	gabapentinoid drug class or gamma-aminobutyric acid (GABA) analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited.(1076, Parijat House, Dr. E. Moses Road, Worli, Mumbai- 400018, India)
	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	on loan from Horizon
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm provided long term studies on 25C. Later provided same data on 30C.
	The status in reference regulatory authorities	Attached (Lyrica 100mg Capsule) US FDA
	GMP status of the firm	New DML dated 28.03.2025
	Evidence of approval of manufacturing facility	New DML dated 28.03.2025
	Evaluation Remarks	
	Long term Drug Substance studies were provided on 25C. In response to query, same data is provided on 30C.	
	Decision	
	Rejected Registraiton Board rejected the application due to falsification of temperature and humidity conditions of drug substance stability summary sheets	
16	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(EUM-A29-TM6N, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-01-02,
	The proposed proprietary name / brand name	**DELZO 60mg CAPSULES**
	Label Claim	Each capsule contain: Dexlansoprazole DDR Pellets Eq. to Dexlansoprazole..... 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10's,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	PPI inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S SURGE LABORATORIES (PVT) LTD, 10th KM, Faisalabad Road Bikhi, District Sheikhupura-Pakistan.

	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches
	The status in reference regulatory authorities	Attached (DEXILANT 60mg Capsule) US FDA
	GMP status of the firm	New DML dated 28.03.2025
	Evidence of approval of manufacturing facility	New DML dated 28.03.2025
	Evaluation Remarks	
	UV spectra have same graphical presentation which firm claims to be technical glitch in the report generation template during the final data export during the PDF conversion a purely digital rendering error in PDF Software.	
	Decision	
	Rejected Registation Board rejected the application due to submission of falsified UV spectra in dissolution testing for stability batches	
17	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	(6MH-46W-Q6SJ, 2025-09-30)
	Detail of Fee Submitted	75000.0, 2025-05-30,
	The proposed proprietary name / brand name	**Darox Tablets 50mg**
	Label Claim	Each film coated tablet contains Daridorexant HCl eq. to: Daridorexant 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C at cool & dry place
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Daridorexant is a dual orexin receptor antagonist (DORA)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	DRTH-001 DRTH-002 DRTH-003 Each of 1500 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached with Invoice No DIL-C-A09912
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pperformed with QUVIVIQ 50mg Tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated and Real time stability studies conducted on Zone IV a stability conditions
	The status in reference regulatory authorities	UK (MHRA)
	GMP status of the firm	Valid w.e.f 14-04-2025
	Evidence of approval of manufacturing facility	DML#000427 w.e.f 01-04-21
	Evaluation Remarks	

	The applicaiton fulfils codal formalities.	
	Decision	
	Deferred Registration Board deferred the application for submission of the following: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
18	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	(GE4-VRT-PY4V, 2025-10-07)
	Detail of Fee Submitted	75000.0, 2025-05-30,
	The proposed proprietary name / brand name	**Darox Tablets**
	Label Claim	Each Film Coated Tablet Contains: Daridorexant HCl equivalent to Daridorexant.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Tablets-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30C at cool & dry place
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Daridorexant is a dual orexin receptor antagonist (DORA)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	DRTL-001, DRTL-002, DRTL-003 Each of 1500 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached with invoice number DIL-C-A09912
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with QUVIVIQ Tablets 25mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated and Real time stability studies conducted on Zone IV a stability conditions
	The status in reference regulatory authorities	UK (MHRA)
	GMP status of the firm	Valid w.e.f 14-04-2025
	Evidence of approval of manufacturing facility	DML#000427 w.e.f 01-04-21
	Evaluation Remarks	
	The applicaiton fulfils codal formalities.	
	Decision	
	Deferred Registration Board deferred the application for submission of the following:	

	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
19	Case Category	Import (Abdul Mughees)
	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	(891-6UU-8MV9, 2026-03-19)
	Detail of Fee Submitted	300000.0, 2025-04-18,
	The proposed proprietary name / brand name	**Sunishil**
	Label Claim	Each capsule contains: Sunitinib malate Eq. to Sunitinib.....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Importing Country -Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Sutent Capsule 12.5mg
	Pharmacotherapeutic Group of (API)	Finished Product Import from Shilpa Medicare
	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	Performed
	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):	BASG Austria issued GMP dated 08.04.2024
	Details of Authorization Letter :	Finished Product Import
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	Sunitinib Capsule 12.5mg
	Evaluation Remarks	
	Subject to provision of legalized letter of Authorization and CoPP	
	Decision	
	Approved Registration Board approved the drug subject to submission of legalized letter of Authorization and CoPP and as per import policy	
20	Case Category	Routine (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	(89B-NAH-NLJR, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-29,

	The proposed proprietary name / brand name	**Miroga 2.5mg Tablet**
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF03; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s HENAN JINHUAITANG BIOLOGICAL ENGINEERING., CO.,LTD No.5329,Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice.,China.
	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6: K-1965180806892 dated 06-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 2.5mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved; Batch No. YBN2319
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	Tarlige 2.5mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved;
	GMP status of the firm	GMP dated 19.12.2023
	Evidence of approval of manufacturing facility	DML 000785; Renewal acknowledgment attached
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
21	Case Category	Routine (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	(DEV-D2S-1P17, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Miroga 10mg Tablet**
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF03; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s HENAN JINHUAITANG BIOLOGICAL ENGINEERING., CO.,LTD

		No.5329,Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice.,China.
	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6: K-1965180806892 dated 06-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 10mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	Tarlige 10mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved;
	GMP status of the firm	GMP dated 19.12.2023
	Evidence of approval of manufacturing facility	DML 000785; Renewal acknowledgment attached
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
22	Case Category	Routine (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	(MGS-PT7-36AV, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Miroga 5mg Tablet**
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	DML 000785; Renewal acknowledgment attached
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s HENAN JINHUAITANG BIOLOGICAL ENGINEERING., CO.,LTD No.5329,Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice.,China.
	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6: K-1965180806892 dated 06-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 5mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	Tarlige 5mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved;

	GMP status of the firm	GMP dated 19.12.2023
	Evidence of approval of manufacturing facility	DML 000785; Renewal acknowledgment attached
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
23	Case Category	Routine (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	(SB1-5BU-33ZS, 2024-09-20)
	Detail of Fee Submitted	75000.0, 2024-08-29,
	The proposed proprietary name / brand name	**Miroga 15mg Tablet**
	Label Claim	Each film coated tablet contains: Mirogabalin as Besylate.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF03; Gabapentinoids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s HENAN JINHUAITANG BIOLOGICAL ENGINEERING., CO.,LTD No.5329,Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice.,China.
	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6: K-1965180806892 dated 06-Jun-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige15mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved;
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	Tarlige 15mg tablet, Daiichi Sankyo Co. Ltd Japan, PMDA Approved;
	GMP status of the firm	GMP dated 19.12.2023
	Evidence of approval of manufacturing facility	DML 000785; Renewal acknowledgment attached
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
24	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Zafa Pharmaceutical Laboratories (Pvt) Ltd.** L-1/B Block-22 Federal B Industrial Area, Karachi-75950 **(000513)**

	Application Form Dy. No / Tracking ID & date of submission	(AR4-D8N-QQU8, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2024-04-19,
	The proposed proprietary name / brand name	**Epzin 10mg tablet**
	Label Claim	Each tablet contain 10mg empagliflozin
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 deg
	For generic drugs (me-too Status)	EMPAA 10mg tablets , Horizon Pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	ATC code: A10BK03; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data for three batches of 2500 tablets each at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 29.06.2021
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diampa 10 mg tablets by Getz Pharma, Karachi Batch NO. 116FB5
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data for three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	Approved from DRAP
	GMP status of the firm	GMp certificated dated 25.08.2022
	Evidence of approval of manufacturing facility	DML NO. 00513 dated dated 22.06.20218
	Evaluation Remarks	
	Firm was asked to perform CDP of 12 units which was performed using API from Noushad Trading.	
	Decision	
	Deferred Registration Board deferred the application for submission of justification	
25	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore **(000577)**
	Application Form Dy. No / Tracking ID & date of submission	(QHU-M9V-XJ2R, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-04-03,
	The proposed proprietary name / brand name	**Cthro DS Dry Powder Suspension**
	Label Claim	Each 5ml contains: Clarithromycin (TM Coated pellets 27.5%).....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)20-25°C
	For generic drugs (me-too Status)	Klaricid DS Dry Powder Suspension 250mg/5ml
	Pharmacotherapeutic Group of (API)	J01FA09: macrolide antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE Laboratories (Pvt) Ltd.

	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Surge Laboratories
	Pharmaceutical Equivalence and Comparative Dissolution Profile	KLARICID DS Dry powder for suspension 250mg/5ml by Abbot Laboratoies, Karachi Batch No. (10) 612829XV Mfg 04-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	BIAXIN Granules for oral suspension 250mg/5ml
	GMP status of the firm	GMP dated 15.12.2023
	Evidence of approval of manufacturing facility	DML dated 12.05.2020
	Evaluation Remarks	
	The applciation was applied in different category.	
	Decision	
	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
26	Case Category	New Section (Abdul Mughees)
	Name, address of Applicant.	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore **(000577)**
	Application Form Dy. No / Tracking ID & date of submission	(XDE-W7L-XUN7, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-04-03,
	The proposed proprietary name / brand name	**Cthro Dry Powder Suspension**
	Label Claim	Each 5ml contains: Clarithromycin (TM Coated pellets 27.5%).....125mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)20-25°C
	For generic drugs (me-too Status)	Klaricid Dry Powder Suspension 125mg/5ml
	Pharmacotherapeutic Group of (API)	J01FA09: macrolide antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE Laboratories (Pvt) Ltd.
	Detail of stability batches of drug product	data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Surge Laboratories
	Pharmaceutical Equivalence and Comparative Dissolution Profile	KLARICID Dry powderfor suspension 125mg/5ml by Abbot Laboratories Karachi Batch (10) 622236XV Mfg 04.2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	data of 3 batches
	The status in reference regulatory authorities	BIAXIN Granules for oral suspension 125mg/5ml
	GMP status of the firm	GMP dated 15.12.2023
	Evidence of approval of manufacturing facility	DML dated 12.05.2020: Additional Section 14.02.2024 Dry Powder (General)
	Evaluation Remarks	
	The applciation was applied under different category.	

	Decision	
	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
27	Case Category	New Section (Abdul Mughees)
	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	(5NA-XPV-L3VS, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Ruxonib 15 mg Tablet**
	Label Claim	Each tablet contains: Ruxolitinib free base.....15mg equivalent to 19.8mg of ruxolitinib phosphate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,60's-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)	provided
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6) months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Food and Drug Administration
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	DML
	Evaluation Remarks	
	The CDP chromatograms submitted for 15mg and 20mg strength for innovator samples match with respect to acquired time and retention time. Please justify with data evidence.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for Comparative Dissolution Profile (CDP)	
28	Case Category	New Section (Abdul Mughees)
	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	(7NM-X1J-BTTT, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Ruxonib 5mg Tablet**
	Label Claim	Each tablet contains: Ruxolitinib free base.....5mg equivalent to 6.6mg of ruxolitinib phosphate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Provided
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study{0, 3, 6, months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Food & Drug administration (FDA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached
	Evaluation Remarks	
	1. The PE chromatograms for Sample 1 & 2 for 05mg and 10mg strenghts have the same acquired time and retention times yet different file name and areas. Submit complete audit trail (complete injection sequence), 21 CFR complaince certificate for HPLC, justificaiton for this anamoly and invoices / documents supporting purchase of innovator packs that you claimed. 2. The Stability chromatograms for smaple-A and B for 5mg & 10mg strenght TF-01, TF03 matches w.r.t acquired time and retention times. Submit complete audit trail (complete injection sequence), 21 CFR complaince certificate for HPLC and justificaiton for this anamoly.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for Comparative Dissolution Profile (CDP)	
29	Case Category	New Section (Abdul Mughees)
	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	(B9X-TNH-1WYV, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Ruxonib 20mg Tablet**

	Label Claim	Each tablet contains: Ruxolitinib free base.....20mg equivalent to 26.4mg of ruxolitinib phosphate
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Provided
	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	Accelerated: 6 months Real Time: 6 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated: 6 months Real Time: 24 months
	The status in reference regulatory authorities	Food and Drug Administration
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	The CDP chromatograms submitted for 15mg and 20mg strength for innovator samples match with respect to acquired time and retention time. Please justify with data evidence.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for Comparative Dissolution Profile (CDP)	
30	Case Category	New Section (Abdul Mughees)
	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	(U6X-ULH-J5V4, 2026-03-06)
	Detail of Fee Submitted	75000, 2026-02-20,
	The proposed proprietary name / brand name	**Ruxonib 10mg Tablet**
	Label Claim	Each tablet contains: Ruxolitinib free base.....10mg equivalent to 13.2mg of ruxolitinib phosphate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C in a cool and dry place
	For generic drugs (me-too Status)	Not applicable as it is a new drug product
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study{0, 3, 6, months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Food & Drug administration (FDA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached
	Evaluation Remarks	
	1. The PE chromatograms for Sample 1 & 2 for 05mg and 10mg strenghts have the same acquired time and retention times yet different file name. Submit complete audit trail (complete injection sequence), 21 CFR complaince certificate for HPLC, justificaiton for this anamoly and invoices / documents supporting purchase of innovator packs that you claimed. 2. The Stability chromatogram for smaple-A and B for 5mg & 10mg strenght TF-01, TF 03 matches w.r.t acquired time and retention times. Submit complete audit trail (complete injection sequence), 21 CFR complaince certificate for HPLC and justificaiton for this anamoly.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for Comparative Dissolution Profile (CDP)	
31	Case Category	New Section (Abdul Mughees)
	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	(VPB-8GM-RG23, 2026-03-06)
	Detail of Fee Submitted	75000, 2026-02-20,
	The proposed proprietary name / brand name	**Ruxonib 25mg Tablet**
	Label Claim	Each tablet contains: Ruxolitinib free base.....25mg equivalent to 33mg of ruxolitinib phosphate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 C
	For generic drugs (me-too Status)	Not Applicable since this is a new product.
	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	Accelerated 6 months, Long Term 6 months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided Accelerated 6 months, Long term 24 months.
	The status in reference regulatory authorities	Food and Drug Administration
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	While the same analytical method has been used for assay of all strengths, the retention time in PE chromatograms is around 4 and in CDP it is around 2, with the difference of 20 microL volume of injection for 25mg PE and 10 micoL volume of injection for CDP	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for Comparative Dissolution Profile (CDP)	
32	Case Category	New Section (Abdul Mughees)
	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	(A2N-VTE-S1DB, 2026-02-03)
	Detail of Fee Submitted	75000, 2026-01-12,
	The proposed proprietary name / brand name	**NIRIB**
	Label Claim	Each film coated tablet contains: 318.7 mg Niraparib tosylate monohydrate equivalent to 200mg Niraparib free base
	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 in a cool and dry place. Protect from heat & light.
	For generic drugs (me-too Status)	Not applicable since this is a new drug.
	Pharmacotherapeutic Group of (API)	Poly (ADP-ribose) Polymerase (PARP) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study{0, 3, 6, months }
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution Profile Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
	The status in reference regulatory authorities	Product Name: ZEJULA Manufacturer: GlaxoSmithKline Durham, NC 27701 Reference Regulatory Authority: FOOD & DRUG ADMINISTRATION (FDA)
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	

	The chromatograms submitted in the stability and CDP have the same exact time in the Date acquired for 100mg, 200mg and 300mg with exact retention time for balnk, standard and sample, yet different dates. Please clarify this sameness of time to the exact hour, minute and second.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for stability batches under 3.2.P.8	
33	Case Category	New Section (Abdul Mughees)
	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	(ULL-5TV-V6VM, 2026-02-03)
	Detail of Fee Submitted	75000, 2026-01-12,
	The proposed proprietary name / brand name	**Nirib Tablet 300 mg**
	Label Claim	Each film coated tablet contains: 478.0 mg Niraparib tosylate monohydrate equivalent to 300mg Niraparib free base
	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 in a cool and dry place
	For generic drugs (me-too Status)	Not applicable since it is a new drug.
	Pharmacotherapeutic Group of (API)	Poly (ADP-ribose) Polymerase (PARP) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study{0, 3, 6, months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Anhui Haikang Phar- maceutical Co., Ltd. No. 21 Huancheng West Road Anqing Anhui 246000 China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Food & Drug administration (FDA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached
	Evaluation Remarks	
	The chromatograms submitted in the stability and CDP have the same exact time in the Date acquired for 100mg, 200mg and 300mg with exact retention time for balnk, standard and sample, yet different dates. Please clarify this sameness of time to the exact hour, minute and second.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for stability batches under 3.2.P.8	
34	Case Category	New Section (Abdul Mughees)

	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	(X1U-ZBY-JEQ8, 2026-02-03)
	Detail of Fee Submitted	75000, 2026-01-12,
	The proposed proprietary name / brand name	**Nirib Tablet 100 mg**
	Label Claim	Each film coated Tablet contains 159.3mg Niraparib tosylate monohydrate equivalent to 100mg Niraparib free base
	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 in a cool and dry place
	For generic drugs (me-too Status)	Not applicable since it is a new drug.
	Pharmacotherapeutic Group of (API)	Poly (ADP-ribose) Polymerase (PARP) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Accelerated Stability Study {0, 3 & 6 months(completed)}, Long term / Real time stability study{0, 3, 6, 9 & 12 months (completed)}
	Documents for the procurement of API with approval from DRAP (in case of Import)	Anhui Haikang Phar- maceutical Co., Ltd. No. 21 Huancheng West Road Anqing Anhui 246000 China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	pharmaceutical equivalence and CDP has been provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	provided
	The status in reference regulatory authorities	Food & Drug administration (FDA)
	GMP status of the firm	valid
	Evidence of approval of manufacturing facility	attached
	Evaluation Remarks	
	The chromatograms submitted in the stability and CDP have the same exact time in the Date acquired for 100mg, 200mg and 300mg with exact retention time for balnk, standard and sample, yet different dates. Please clarify this sameness of time to the exact hour, minute and second.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified data for stability batches under 3.2.P.8	
35	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(1E2-ZM6-24NX, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-03-27,
	The proposed proprietary name / brand name	**Sacuvan 200mg Tablet**
	Label Claim	Each film Coated Tablet Contains: Sacubitril...97mg Valsartan...103mg (as sacubitril

		valsartan sodium salt complex)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor-Neprilysin Inhibitor (ARNI)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian Pharma Tech Co., Ltd.(No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China)
	Detail of stability batches of drug product	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	Savesto 200mg Tablet (Reference product) by Getz Pharma Batch number 042FB4
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term and accelerated conditions
	The status in reference regulatory authorities	Attached (Entresto 200mg Film Coated Tablet) EMC
	GMP status of the firm	DML dated 28.03.2025 New License
	Evidence of approval of manufacturing facility	DML dated 28.03.2025
	Evaluation Remarks	
	The chromatograms Sacubitril+Valsartan STD 02 (0 month) and Sacubitril+Valsartan STD 03 (0 month) submitted with stability have same peak morphology. Even the dots at the top of the second peak are similar. The same has been observed for almost all the cromatograms. Therefore you are advised to submit explanation and complete data with properly identified peaks, along with third party audited CFR complaince report of your HPLC.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified chromatograms in stability data.	
36	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(GSX-J5B-59B5, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-03-27,
	The proposed proprietary name / brand name	**Sacuvan 50mg Tablet**
	Label Claim	Each film Coated Tablet Contains: Sacubitril...24mg/Valsartan...26mg (as sacubitril valsartan sodium salt complex)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor-Neprilysin Inhibitor (ARNI)

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian Pharma Tech Co., Ltd.(No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China)
	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 (Entresto 50mg Film Coated Tablet) EMC
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	For this strenght as well, the chromatograms Sacubitril+Valsartan STD 02 (0 month) and Sacubitril+Valsartan STD 03 (0 month) submitted with stability have same peak morphology. Even the dots at the top of the second peak are similar. The same has been observed for almost all the cromatograms. Therefore you are advised to submit explanation and complete data with properly identified peaks, along with third party audited CFR complaince report of your HPLC.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified chromatograms in stability data.	
37	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(TYS-6VB-9ZLP, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-09,
	The proposed proprietary name / brand name	**Gabarol 300mg capsule**
	Label Claim	Each capsule contains: Pregabalin .....300mg Product Spec´s .... BP
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	gabapentinoid drug class or gamma-aminobutyric acid (GABA) analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited.(1076, Parijat House, Dr. E. Moses Road, Worli, Mumbai- 400018, 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	Attached (Lyrica 300mg Capsule) US FDA
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	In other strenghts the firm has submitted same long term DS data at 30 as of 25C.	
	Decision	
	Rejected Registraiton Board rejected the application due to falsification of temperature and humidity conditions of drug substance stability summary sheets	
38	Case Category	New Section (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	(37U-M8Q-N8ZU, 2025-10-02)
	Detail of Fee Submitted	38700.0, 2025-08-18,
	The proposed proprietary name / brand name	**Colidium 3MIU Injection**
	Label Claim	Each lyophilized vial Contains: Colistimethate sodium (3MIU) eq. to Colistin Base Activity (appox).....102mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C.
	For generic drugs (me-too Status)	Colmat 3MIU dry powder injection by Vision Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Polymyxin antibiotic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Detail of stability batches of drug product	046T25, 047T25, 048T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Assay is attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 30oC ± 2oC and 65% ± 5% RH (24 Months), Accelerated: 40oC ± 2oC and 75% ± 5% RH (6 Months)
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Dry powder Injection section dated 26.08.2024
	Evaluation Remarks	
	The firm applied under different category.	
	Decision	

	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
39	Case Category	New Section (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	(587-5EB-JTS6, 2025-09-25)
	Detail of Fee Submitted	38700.0, 2025-08-18,
	The proposed proprietary name / brand name	**Colidium 4.5MIU Injection**
	Label Claim	Each lyophilized vial Contains: Colistimethate sodium (4.5MIU) eq. to Colistin Base Activity (appox).....150mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C.
	For generic drugs (me-too Status)	Colmat 4.5MIU dry powder injection by Vision Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Polymyxin antibiotic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Detail of stability batches of drug product	049T25, 050T25, 051T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Assay is attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 30oC ± 2oC and 65% ± 5% RH (24 Months), Accelerated: 40oC ± 2oC and 75% ± 5% RH (6 Months)
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Dry powder Injection section (Letter Attached)
	Evaluation Remarks	
	The firm applied under different category.	
	Decision	
	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
40	Case Category	New Section (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	(DGN-E5R-4DVG, 2025-09-30)

	Detail of Fee Submitted	38700.0, 2025-08-18,
	The proposed proprietary name / brand name	**Colidium 1MIU Injection**
	Label Claim	Each lyophilized vial Contains: Colistimethate sodium (1MIU) eq. to Colistin Base Activity (approx)..... 34mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C.
	For generic drugs (me-too Status)	Colmat 1MIU dry powder injection by Vision Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Polymyxin antibiotic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Detail of stability batches of drug product	040T25, 041T25, 042T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Assay is attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 30oC ± 2oC and 65% ± 5% RH (24 Months), Accelerated: 40oC ± 2oC and 75% ± 5% RH (6 Months)
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Dry powder Injection section (Letter Attached)
	Evaluation Remarks	
	The firm applied under different category.	
	Decision	
	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
41	Case Category	New Section (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	(QT6-W1B-9RX4, 2025-10-02)
	Detail of Fee Submitted	38700.0, 2025-08-18,
	The proposed proprietary name / brand name	**Colidium 2MIU Injection**
	Label Claim	Each lyophilized vial Contains: Colistimethate sodium (2MIU) eq. to Colistin Base Activity (approx)..... 68mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C.
	For generic drugs (me-too Status)	Colmat 2MIU dry powder injection by Vision Pharmaceuticals (Pvt) Ltd

	Pharmacotherapeutic Group of (API)	Polymyxin antibiotic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Detail of stability batches of drug product	043T25, 044T25, 045T25
	Documents for the procurement of API with approval from DRAP (in case of Import)	SUMAR BIOTECH LLPPLOT NO, 112.113.114 GIDC ESTATE GOZARIYA, DIST MEHSANA GUJARAT INDIA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Assay is attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term: 30oC ± 2oC and 65% ± 5% RH (24 Months), Accelerated: 40oC ± 2oC and 75% ± 5% RH (6 Months)
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	Provided
	Evidence of approval of manufacturing facility	Dry powder Injection section (Letter Attached)
	Evaluation Remarks	
	The firm applied under different category.	
	Decision	
	Approved Registration Board approved the product subject to submission of pre-registration variation fee of Rs. 9400/-	
42	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	(1L4-B2L-6DP5, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-21,
	The proposed proprietary name / brand name	**Cefadroxil 125mg/5ml**
	Label Claim	Each 5ml contains (Reconstituted): Cefadroxil Monohydrate Equivalent to Cefadroxil....125mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml x1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	CEDROX Dry powder for oral suspension (Platinum Pharmaceuticals (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions

	The status in reference regulatory authorities	Biodroxil 125mg/5ml (Sandoz GMBH, Austria)
	GMP status of the firm	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
43	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	(L91-WP6-WM4X, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-12,
	The proposed proprietary name / brand name	**Cefadroxil 500mg capsule**
	Label Claim	Each Capsule contains: Cefadroxil as monohydrate....500mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x12's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Neucef 500 mg capsule (Sami Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosposrins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions
	The status in reference regulatory authorities	Cefadroxil 500 mg capsule (MHRA Approved)
	GMP status of the firm	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
44	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	(71Z-P38-VRZX, 2026-04-15)

	Detail of Fee Submitted	38700, 2026-04-07,
	The proposed proprietary name / brand name	**Trigaba 150mg Capsule**
	Label Claim	Each Capsule Contains: Pregabalin...150mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	14's -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Lyrica 150mg Capsule (AGP Limited)
	Pharmacotherapeutic Group of (API)	Almelo Pvt.Ltd, India
	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	Pregablin Tillomed Capsule 150mg (MHRA Approved)
	GMP status of the firm	Available; Attached
	Evidence of approval of manufacturing facility	Available; Attached
	Evaluation Remarks	
	The loan request is dated 18.06.2025 and the stability was initiated on 18.08.2025. However, the intimation of loan to DRAP was given on 03.09.2025. Please justify development of product on borrowed API in light of the DRAP's notification No.14-1/2022-PEC dated 01.08.2025 wherein the borrowing of APIs on a loan basis was exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs).	
	Decision	
	Deferred	
45	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	(8A5-R5N-J2PR, 2026-02-25)
	Detail of Fee Submitted	38700, 2025-10-27,
	The proposed proprietary name / brand name	**Elbum Dry powder injection 40mg**
	Label Claim	Each Vial contains: Esomeprazole as Sodium....40mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 25°C
	For generic drugs (me-too Status)	E-zole 40mg Lyophilized injection (BIO-LABS Private Limited)
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	

	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions
	The status in reference regulatory authorities	Esomeprazole sodium Injection (USFDA Approved)
	GMP status of the firm	Approval letter for Dry Powder Injection (General) New dated 25 June 2025
	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (General) New dated 25 June 2025
	Evaluation Remarks	
	submitted stability chromatograms were acquired on 26/05/2025 where as the audit trail for sample is provided for 25/05/2025.	
	Decision	
	Deferred Registration Board deferred the product for submission of complete audit trail with complete injection sequence for the submitted data in stability	
46	Case Category	New License (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	(33B-GX9-GPLD, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-10,
	The proposed proprietary name / brand name	**Cephradine 500mg Capsule**
	Label Claim	Each Capsule contains: Cephradine as Monohydrate.....500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x6's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Velosef Capsules 500mg (GSK)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches
	The status in reference regulatory authorities	Cefradine Capsule 500mg (MHRA Approved)
	GMP status of the firm	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025

	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evaluation Remarks	
	The applciation fulfils codal formalities.	
	Decision	
	Approved	
47	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	(92X-LAS-NYSW, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**Cephradine 250mg Capsule**
	Label Claim	Each Capsule Contains: Cephradine as Monohydrate.....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x6's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Velosef Capsules (GSK)
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions
	The status in reference regulatory authorities	Cefradine Capsule 250mg (MHRA Approved)
	GMP status of the firm	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (Ceph) New dated 25 June 2025
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
48	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	**Nutrabiotics Pharmaceuticals** PLOT NO 89-K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR **(001008)**
	Application Form Dy. No / Tracking ID & date of submission	(2ZE-5XZ-GN93, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-03-09,
	The proposed proprietary name / brand name	**Sacuvan 100mg Tablet**

	Label Claim	Each film Coated Tablet Contains: Sacubitril...49mg Valsartan...51mg (as sacubitril valsartan sodium salt complex)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	2x7's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor- Neprilysin Inhibitors (ARNIs),
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Haotian Pharma Tech Co., Ltd.(No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China)
	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 (Entresto 100mg Film Coated Tablet) EMC
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	the chromatograms Sacubitril+Valsartan STD 02 (0 month) and Sacubitril+Valsartan STD 03 (0 month) submitted with stability have same peak morphology. Even the dots at the top of the second peak are similar. The same has been observed for almost all the cromatograms. Therefore you are advised to submit explanation and complete data with properly identified peaks, along with third party audited CFR complaince report of your HPLC. Our investigation confirms that the observed "dots" are Peak Top Identification Cursors (visual annotations). These were mistakenly activated in the software's "Peak Labeling" settings by the analyst during the reporting phase. They are purely graphical markers used to identify the apex of a peak and are not part of the chemical signal. Batch Processing Consistency: The reason these markers and the general morphology appear identical across multiple chromatograms is due to the use of a Standardized Batch Integration Method. The software applies a uniform "Visual Template" to all samples in the sequence to ensure consistent reporting, which duplicated the placement of the peak-top annotation across the set.	
	Decision	
	Rejected Registration Board rejected the application due to submission of falsified chromatograms in stability data.	
49	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(NDT-A8H-LHJZ, 2025-10-08)
	Detail of Fee Submitted	38700, 2025-09-08,
	The proposed proprietary name / brand name	**Betaris Cream**
	Label Claim	Each gram of cream of contains: Betamethasone(as betamethasone

		valerate).....1mg(0.1%w/w) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15gm , 30gm -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25 ºC, protected from light
	For generic drugs (me-too Status)	Betaderm Cream by ATCO Laboratories Limited
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Mahima Life Sciences Private Limited
	Detail of stability batches of drug product	2 batches having batch size of 500 Tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 14-04-2022 specifying 02kg Betamethasone valerate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Betaderm Cream 0.1% w/w manufactured by Atco Laboratories Limited
	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	Beta-Val Cream by Cosette Pharmaceuticals, Inc USFDA Approved.
	GMP status of the firm	Firm has submitted copy of panel inspection report for grant of cGMP certificate dated 04-08-2025 concluding that firm was working at satisfactory level of GMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Cream/Ointment (Steroid) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 03 years from date of issue. (date of issue; 13-08-2024)
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved	
50	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(1TX-QHL-JL83, 2025-11-07)
	Detail of Fee Submitted	38700, 2025-09-26,
	The proposed proprietary name / brand name	**Methrosol 500mg Injection**
	Label Claim	Each vial contains: Methylprednisolone sodium succinate equivalent to methylprednisolone..... 500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius.
	For generic drugs (me-too Status)	Solu-Medrol Injection 500mg by Pfizer Limited
	Pharmacotherapeutic Group of (API)	Corticosteroid

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symbiotec Pharmalab Private Limited,
	Detail of stability batches of drug product	3 batches having batch size of 160 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 19-02-2025 specifying 01kg Methylprednisolone Sodium succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Solu-Medrol 500mg for injection manufactured by Pfizer Ltd.
	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	MHRA Approved Solu-Medrone 500 mg for injection Methylprednisolone 500 mg Powder for Solution for Injection marketed by Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justify the number of units required for complete stability testing of applied product including testing throughout proposed shelf life	the firm submitted that the quantity of units placed on stability is scientifically justified, and sufficient to support complete stability evaluation of the applied product throughout the proposed shelf life and in case of repetition of test. (Total batch: 160 Vials, FPP 135 Vials charged on stability: 160Vials. 11 Vials for each time point (3rd, 6th, 9th, 12th, 18th, 24th, 36th, 48th and 25 Vials for 60th).
	Decision	
	Approved	
51	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(1XR-14J-UWVY, 2025-11-07)
	Detail of Fee Submitted	38700, 2025-09-26,
	The proposed proprietary name / brand name	**Methrosol 1gm Injection**
	Label Claim	Each vial contains: Methylprednisolone sodium succinate equivalent to methylprednisolone..... 1gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15-30 degree celsius
	For generic drugs (me-too Status)	Solu-Medrol Injection 1000mg by Pfizer Limited
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symbiotec Pharmalab Private Limited,
	Detail of stability batches of drug product	3 batches having batch size of 160 vials each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 19-02-2025 specifying 01kg Methylprednisolone Sodium succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Solu-Medrol 1gm for injection manufactured by Pfizer Ltd.
	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	MHRA Approved Methylprednisolone 1000 mg Powder for solution for injection marketed by Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó 8, 8A e 8B – Fervença 2705-906 Terrugem Portugal
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Justify the number of units required for complete stability testing of applied product including testing throughout proposed shelf life	The firm submitted that the quantity of units placed on stability is scientifically justified, and sufficient to support complete stability evaluation of the applied product throughout the proposed shelf life and in case of repetition of test. (Total batch: 160 Vials, FPP 135 Vials charged on stability: 160Vials. 11 Vials for each time point (3rd, 6th, 9th, 12th, 18th, 24th, 36th, 48th and 25 Vials for 60th).
	Decision	
	Approved	
52	Case Category	Routine (Dr. Farhad Ullah)
	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	(48E-Z85-1EHW, 2024-08-22)
	Detail of Fee Submitted	75000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Salzina**
	Label Claim	Each gastro-resistant tablet contains: Mesalazine 1600mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C, Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 08-04-2023 specifying 50kg Mesalazine.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Asacol 1600mg Gastro Resistant Tablets by M/s Tillotts Pharma Spain.
	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	Asacol 1600 mg gastro-resistant tablets, Tillotts Pharma Spain, , CIMA Spain Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-09-2021 specifying Tablet (General)-revised section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Registration Board further decided that registration letter shall be issued upon submission of following information/ documents: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
53	Case Category	Routine (Dr. Farhad Ullah)
	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	(6NH-Z1M-HQYN, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Salzina**
	Label Claim	Each gastro resistant prolonged release tablet contains: Mesalazine 1200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C, Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP	Firm has submitted copy of clearance certificate dated 08-04-2023 specifying 50kg Mesalazine.

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Mezavant 1200mg gastro Resistant Prolonged Release tablets by M/s Takeda Pharma Pvt. Ltd
	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	Mezavant 1200mg gastro-resistant prolonged release Tablet, Takeda Pharmaceuticals International AG, Ireland
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-09-2021 specifying Tablet (General)-revised section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Registration Board further decided that registration letter shall be issued upon submission of following information/ documents: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
54	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(5JQ-HVN-A6G4, 2024-04-02)
	Detail of Fee Submitted	30000.0, 2024-01-30,
	The proposed proprietary name / brand name	**VOZACTI TABLET 20mg**
	Label Claim	Each film coated tablet contains: Vonoprazan fumarate eq. to Vonoprazan.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15oC - 30oC.
	For generic drugs (me-too Status)	Vonozan(GETZ PHARMA)
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (PCAB)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Enantiotech Corporation Limited.
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 16-12-2022 specifying 0.3kg Vonoprazan Fumarate. The form 6 is issued by AD (I&E)

		DRAP Firm has also submitted copy of form3, form 7, packing list, invoice and goods declaration.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Vonozan 20mg Tablet by M/s Getz Pharma
	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	VOQUEZNA (10mg, 20mg) film coated tablets USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 30-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 31-10-2023 specifying Tablet (General) section.
	Evaluation Remarks	
	Shortcomings	Firm's response
	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted Guangdong GMP evaluation report issued by Guangdong pharmaceutical industry association valid upto 09-06-2025. Firm also submitted copy of license issued by Zhongshan Municipal Administration Beauro for industry and commerce
	Justification shall be submitted for selection of different dissolution medium, phosphate buffer pH 6.8 in dissolution test of finished product than innovators product (pH 4.5 acetate buffer,)	Firm has submitted revised dissolution method of finished product selecting dissolution medium as per innovator's product. Firm has also submitted fee Rs. 9400/- on deposit slip#91638044744 for revision of dissolution medium
	Decision	
	Approved Registration Board further decided that registration letter shall be issued upon submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	
55	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(TW3-WN3-EAG1, 2024-02-20)
	Detail of Fee Submitted	30000.0, 2024-01-30,
	The proposed proprietary name / brand name	**VOZACTI 10mg tablet**
	Label Claim	Each film coated tablet contains:Vonoprazan fumarate equivalent to Vonoprazan..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store between 15oC - 30oC.
	For generic drugs (me-too Status)	Vonozan(GETZ PHARMA)
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (PCAB)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Manufacturer: Enantiotech Corporation Limited. Address : Zhongshan Torch Hi-Tech Industrial Development Zone, Guangdong Province, China. Tel: +86-760-85282375 Fax: +86-760-85282626 E-mail: qm@ena

	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 16-12-2022 specifying 0.3kg Vonoprazan Fumarate. The form 6 is issued by AD (I&E) DRAP. Firm has also submitted copy of goods declaration, commercial invoice, packing list, form 3 and form 7 for procurement of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Vonozan 10mg Tablet by M/s Getz Pharma
	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	VOQUEZNA (10mg, 20mg) film coated tablets USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 30-05-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 31-10-2023 specifying Tablet (General) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted Guangdong GMP evaluation report issued by Guangdong pharmaceutical industry association valid upto 09-06-2025 Firm also submitted copy of license issued by Zhongshan Municipal Administration Beauro for industry and commerce
	Justification shall be submitted for selection of different dissolution medium, phosphate buffer pH 6.8, than innovators product (pH 4.5 acetate buffer,)	Firm has submitted revised dissolution method of finished product selecting dissolution medium as per innovator's product. Firm has also submitted fee Rs. 9400/- on deposit slip# 926246445757 for revision of dissolution medium
	Decision	
	Approved Registration Board further decided that registration letter shall be issued upon submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	
56	Case Category	Routine (Dr. Farhad Ullah)
	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	(23H-9AQ-GULU, 2024-09-26)
	Detail of Fee Submitted	30000.0, 2024-02-01,
	The proposed proprietary name / brand name	**D-TIN CAPSULE 60 MG**
	Label Claim	Each Capsule contains: Duloxetine (as HCl) E.C Pellets eq.to Duloxetine USP .....60 mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	2 x 7-As per SRO
Shelf Life (Unit)	2 Year(s)store at below 30 degree.
For generic drugs (me-too Status)	Duzalta Capsule 60mg by PharmEvo (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Selective Serotonin-norepinephrine reuptake inhibitors (SNRIs)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	VISION PHARMACEUTICALS (PVT).LTD
Detail of stability batches of drug product	3 batches having batch size of 5000 capsule each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Sales Tax Invoice dated 05-06-2022 specifying 3kg Duloxetine (HCl) EC Pellets 17% from M/s Vision Pharma in the name of Jawa Pharmaceuticals.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Duzalta Capsule 60mg by Pharm Evo (Pvt) Ltd.
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	Cymbalta 60mg hard gastro-resistant Capsules MHRA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 13-10-2023 and 07-11-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-12-2022 specifying Capsule (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Copy of DML of API manufacturer valid upto 02-12-2019 is submitted.
You have specified limits of disintegration test in finished product specifications as" does not disintegrate in 0.1N HCl after 2hr and must disintegrate in buffer in 45 min. Please clarify	1. With reference to the query regarding the disintegration testing conditions for D-tin 30 mg and 60 mg capsules, we would like to provide the following justification. 2. During product development and stability studies, disintegration testing was performed in accordance with both the United States Pharmacopeia (USP) and the British Pharmacopoeia (BP). The approved product specification is based on USP requirements, and the product complies fully with the applicable USP acceptance criteria. 3. As per USP General Chapter Disintegration for delayed-release capsules, the requirement for the acid stage is that no unit should show evidence of disintegration, cracking, or softening after 1 hour, after which the test proceeds to the buffer stage. 4. In comparison, BP requirements for gastro-resistant capsules are more stringent, requiring that no capsule shows signs of disintegration or rupture after 2 hours in the acid stage prior to proceeding to the buffer stage. 5. It is important to highlight that the product demonstrated no evidence of disintegration after 2 hours in the acidic medium, thereby complying with BP requirements. Given that the BP acid stage duration (2 hours) is more stringent than that of

		USP (1 hour), compliance under BP conditions provides strong scientific assurance that the product also meets USP acceptance criteria. 6. This approach is scientifically justified, as the application of more stringent test conditions provides additional assurance of the integrity and performance of the dosage form. The extended resistance to disintegration in acidic media confirms the robustness of the enteric coating and supports the intended delayed-release characteristics of the product. 7. Furthermore, this justification is consistent with the principles outlined in ICH Q6A, which state that specifications define the criteria to which a drug product should conform to be considered acceptable for its intended use. The use of conditions that provide an equivalent or greater level of assurance of product quality is considered scientifically appropriate when adequately justified. 8. In conclusion, the disintegration results obtained under BP conditions demonstrate compliance with USP requirements and provide additional assurance of product performance. Therefore, the applied testing approach is considered acceptable and justified.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required	Audit trail reports on product testing is submitted.
	Decision	
	Approved	
57	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(65L-3YH-NS1P, 2025-09-17)
	Detail of Fee Submitted	38700.0, 2025-08-19,
	The proposed proprietary name / brand name	**Neuhyzon 250mg Powder for Injection**
	Label Claim	Each vial contains: Hydrocortisone sodium succinate equivalent to Hydrocortisone.....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15-30 degree celsius. Unused solution may be stored at 2°-8°C for not more than 24 hours provided aseptic procedures are followed.
	For generic drugs (me-too Status)	Hyzonate Injection 250mg (Reg # 019226) by Amson Vaccines & Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches having batch size of 250 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 25-01-2025 specifying 1kg Hydrocortisone sodium succinate. Firm has also submitted clearance certificate issued dated 19-02-2025 specifying 1kg Hydrocortisone sodium succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Hyzonate 250mg injection manufactured by Amson Vaccine & Pharma
	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	TGA Approved SOLU-CORTEF ACT-O-VIAL 250mg powder for injection marketed by Pfizer Australia Pty Ltd
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).
	Evaluation Remarks	
	Certain observations were communicated to the firm; however, no response was submitted to the other shortcomings, and only the following response has been provided.	
	Shortcomings	Firm's Response
	You have applied another application with same strength, same molecule and brand Neuhyzon 250mg Injection under tracking ID#LL5-E7M-39AX. Clarify the difference between two formulations	We respectfully request withdrawal of this dossier submitted under Tracking ID: 65L-3YH-NS1P due to certain ambiguities in the provided data. A revised dossier for the same strength with correction has already been submitted under Tracking ID: LL5-E7M-39AX. Kindly consider the revised dossier submitted under Tracking ID LL5-E7M-39AX for further evaluation and processing.
	Decision	
	Rejected Registration Board acceded the request of the firm and decided to reject the instant application	
58	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura **(000914)**
	Application Form Dy. No / Tracking ID & date of submission	(A98-US4-J5UV, 2024-04-22)
	Detail of Fee Submitted	30000.0, 38700 2024-03-13, 2025-12-30
	The proposed proprietary name / brand name	**NALBO 10MG INJECTION**
	Label Claim	Each ampoule contains Nalbuphine HCl 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5s-As per SRO
	Shelf Life (Unit)	24 MonthAt room temperature below 25 degree centrigrade
	For generic drugs (me-too Status)	Kinz 10mg Injection by Sami pharmaceuticals Pvt Registration Number 018686Ltd
	Pharmacotherapeutic Group of (API)	

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Micro Orgo Chem India C1 B-57 LIC sector GIDC vapi396 195 Gujrat 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	Nalbuphine Hydrochloride by HOSPIRA USFDA Approved
GMP status of the firm	
Evidence of approval of manufacturing facility	

Evaluation Remarks

Deferred in 353rd meeting of Registration Board;

Deferment Reason	Firm's Response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of cGMP certificate of API manufacturer valid upto10-09-2027
Justification for the declared description of water solubility as given in section 3.2.S.1.3 against the reference product literature.	The innovator brand is not manufacturer of API and the limit written in reference product literature is a general limit and not applicable to API manufacturer because the material Nalbuphine HCl is not a compendiaL salt and manufactured on In-house Specifications that may differ from one manufacturer to another. Therefore the solubility range mention in Drug Master File is 10mg/ml at 25ºC as HCl salt because the material specifications are In-house and the API manufacturer can set its own limit which may vary from other manufacturer.
Justification for the declared limits of pH test in variation to that recommended by the innovator drug product literature.	The innovator brand selected by Variant Pharma is Nalbuphine Hydrochloride Injection manufactured by Hospira, Inc. Lake Forest, IL 30045 USA containing product license number ANDA 070917 USFDA approved. This innovator brand set the pH limit from 3.0-4.5 and same pH limit we mentioned in our specifications of drug product. Reference literature is submitted.
COAs of drug product stability batches	Submitted
Evidence of availability of "Liquid Particle Counter. Required for the performance of	Firm has submitted quality control log book record for LPC, recent LPC analytical results

	"particulate matter" test,	slip, photographs of installed LPC, calibration certificate and calibration sticker affixed on the instrument
	Decision	
	Approved	
59	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(LL5-E7M-39AX, 2025-11-07)
	Detail of Fee Submitted	38700, 2025-10-14,
	The proposed proprietary name / brand name	**Neuhyzon 250mg Injection**
	Label Claim	Each vial contains: Hydrocortisone sodium succinate equivalent to Hydrocortisone.....250mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store unreconstituted product at controlled room temperature 20°C to 25°C
	For generic drugs (me-too Status)	Hyzonate Injection 250mg (Reg # 019226) by Amson Vaccines & Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symbiotec Pharmalab Private Limited,
	Detail of stability batches of drug product	3 batches having batch size of 250 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 25-01-2025 specifying 1kg Hydrocortisone sodium succinate. Firm has also submitted clearance certificate issued dated 19-02-2025 specifying 1kg Hydrocortisone sodium succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	P.E is performed against Hyzonate 250mg injection manufactured by Amson Vaccine & Pharma
	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	TGA Approved SOLU-CORTEF ACT-O-VIAL 250mg powder for injection marketed by Pfizer Australia Pty Ltd
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).
	Evaluation Remarks	
	Shortcomings	Firm's Response
	The USP monograph states that applied product is prepared by freeze-drying, having been filled into its container in the form of a true solution while you have manufactured the product by	We would like to submit that the Monograph explained packaging may be supplied in: 1) Single compartment containers (in solution form) and 2) Dual-compartment containers (one contains dry powder other contains a solvent).

	directly filling the powder into the vial. Clarification is required.	However, USP monograph is attached for your assistance. Comparative data demonstrate that our product (powder fill) is bioequivalent and physically identical to the reference product. Technically our product is sterile, on pyrogenic, lyophilized powder filled under aseptic conditions and the reconstitution time is same as the reference. Product is stable and equivalent to reference. DRAP already registered the same product (324,336,339,353) and available in market with no in stability or any issues.
	Submit evidence of applied product in reference regulatory which indicate that the applied product is manufactured by direct filling technique	We would like to submit that reference is sterile powder and the comparative brand (hyzonate inj) is also same in physical form that is approved by the DRAP. Both the innovator and Neutro product are chemically stable and comparable.
	Justify the number of units required for complete stability testing of applied product including testing throughout proposed shelf life	We would like to submit that the quantity of units placed on stability is scientifically justified, and sufficient to support complete stability evaluation of the applied product throughout the proposed shelf life and in case of repetition of test.(Total batch: 250 Vials, FPP 25 Vials charged on stability: 200Vials. 12 Vials for each time point(3rd , 6th (25 Vials for each ACC & RT),9th ,12th ,18th ,24th ,36th ,48th and 25 Vials for 60th).
	The reference formulation in the RRA is presented in an ACT-O-VIAL dual-compartment system (containing sterile powder and diluent for reconstitution), whereas the applied product is proposed in a simple vial. Please justify that the proposed container-closure system has no impact on product quality and stability with reference to international guidelines.	We would like to submit that our product is presented in a single sterile vial containing lyophilized powder, whereas the reference product in the RRA is supplied in an ACT-O-VIAL dual-chamber system (powder + diluent). The primary container-closure system is same Type I glass vial. Same primary packaging material (Type I glass) used by reference product. But so far, our product Maintains Real-time stability data, maintained sterility assurance or stability (Stability studies confirm no change in: Assay, Degradation profile, Reconstitution time, Particulate matter). The proposed container-closure system complies with ICH Q1A(R2), USP <660>, <381>/<382>, <1207>, and Ph. Eur. 3.2.1 & 3.2.9 requirements. Stability studies conducted in the proposed marketing container demonstrate maintenance of product quality, sterility, and integrity throughout the proposed shelf life in accordance with DRAP and ICH guidelines.
	Decision	
	Approved	
60	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**

Application Form Dy. No / Tracking ID & date of submission	(2J6-7LN-BMV6, 2025-11-07)
Detail of Fee Submitted	38700, 2025-10-14,
The proposed proprietary name / brand name	**Neuhyzon 500mg Injection**
Label Claim	Each vial contains: Hydrocortisone sodium succinate equivalent to Hydrocortisone.....500mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's/As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store unreconstituted product at controlled room temperature 20°C to 25°C
For generic drugs (me-too Status)	Hyzonate 500mg Injection (Reg# 019227) Manufactured by Amson Vaccines & Pharma
Pharmacotherapeutic Group of (API)	Corticosteroid
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Symbiotec Pharmalab Private Limited
Detail of stability batches of drug product	3 batches having batch size of 250 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 25-01-2025 specifying 1kg Hydrocortisone sodium succinate. Firm has also submitted clearance certificate issued dated 19-02-2025 specifying 1kg Hydrocortisone sodium succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Hyzonate 500mg injection manufactured by Amson Vaccine & Pharma
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	FDA Approved SOLU CORTEF 500mg marketed by PHARMACIA AND UPJOHN
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).

Evaluation Remarks

Shortcomings	Firm's Response
The USP monograph states that applied product is prepared by freeze-drying, having been filled into its container in the form of a true solution while you have manufactured the product by directly filling the powder into the vial. Clarification is required.	We would like to submit that the Monograph explained packaging may be supplied in: 1) Single compartment containers (in solution form) and 2) Dual-compartment containers (one contains dry powder other contains a solvent). However, USP monograph is attached for your assistance. Comparative data demonstrate that our product (powder fill) is bioequivalent and physically identical to the reference product. Technically our product is sterile, on pyrogenic, lyophilized powder filled under aseptic conditions and the reconstitution time is same as the reference. Product is stable and equivalent to reference. DRAP already registered the same product (324,336,339,353) and available in market with no in stability or any issues.

	Submit evidence of applied product in reference regulatory which indicate that the applied product is manufactured by direct filling technique	We would like to submit that reference is sterile powder and the comparative brand (hyzonate inj) is also same in physical form that is approved by the DRAP. Both the innovator and Neutro product are chemically stable and comparable.
	Justify the number of units required for complete stability testing of applied product including testing throughout proposed shelf life	We would like to submit that the quantity of units placed on stability is scientifically justified, and sufficient to support complete stability evaluation of the applied product throughout the proposed shelf life and in case of repetition of test.(Total batch: 250 Vials, FPP 25 Vials charged on stability: 200Vials. 12 Vials for each time point(3rd , 6th (25 Vials for each ACC & RT),9th ,12th ,18th ,24th ,36th ,48th and 25 Vials for 60th).
	The reference formulation in the RRA is presented in an ACT-O-VIAL dual-compartment system (containing sterile powder and diluent for reconstitution), whereas the applied product is proposed in a simple vial. Please justify that the proposed container-closure system has no impact on product quality and stability with reference to international guidelines.	We would like to submit that our product is presented in a single sterile vial containing lyophilized powder, whereas the reference product in the RRA is supplied in an ACT-O-VIAL dual-chamber system (powder + diluent). The primary container-closure system is same Type I glass vial. Same primary packaging material (Type I glass) used by reference product. But so far, our product Maintains Real-time stability data, maintained sterility assurance or stability (Stability studies confirm no change in: Assay, Degradation profile, Reconstitution time, Particulate matter). The proposed container-closure system complies with ICH Q1A(R2), USP <660>, <381>/<382>, <1207>, and Ph. Eur. 3.2.1 & 3.2.9 requirements. Stability studies conducted in the proposed marketing container demonstrate maintenance of product quality, sterility, and integrity throughout the proposed shelf life in accordance with DRAP and ICH guidelines.
	Decision	
	Approved	
61	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Skywin Pharmaceuticals Pvt. Ltd** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)**
	Application Form Dy. No / Tracking ID & date of submission	(YD4-1BQ-GMY8, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-07,
	The proposed proprietary name / brand name	**Progest 100mg Tablet**
	Label Claim	Each Vaginal tablet contains: Progesterone.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10’s , 2x10’s, 3x10’s, 4x7’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)	Lunagest Vaginal Tablet 100mg by M/s Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Progestogens
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HubeiGedian Humanwell Pharmaceutical Co.,Ltd., Company address: Gedian Economic Development Districr E-Zhou City, Hubei Province, China
	Detail of stability batches of drug product	3 batches having batch size of 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted loan letter from Star laboratories of procurement of API, MOU between the firm and clearance certificate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Lutinus 100mg Vaginal Tablet
	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	Lutinus 100 mg Vaginal Tablets of M/s Ferring Ireland Limited Address: United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, , Ireland (EMA Approved)
	GMP status of the firm	New section
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 26-01-2024 specifying Tablet Section (Hormone) Steroidal.

Evaluation Remarks

Shortcomings	Firm's response
Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of Written confirmation for active substance exported to EU of API manufacturer issued by deputy director of the Hubei Medical Products Administration which states that manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice and is valid upto 09-04-2028.
Details of innovator/comparator product including name of marketing authorization holder, batch No#, manufacturing date and expiry date shall be submitted	Firm has submitted details of comparator product including name of marketing authorization holder, batch No#, manufacturing date and expiry date is submitted
Loan intimation letter for API submitted in DRAP shall be submitted	Firm has submitted loan intimation letter dated 16-01-2025
Compliance Record of HPLC Software 21CFR & Audit Trail Reports on Product Testing is required	Audit Trail Reports on Product Testing is submitted

Decision

Approved

Registration Board further decided that the Registration Letter shall be issued after;

- Submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Verification of the loan documents of API.

62	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(PVQ-GHT-BYD3, 2025-11-07)

Detail of Fee Submitted	38700, 2025-10-14,
The proposed proprietary name / brand name	**NEUHYZON 100MG INJECTION**
Label Claim	Each vial contains: Hydrocortisone sodium succinate equivalent to Hydrocortisone.....100mg (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's/As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store unreconstituted product at controlled room temperature 20°C to 25°C
For generic drugs (me-too Status)	Hyzonate Injection 100mg (Reg # 019228) manufactured by Amson Vaccines & Pharma
Pharmacotherapeutic Group of (API)	Corticosteroid
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Symbiotec Pharmalab Private Limited,
Detail of stability batches of drug product	3 batches having batch size of 250 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 issued dated 25-01-2025 specifying 1kg Hydrocortisone sodium succinate. Firm has also submitted clearance certificate issued dated 19-02-2025 specifying 1kg Hydrocortisone sodium succinate.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Hyzonate 100mg injection manufactured by Amson Vaccine & Pharma
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	Hydrocortisone 100mg powder for solution for injection/infusion MHRA Approved.
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid).

Evaluation Remarks

Shortcomings	Firm's Response
The USP monograph states that applied product is prepared by freeze-drying, having been filled into its container in the form of a true solution while you have manufactured the product by directly filling the powder into the vial. Clarification is required.	We would like to submit that Monograph explained packaging may be supplied in: 1) Single compartment containers (in solution form) and 2) Dual-compartment containers (one contains dry powder other contains a solvent). However, USP monograph is attached for your assistance. Comparative data demonstrate that our product (powder fill) is bioequivalent and physically identical to the reference product. Technically our product is sterile, on pyrogenic, lyophilized powder filled under aseptic conditions and the reconstitution time is same as the reference. Product is stable and equivalent to reference. DRAP already registered the same product (324,336,339,353) and available in market with no in stability or any issues.
Submit evidence of applied product in reference regulatory which indicate that the applied product is manufactured by direct filling technique	We would like to submit that reference is sterile powder and the comparative brand (hyzonate inj) is also same in physical form that is approved by the DRAP. Both the innovator and Neutro product are chemically stable and comparable.

	Justify the number of units required for complete stability testing of applied product including testing throughout proposed shelf life	We would like to submit that the quantity of units placed on stability is scientifically justified, and sufficient to support complete stability evaluation of the applied product throughout the proposed shelf life and in case of repetition of test.(Total batch: 250 Vials, FPP 25 Vials charged on stability: 200Vials. 12 Vials for each time point(3rd , 6th (25 Vials for each ACC & RT),9th ,12th ,18th ,24th ,36th ,48th and 25 Vials for 60th).
	Decision	
	Approved	
63	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(TSP-JRZ-95QB, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-05-22,
	The proposed proprietary name / brand name	**R-Stine 20mg Tablet**
	Label Claim	Each film coated tablet contains Ebastine... 20mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10's -As per SRO
	Shelf Life (Unit)	24 Year(s)25 degree
	For generic drugs (me-too Status)	Kestine 20mg by Highnoon Lab
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S BAL PHARMA LIMITED, 61-B, BOMMASANDRA INDUSTRIAL AREA, BANGALORE- 560099 AND REGD. OFF. AT 21-22 , BOMMASANDRA INDUSTRIAL AREA, BANGALORE- 560099 INDIA(India)
	Detail of stability batches of drug product	3 batches having batch size of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 31-10-2022 specifying 500gm Ebastine
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Kestine tablet 20mg by M/s Highnoon Pharma
	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	Kestine 20mg tablet by Industrias Farmaceuticas Almirall S.A (IFA) Spain
	GMP status of the firm	Firm has submitted copy of cGMP certificate based on inspection dated 05-01-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Additional section dated 07-05-2005 specifying Tablet (Antibiotic) section
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Clarify the discrepancy in the drug substance manufacturing and expiry dates, which are mentioned as Feb-2021/Jan-2026 in the API manufacturer's COA and Feb-2022/Jan-2027 in	With reference to the observed discrepancy in the manufacturing and expiry dates of the drug substance, kindly note that this occurred due to a PDF file combining error during document

the COA submitted by the drug product manufacturer.	compilation. Please be informed that the Active Pharmaceutical Ingredient (API) used corresponds to the following details: Batch No.: 5001092102001 Manufacturing Date: February 2022 Expiry Date: January 2027 The initially reflected dates (Feb-2021 / Jan-2026) were mistakenly included from a different document during file merging and do not pertain to the API used in the subject batch. For your verification, the correct Certificate of Analysis (COA) and No Objection Certificate (NOC) for the above-mentioned batch, along with the relevant testing details, are attached herewith. Firm has also submitted complete documents for procurement of API
Justify the method verification study of the applied product conducted without the use of an internal standard, as required by the JP monograph.	With reference to the query regarding the method verification study conducted without the use of an internal standard as specified in the JP monograph, we would like to clarify that the internal standard was not used due to its unavailability at the time of analysis. Despite this limitation, the method verification was carried out using the available validated conditions to ensure the reliability of the results. However, we acknowledge that the inclusion of an internal standard is a requirement as per the JP monograph. We hereby confirm that for all commercial production batches, the analysis will be performed strictly in accordance with the JP monograph, including the use of the prescribed internal standard. The required internal standard will be procured, and all future testing will be conducted as per the specified compendial method and specifications.
Justify the use of a working standard with a validity date of December 2022 for analysis of the applied product manufactured in November 2022, given that the 3rd month and 6th month stability time points fall after the stated validity period.	With reference to the query regarding the use of a working standard with a stated validity of December 2022 for analysis of the applied product, kindly note that this discrepancy occurred due to a PDF compiling error during document submission. Please be informed that the actual working standard used for analysis has the following correct details: Batch No.: WS-EBS50-0119 Manufacturing Date: 01-March-2022 Expiry Date: 30-April-2025 The above-mentioned working standard was valid at the time of analysis as well as during the 3rd and 6th month stability testing. The previously reflected validity (December 2022) does not pertain to the working standard used and was inadvertently included due to document compilation error. The Certificate of Analysis (COA) and No Objection Certificate (NOC) for the same batch, along with relevant testing details, are attached for reference.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Audit trail reports on product testing is submitted.
Decision	
Approved Registration Board further decided that registration letter shall be issued upon submission of method verification study for the applied product conducted using internal standard as per JP monograph	

64	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(X5U-6ZQ-6HYE, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-04-30,
	The proposed proprietary name / brand name	**Neudex Tablet 0.5mg**
	Label Claim	Each uncoated tablet contains: Dexamethasone.....0.5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-As per SRO,1000's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25 C
	For generic drugs (me-too Status)	Dexamethasone Tablet 0.5mg by Amros Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	HENAN LIHUA PHARMACEUTICAL CO.,LTD
	Detail of stability batches of drug product	2 batches having batch size of 5000 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 30-09-2024 specifying 10gm Dexamethasone.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Kanadex 0.5mg tablet manufactured by ISIS Pharmaceuticals & Chemical Works
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	The status in reference regulatory authorities	Dexamethasone 0.5mg Tablets MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Tablet (Steroid) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Stability study data of three batches of API as per zone IV till claimed shelf life shall be submitted	Firm has submitted stability study data of 3 batches of drug substance as per zone IV till 12 months
	Submit the analytical record of the Comparative Dissolution Profile (CDP) studies conducted in three physiological media (pH 1.2, pH 4.5, and pH 6.8), including individual and mean dissolution data and standard deviations comparing test and reference products.	Analytical record of the Comparative Dissolution Profile (CDP) studies is submitted
	Decision	
	Approved	
65	Case Category	Routine (Dr. Farhad Ullah)
	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	(ZWR-76Q-WN86, 2024-10-09)

Detail of Fee Submitted	37000.0, 2024-09-25,
The proposed proprietary name / brand name	**Bupro 75mg tablet**
Label Claim	Bupro 75mg Tablet Each Film coated tablet contains: Bupropion HCl 75mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2x10's-As per SRO
Shelf Life (Unit)	2 Year(s)At room temperature
For generic drugs (me-too Status)	Butrin 75mg Tablet by M/s Genetics Pharmaceuticals Reg. No.: 068381
Pharmacotherapeutic Group of (API)	Aminoketone (Antidepressent)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Name: Karunesh Remedies, Addd Plot No. 471/2 & 417/1/A, Phase-II, G.I.D.C., Estate Panoli – 394 116.Ta. Ankleshwar, Dist. Bharuch, Gujraat (INDIA).
Detail of stability batches of drug product	3 batches having batch size of 1000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 27-02-2024 specifying 2kg Bupropion Hydrochloride. Firm has also submitted copy of form 6 issued dated 20-02-2024 specifying 2kg Bupropion Hydrochloride..
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Butrin Tablets 75mg
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	WELLBUTRIN 75mg, 100mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-10-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 11-05-2020 specifying Tablet (General) section.

Evaluation Remarks

Shortcomings	Firm's Response
Name of applicant in eApp is different than given in module I (Siam pharma), clarify or correct details in submitted application along with submission of applicable fee.	Firm submitted that the old name of Applicant is Siam Pharmaceutical, which is changed to new name Cell Health Sciences. Letter of change of name is attached herewith. Fee for correction of name of applicant in module I is required
Submit a scientific justification for the use of a different dissolution medium, medium volume, dissolution time, and UV detection wavelength than those specified in the USP monograph,	As per Performance Test requirements, dissolution is conducted in accordance with the official monograph of the United States Pharmacopeia. However, for Comparative Dissolution Profile (CDP) studies, dissolution is conducted in three media (0.1 N HCl, acetate buffer pH 4.5, and phosphate buffer pH 6.8) to evaluate product performance across different pH conditions, as per comparative dissolution requirements. Further, the wavelength "224 nm" mentioned in the analytical worksheet is a typographical error. The actual wavelength used was 252 nm, strictly as per the USP monograph.

		The attached UV spectrum confirms analysis at 252 nm.
	Decision	
	Approved Registration Board further decided that the registration letter shall be issued after submission of the Pre-Registration Variation fee of Rs. 9,400/-, as per S.R.O. 1399(I)/2025 dated 01-08-2025.	
66	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(HH9-S4Y-DTS6, 2026-02-03)
	Detail of Fee Submitted	38700, 36300 2025-10-24, 2026-03-16
	The proposed proprietary name / brand name	**NeuPred-M 4mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Methylprednisolone ....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's, 14's, 28's/As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Glucocorticoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Lihua Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 20-02-2025 specifying 0.0350kg Methylprednisolon base.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Medrol 4mg tablets manufactured by Pfizer Ltd.
	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	Medrone Tablets 4mg MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Tablet (Steroid) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Submit differential fee as the applied product is a new formulation	Firm has submitted differential fee Rs. 36300 on deposit slip#39949415246 as the applied product is new formulation
	Results of dissolution test are not reported in Pharmaceutical equivalence studies, clarify	Firm has submitted revised pharmaceutical equivalence report in results of dissolution test are reported.
	Decision	
	Approved Registration Board further decided that registration letter shall be issued after submission of following information/ documents:	

	i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
67	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(ES1-BPS-5VPW, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-08-06,
	The proposed proprietary name / brand name	**Danzine Gastro Resistant Prolonged Release Tablet 1.2g**
	Label Claim	Each gastro resistant prolonged release tablet contains: Mesalazine 1200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC, Protect from heat, light and moisture
	For generic drugs (me-too Status)	Intestinal anti-inflammatory agent
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 08-04-2023 specifying 50kg Mesalazine.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Mezavant 1200mg gastro Resistant Prolonged Release tablets by M/s Takeda Pharma Pvt. Ltd
	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	Mezavant XL 1200mg gastro-resistant, prolonged release tablets HPRA Ireland Approved
	GMP status of the firm	Genix Pharma Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023. Daneen Pharma Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23-10-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-09-2021 specifying Tablet (General)-revised section.
	Evaluation Remarks	
	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	

	Approved Registration Board further decided that registration letter shall be issued after submission of following information/ documents: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
68	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(86B-6HB-HA6P, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-08-02,
	The proposed proprietary name / brand name	**Danzine Gastro Resistant Tablet 1.6g**
	Label Claim	Each gastro resistant tablet contains: Mesalazine 1600mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C, Protect from heat, light and moisture
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent
	Name, address of Manufacturing site:	Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi-
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 08-04-2023 specifying 50kg Mesalazine.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Asacol 1600mg Gastro Resistant Tablets by M/s Tillotts Pharma Spain.
	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	Asacol 1600mg gastro-resistant Tablet, Tillotts Pharma Spain, SLU, Spain Approved
	GMP status of the firm	Genix Pharma Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-09-2021 specifying Tablet (General)-revised section.
	Evaluation Remarks	

	The application fulfills codal formalities and is submitted for consideration by the Registration Board.	
	Decision	
	Approved Registration Board further decided that registration letter shall be issued after submission of following information/ documents: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
69	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore **(000228)**
	Application Form Dy. No / Tracking ID & date of submission	(GEQ-484-5ZZQ, 2024-10-01)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-07, 2024-09-30
	The proposed proprietary name / brand name	**Reptor Tablet 1mg**
	Label Claim	Each film coated tablet contains: Prucalopride as Succinate.....1mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28s Tablets packed i-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30C
	For generic drugs (me-too Status)	Prucalo 1mg Tablet by M/s Wilshire Laboratories (Private) Limited
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xier Kangtai Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 25-01-2024 specifying 50gm Prucalopride Succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Resolor 1mg tablet manufactured by Takeda Pharmaceuticals International AG Ireland branch
	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	Resolor 1mg film coated tablet EMA Approved https://www.ema.europa.eu/en/documents/product-information/resolor-eparproduct information_en.pdf
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-06-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 01-08-2025 specifying Tablet Section (General)

Evaluation Remarks

Shortcomings	Firm's Response
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 30-05-2024 Firm has submitted copy of DML of API manufacturer valid upto 14-08-2030. The former Shandong Xierkangtai Pharmacentical Co., Ltd. has officially changed its name to Jining Shenzhou Pharmaceutical Co., Ltd. in October 2025, upon approval by the market supervision and administration department.
Stability study data of applied product at 6th month time shall be submitted	Submitted

Decision

Approved

70	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore **(000228)**
	Application Form Dy. No / Tracking ID & date of submission	(88W-64W-ER8A, 2024-08-16)
	Detail of Fee Submitted	30000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Reptor Tablet 2mg**
	Label Claim	Each Film coated tablet contains: Prucalopride as Succinate 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28s Tablets packed i-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30C
	For generic drugs (me-too Status)	Prucalo 2mg Tablet by M/s Wilshire Laboratories (Private) Limited
	Pharmacotherapeutic Group of (API)	Other drugs for constipation
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Xier Kangtai Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 25-01-2024 specifying 50gm Prucalopride Succinate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Resolor 2mg tablet manufactured by Takeda Pharmaceuticals International AG Ireland branch
	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	Resolor 2mg film coated tablet EMA Approved https://www.ema.europa.eu/en/documents/product information/resolor-epar-product information_en.pdf
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-06-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 01-08-2025 specifying Tablet Section (General)

Evaluation Remarks

Shortcomings	Firm's Response

	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto 30-05-2024 Firm has submitted copy of DML of API manufacturer valid upto 14-08-2030. The former Shandong Xierkangtai Pharmacentical Co., Ltd. has officially changed its name to Jining Shenzhou Pharmaceutical Co., Ltd. in October 2025, upon approval by the market supervision and administration department.
	Stability study data of applied product at 6th month time shall be submitted	Submitted
	Decision	
	Approved	
71	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(EEB-N19-PVTY, 2025-11-07)
	Detail of Fee Submitted	75000, 2025-10-14,
	The proposed proprietary name / brand name	**Neusone 20mg Tablet**
	Label Claim	Each uncoated Tablet contains Hydrocortisone.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Lihua Pharmaceutical. Co. Ltd
	Detail of stability batches of drug product	2 batches having batch size of 5000 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 20-02-2025 specifying 0.5kg Hydrocortisone base.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Hydrocortisone 20mg tablet manufactured by Bristol Laboratories Ltd.
	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	Hydrocortisone 20mg Tablet by Bristol Laboratories Limited UK (MHRA)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Tablet (Steroid) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of DML of API manufacturer valid upto 31-12-2025. Firm has submitted copy of Written confirmation for active substance exported to EU of API manufacturer issued by deputy director of the Henan Medical

		Products Administration which states that manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice and is valid upto 15-01-2029.
	In section 3.2.P.1(a), the drug product is described as a white, viscous, homogeneous cream packed in an aluminum tube; however, the applied product is a tablet. Please clarify and provide the correct description of the applied product.	Firm has submitted details of container closure system of applied product
	Decision	
	Approved Registration Board further decided that registration letter shall be issued after submission of following information/ documents: i. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. ii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iii. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. iv. Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin	
72	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(H6G-P54-G957, 2024-09-25)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-09-20
	The proposed proprietary name / brand name	**SAPZ-D 40mg TABLET**
	Label Claim	Each Tablet contains: Drotaverine HCl 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	24 Year(s)25 degree
	For generic drugs (me-too Status)	NO-SPA 40mg tablet by Hoechst Pakistan Limited (006168)
	Pharmacotherapeutic Group of (API)	Antispasmodics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Integrin Life Sciences Pvt. Ltd.Plot No. 69-71 & 75-77, APIIC Industrial Park, Tirumalagiri Village, Jaggaiahpeta Mandal, Krishna District – 521 175. Andhra Pradesh, INDIA.
	Detail of stability batches of drug product	2 batches having batch size of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Venus Pharma and loan intimation submitted in DRAP for 1.5kg Drotaverine HCl. Firm has also submitted copy of clearance certificate dated 16-

		11-2023 specifying 50kg drotaverine in name of M/s Venus Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against NOSPA 40mg tablet by M/s Sanofi-Aventis Pakistan
	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	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Latvia (both as un-coated and coated tablets).
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 05-01-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 29-02-2024 specifying Tablet (General) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto one year from the date of issue. (date of issue; 23-05-2023)
	Justification shall be submitted for not including the test for dissolution test in pharmaceutical equivalence studies as per submitted specifications	Please note that the dissolution testing of both the reference product Spaz D and our finished product was performed. The omission of this information from the Pharmaceutical Equivalence Report was due to a report writing error.(testing of reference product is attached for reference)
	Stability study data of applied product at 6th month time point shall be submitted	Submitted
	Decision	
	Approved Registration Board further decided that registration letter shall be issued after submission of valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin	
73	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(J72-XUN-4S58, 2024-11-05)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-10-24
	The proposed proprietary name / brand name	**Spaz-D 80mg Tablet**
	Label Claim	Spaz-D 80mg TABLET Each Tablet contains: Drotaverine HCl 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)15-30ºC
	For generic drugs (me-too Status)	No-Spa Forte Tablet by Hoechst Pakistan Limited (029431)
	Pharmacotherapeutic Group of (API)	Antispasmodics
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Integrin Life Sciences Pvt. Ltd.Plot No. 69-71 & 75-77, APIIC Industrial Park, Tirumalagiri Village, Jaggaiahpeta Mandal, Krishna District – 521 175. Andhra Pradesh, INDIA.
	Detail of stability batches of drug product	2 batches having batch size of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of loan letter from M/s Venus Pharma and loan intimation submitted in DRAP for 1.5kg Drotaverine HCl. Firm has also submitted copy of clearance certificate dated 16-11-2023 specifying 50kg drotaverine in name of M/s Venus Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against NOSPA 80mg tablet by M/s Sanofi-Aventis Pakistan
	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	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Latvia (both as un-coated and coated tablets).
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 05-01-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 29-02-2024 specifying Tablet (General) section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of API manufacturer valid upto one year from the date of issue. (date of issue; 23-05-2023)
	Justification shall be submitted for not including the test for dissolution test in pharmaceutical equivalence studies as per submitted specifications	Please note that the dissolution testing of both the reference product Spaz D and our finished product was performed. The omission of this information from the Pharmaceutical Equivalence Report was due to a report writing error.
	Stability study data of applied product at 6th month time point shall be submitted	Submitted
	Decision	
	Approved Registration Board further decided that registration letter shall be issued after submission of valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin	
74	Case Category	New Section (Dr. Farhad Ullah)
	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	(UD4-BNV-HWNM, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-03-19,
	The proposed proprietary name / brand name	**Lenamide Capsule 10mg**
	Label Claim	Each capsule contains: Lenalidomide..... 10mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100's-As per SRO,21'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)	Lemiryl Capsule 10mg by M/s Oncogen Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Antineoplastic agent and immonomodulating agent. ATC Code; L04AX04
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Confucius Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 800 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 12-11-2025 specifying 0.1750kg Lenalidomide.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Revlimid Capsule 10mg by Celgene Corporation (Bristol Myers Squibb)
	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 II
	The status in reference regulatory authorities	REVLIMID 10mg Capsule USFDA Approved.
	GMP status of the firm	New section Firm has submitted copy of cGMP certificate of the firm based on inspection dated 20-11-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 10-05-2024 specifying Capsule Cytotoxic (New) Section.

Evaluation Remarks

Sr. No	Shortcomings
1	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2	Stability study data of 03 batches of API as per zone IV till claimed shelf life is required
3	Details of innovator/comparator product including batch No#, manufacturing date and expiry date shall be submitted
4	Stability study data of applied product at 6th month time point shall be submitted
5	Clarification shall be submitted since the sampling and testing date of API (06-11-2025) by drug product manufacturer is prior to the clearance certificate.
6	Justify the identical time in “date acquired” to the exact hour, minute, and second in chromatograms for 10mg and 25mg samples in CDP and pharmaceutical equivalence studies, along with identical peak retention times for blank, standard, and sample.
7	Clarify why chromatograms of imatinib tablets have been submitted under sample assay in the pharmaceutical equivalence studies.

Decision

Rejected

Keeping in view the unexplained discrepancies in the submitted data, including API sampling/testing prior to issuance of the clearance certificate, identical acquisition times and retention times in chromatograms for different strengths in CDP and pharmaceutical equivalence studies, and submission of chromatograms of imatinib tablets under sample assay in the pharmaceutical equivalence studies, Registration Board decided to reject the instant application.

75	Case Category	New Section (Dr. Farhad Ullah)
	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	(LDT-JPU-E9SD, 2026-03-31)
Detail of Fee Submitted	38700, 2026-03-19,
The proposed proprietary name / brand name	**Lenamide Capsule 25mg**
Label Claim	Each capsule contains: Lenalidomide 25mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100's-As per SRO,21'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)	Lemiryl Capsule 25mg by M/s Oncogen Pharma (Pvt) Limited
Pharmacotherapeutic Group of (API)	Antineoplastic agent and immonomodulating agent. ATC Code; L04AX04
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Confucius Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	3 batches having batch size of 400 capsule each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 12-11-2025 specifying 0.1750kg Lenalidomide.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Revlimid Capsule 25mg by Celgene Corporation (Bristol Myers Squibb)
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 II
The status in reference regulatory authorities	REVLIMID 25mg Capsule USFDA Approved.
GMP status of the firm	New section Firm has submitted copy of cGMP certificate of the firm based on inspection dated 20-11-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 10-05-2024 specifying Capsule Cytotoxic (New) Section.

Evaluation Remarks

Sr. No	Shortcomings
1	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2	Stability study data of 03 batches of API as per zone IV till claimed shelf life is required
3	Details of innovator/comparator product including country name of MAH, batch No#, manufacturing date and expiry date shall be submitted
4	Stability study data of applied product at 6th month time point shall be submitted
5	Clarification shall be submitted since the sampling and testing date of API (06-11-2025) by drug product manufacturer is prior to the clearance certificate.
6	Justify the trial batch size in relation to the number of units required for complete stability studies of the applied drug product, covering the proposed shelf life.
7	Justify the identical time in “date acquired” to the exact hour, minute, and second in chromatograms for 10mg and 25mg samples in CDP and pharmaceutical equivalence studies, along with identical peak retention times for blank, standard, and sample.
8	Clarify why chromatograms of Platinum Pharmaceuticals (Pvt.) Ltd. have been submitted in the pharmaceutical equivalence and stability studies of the applied product.

Decision

Rejected

Keeping in view the unexplained discrepancies in the submitted data, including API sampling/testing prior to issuance of clearance certificate, identical acquisition times and retention times in chromatograms for different strengths in CDP and pharmaceutical equivalence studies, and submission of chromatograms of another firm in pharmaceutical equivalence and stability studies of the applied product, Registration Board decided to reject the instant application.

76	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(JZ8-AZ5-QUSZ, 2025-11-07)
	Detail of Fee Submitted	38700, 2025-10-14,
	The proposed proprietary name / brand name	**Neusone 10mg Tablet**
	Label Claim	Each uncoated Tablet Contains: Hydrocortisone.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature
	For generic drugs (me-too Status)	Corticort Tablet 10mg by Tabros Pharma Pvt. Limited
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Lihua Pharmaceutical. Co. Ltd.
	Detail of stability batches of drug product	2 batches having batch size of 5000 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of final clearance certificate issued dated 20-02-2025 specifying 0.5kg Hydrocortisone base.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Hydrocortisone 10mg tablet manufactured by Hualan Pharmaceuticals Ltd.
	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	Hydrocortisone 10mg Tablet by Bristol Laboratories Limited UK (MHRA)
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Tablet (Steroid) Section.

Evaluation Remarks

Shortcomings	Firm's Response
Mentioned the name of country of MAH of product used in Pharmaceutical Equivalence and CDP studies	Bristol Laboratories Ltd.,(Berkhamsted, Herts, HP4 1EG,UK)
Clarify the discrepancy in the manufacturer of the reference product used in the PE and CDP studies, as the original dossier identifies Hualan Pharmaceuticals Ltd., whereas the later submission identifies Bristol Laboratories Ltd (Berkhamsted, Herts, HP4 1EG,UK). Submit pictorial evidence of the reference product showing manufacturer name, batch number, manufacturing date, and expiry date.	Firm has submitted pictorial evidence of reference product in which MA holder was Hualan Pharmaceuticals Ltd., 16/17 College Green, Dublin, Ireland. The pictorial evidence also contains batch number and expiry date.

Decision

	Approved	
77	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(TZU-6GU-UU3H, 2026-03-31)
	Detail of Fee Submitted	38700, 2025-10-15,
	The proposed proprietary name / brand name	**Legolix Tablets 200mg**
	Label Claim	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's x 1-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30 C
	For generic drugs (me-too Status)	Elago Tablets 200mg of The Searle Company Limited
	Pharmacotherapeutic Group of (API)	HO1CC - Anti gonadotrophin releasing hormones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Kangle Pharmaceutical Co. Ltd,
	Detail of stability batches of drug product	Detail of Stability Batches (TR-EGLX-04, TR-EGLX-05, TR-EGLX-06) 1000 tablets each 06 months accelerated and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-03-2024 for 1.5kg material is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Orlissa tablet by M/s Abbvie, USA.
	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 zone IV-A.
	The status in reference regulatory authorities	Orilissa 200mg Tablet of AbbVie Corporation (US-FDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-04-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved in place of Capsule General Section. The firm has stated that there are no products registered in Capsule General Section.
	Evaluation Remarks	
	Decision	
	Approved	
78	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(5P4-G2M-ALL4, 2026-03-31)

	Detail of Fee Submitted	38700, 2025-10-15,
	The proposed proprietary name / brand name	**Legolix Tablets 150mg**
	Label Claim	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30 C
	For generic drugs (me-too Status)	Elago Tablets 150mg Manufactured by/Registration holder: The Searle Company Limited Registration Number: 129447
	Pharmacotherapeutic Group of (API)	HO1CC- Anti-gonadotropin Releasing Hormones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Kangle Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Stability Batches (TR-EGLX-01, TR-EGLX-02, TR-EGLX-03) 1000 tablets each 06 months accelerated and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 08-03-2024 for 1.5kg material is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE an dCDP studies have been performed against the reference product i.e. Orlissa tablet by M/s Abbvie, USA.
	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 zone IV-A.
	The status in reference regulatory authorities	Orilissa 150mg tablets-United States Food and Drug Administration (US-FDA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-04-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved in place of Capsule General Section. The firm has stated that there are no products registered in Capsule General Section.
	Evaluation Remarks	
	Decision	
	Approved	
79	Case Category	Routine (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	(ZJ9-JNG-GXVU, 2024-08-02)
	Detail of Fee Submitted	75000.0, 2024-06-27,
	The proposed proprietary name / brand name	**Lefnil**
	Label Claim	Each film coated tablet contains; Lefamulin as acetate --- 600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 30 degree Centigrade

	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Pleuromutilin Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Pharmaceutical (Group) Company Limited.
	Detail of stability batches of drug product	03 batches : 1000 tablets each 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 08-04-2023 for 5kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the reference product i.e. Xenelta tablet by M/s Nabriva Therapeutic Inc., US.
	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 zone IV-A.
	The status in reference regulatory authorities	Xenleta Tablet 600mg manufactured by Nabriva Therapeutics US, Inc. Fort Washington. Food & Drug Administration (FDA) of USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The firm shall submit Valid GMP/DML of drug substance manufacturer.	
	Decision	
	Approved	
80	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(QRW-XJQ-GWH7, 2024-10-09)
	Detail of Fee Submitted	75000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Timod 25mg Tablet**
	Label Claim	Each film coated tablet contains: Iguratimod 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s, 14s,20s, 28s,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30ºC. Protect from light, heat & moisture
	For generic drugs (me-too Status)	Iguramod tablet by M/s Kaizen
	Pharmacotherapeutic Group of (API)	Anti-inflammatory agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Allastir Private Limited, Plot no.12, Shed no.9a, Sidco industrial estate, vichoor, Chennai 600 103
	Detail of stability batches of drug product	03 batches / 3000 tablets 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 12-02-2024 for 600grams material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Careram 25mg tablet by M/s Eisai Pharmaceutical Co., Ltd., Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months and 18 months real time stability data o 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Careram 25mg Tablet, Eisai Co, Ltd Japan
	GMP status of the firm	GMP certificate issued on the basis of inspection
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Form 6 dated 12-02-2024 for 600grams material is submitted.	
	Decision	
	Approved	
81	Case Category	Routine (Farooq Aslam)
	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	(EBB-ZE6-ZVU6, 2024-05-20)
	Detail of Fee Submitted	, 30000.0 , 2023-12-29
	The proposed proprietary name / brand name	**EpiCell 250mg tablets**
	Label Claim	Each film coated tablet contains: Divalproex Sodium equivalent to Valproic Acid.....250mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)25c
	For generic drugs (me-too Status)	Epival 250mg tablet(Abbot Laboratories (Pakistan) Ltd)007160
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: (Batches Size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	..
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Diprate SR 250mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36month real time and 06 months accelerated stability data of 03 batches is submitted according the conditions of zone IV-A.
	The status in reference regulatory authorities	FDA approved Divalproex Sodium….250 mg tablets(Lindsay Slowiczek, by University of Illinois)
	GMP status of the firm	Inspection report dated 06-12-2021 & 26-01-2022 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has submitted a request for withdrawal of this application.	
	Decision	
	Rejected	

	The Board acceded the request of the firm and decided to reject the application.	
82	Case Category	Routine (Farooq Aslam)
	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	(PXV-UEV-RE59, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-29,
	The proposed proprietary name / brand name	**EpiCell SR 500mg tablets**
	Label Claim	Each film coated delayed released tablet contains: Divalproex Sodium equivalent to Valproic Acid.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)25
	For generic drugs (me-too Status)	Epival 500mg tablet (Abbot Laboratories (Pakistan) Ltd)007160
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Alcon Bio Sciences pvt.Ltd
	Detail of stability batches of drug product	Batches: T01DivJ23 , T02DivJ23 . T03DivJ23 (Batches Size: 1000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Diprate SR 500mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36month real time and 06 months accelerated stability data of 03 batches is submitted according the conditions of zone IV-A.
	The status in reference regulatory authorities	DEPAKOTE ER 500mg tablet by M/s Abvie INC, USFDA Approved
	GMP status of the firm	Inspection report dated 06-12-2021 & 26-01-2022 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has submitted a request for withdrawal of this application.	
	Decision	
	Rejected The Board acceded the request of the firm and decided to reject the application.	
83	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**Focus & Rulz Pharmaceuticals (Pvt) Ltd** 44 - Industrial Triangle, Kahuta Road **(000628)**
	Application Form Dy. No / Tracking ID & date of submission	(W8D-GV8-8RGY, 2026-01-05)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**Tadalin 20mg Tablets**
	Label Claim	Each film coated tablet contains; Tadalafil .....20mg USP specifications
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	10's-As per SRO, 4's-As per SRO,14's -As per SRO,2's-As per SRO,28-As per SRO,2x6's -As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Tadalis 20mg Tablets by HILTON PHARMA - Pakistan
	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	03 batches (Batch size: 1000 tablets) 06 months accelerated and 6 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 21-03-2025 for 0.125kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pe and CDP studies have been submitted against Readitic tablet by Cinfa SA Spain.
	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	Readitic 20mg Tablet, SPAIN Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-05-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
84	Case Category	Routine (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	(B7J-W18-2B8Q, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	**Eslicar 800mg Tablet**
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....800mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, As per 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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference roduct i.e Apitom Tablets.
	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	APTIOM 800mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm does not have the audit trail report/system log. Chromatograms for AMV studies drug product and CDP studies.	
	Decision	
	Not Applicable	
85	Case Category	Routine (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	(DJ6-EG3-TUM1, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	**Eslicar 600mg Tablet**
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, As per 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)	could not be confirmed
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
	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	APTIOM 600mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm does not have the audit trail report/system log. Chromatograms for AMV studies drug product and CDP studies are not submitted.	
	Decision	
	Not Applicable	
86	Case Category	Routine (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	(MTR-XE5-VTZX, 2024-11-14)
	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	**Eslicar 400mg Tablet**
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, As per -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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
	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	APTIOM 400mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm does not have the audit trail report/system log. Chromatograms for AMV studies drug product and CDP studies are not submitted.	

	Decision	
	Not Applicable	
87	Case Category	Routine (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	(T8L-AH3-Y3GZ, 2024-11-13)
	Detail of Fee Submitted	75000.0, 2024-11-05,
	The proposed proprietary name / brand name	**Eslicar 200mg Tablet**
	Label Claim	Each tablet contains: Eslicarbazepine acetate.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30'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)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited.
	Detail of stability batches of drug product	03 batches (Batch size: 1000 tables) 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)	AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Apitom Tablets.
	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	APTIOM 200mg tablets; Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA.; FDA Approved
	GMP status of the firm	GMP certificate issued on the basis on inspection conducted on 14-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm does not have the audit trail report/system log. Chromatograms for AMV studies drug product and CDP studies are not submitted.	
	Decision	
	Not Applicable	
88	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Werrick Pharmaceuticals** Plot No. 216 - 217, I-10/3, Industrial Area Islambad **(000340)**

	Application Form Dy. No / Tracking ID & date of submission	(G41-9HU-GX5A, 2024-10-29)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**Flowaid 5mg Tablets**
	Label Claim	Each tablet contains: Metolazone.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	MetXone 5mg Tablets By Genome Pharma
	Pharmacotherapeutic Group of (API)	quinazoline diuretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	03 batches : 1500 tablets 06 moths 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)	Airway No. 607-8489-5801 Packing list and AD attested invoice No. CP/EXP/C/612/18-19 issued on 08-03-20219 for 0.135kg.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Metxone Tablet 5mg by M/s Genome.
	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	Metolazone Tablets 5mg USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 19-11-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm has performed the CDP studies by using 6 units. The firm has stated that the performance will be done on commercial batches.	
	Decision	
	Deferred for submission of CDP studies using 12 units.	
89	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)**
	Application Form Dy. No / Tracking ID & date of submission	(NQ6-MEP-R5BA, 2024-07-01)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	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 (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)	Rovista EZ 5mg+10mg Tablet by Getz Pharma 073716
	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	USFDA approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied strength was approved in 352nd meeting. The applicant and manufacturer was M/s Wnsfeild Pharmacetuicals.	
	Decision	
	Approved	
90	Case Category	Routine (Farooq Aslam)
	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	(6D2-YGH-99QN, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Vetram 1000mg Film Coated Tablets**
	Label Claim	Each Film Coated Tablet Contains: Levetiracetam.....1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Lerace 1000mg Tablets, Manufacturer: Hilton Phrama (Pvt.) Ltd.
	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: 500 tablets 06 months accelerated and 06 months real time stability data.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan agreement dated 08-01-2024 from Seraph Pharmaceuticals is submitted. Clearance certificate dated 28-04-2023 from Seraph pharma is submitted for 250kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Lerace M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Levetiracetam 1000mg Tablets, Manufacturer: Camber Pharmaceuticals Inc. (Registered in United States)
	GMP status of the firm	NEW DML was approved w.e.f 17-01-2024.
	Evidence of approval of manufacturing facility	Tablet section is approved.
	Evaluation Remarks	

	Loan agreement dated 08-01-2024 from Seraph Pharmaceuticals is submitted.Clearance certificate dated 28-04-2023 from Seraph pharma is submitted for 250kg material.	
	Decision	
	Approved subject to verification of loan letter.	
91	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**QASIM TRADERS** Shop No.7 Medicine Centre Kutchi Gali No.1, Denso Hall, Marriot Road **(645.)**
	Application Form Dy. No / Tracking ID & date of submission	(BPH-SDG-E6EN, 2026-02-16)
	Detail of Fee Submitted	313500, 2025-11-12,
	The proposed proprietary name / brand name	**Calcium Gluconate Injection**
	Label Claim	Each mL contains: Calcium gluconate monohydrate.....100 mg (eq. to 94mg of calcium gluconate and 4.5mg of Calcium Secharate tetrahydrate)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature
	For generic drugs (me-too Status)	..
	Pharmacotherapeutic Group of (API)	Solutions affecting the electrolyte balance, electrolytes
	Name, address of Manufacturing site:	Shandong Qidu Pharmaceutical Co., Ltd.-No.17, Hongda Road, Linzi District, Zibo City, Shandong Province, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed againstCalcium GLuconate injection by M/s Fresnius Kabi USA LLC.
	Name, address of Marketing Authorization Holder:	Shandong Qidu Pharmaceutical Co., Ltd., No.17, Hongda Road, Linzi District, Zibo City, Shandong Province, China, China
	Details of Certificates (CoPP/FSC/cGMP):	DML No. Lu20160064 valid till 23-11-2025 is submitted which includes the scope of manufacturing of injectables.
	Details of Authorization Letter :	CoPP: Copy of CoPP No. Shandong20243051 valid till 25-03-2026 is submitted. The product is available in free sale in exporting country and, the facilities nad operations conform to WHO-GMP. LOA: Agency agreement dated 14-07-2025 is submitted. DSL: DSL valid till 23-03-2029 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted.
	The status in reference regulatory authorities	..
	Evaluation Remarks	
	Copy of CoPP No. Shandong20243051 valid till 25-03-2026 is submitted. The product is available in free sale in exporting country and, the facilities and operations conform to WHO- The application has been processed on priority in compliance to the decision of DRAP Authority regarding imported drug products (220th meeting).	
	Decision	

	Approved Subject to submission of valid legalized/apostille CoPP and Notarized letter of authorization.	
92	Case Category	Routine (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	(XEP-EZW-AQSH, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Safcort Oral Suspension**
	Label Claim	Each ml contains:- Deflazacort.....22.75mg
	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 below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: (Batch size: 250 bottles:13mL) 06 months real time and 06 months accelerated stability data is submitted 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 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Emflaza 22.75/mL suspension by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA Oral Suspension ; PTC Therapeutics, Inc. South Plainfield, NJ 07080 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS. The firm does not have audit trail report/system log for submitted stability studies for drug product.	
	Decision	
	Not Applicable	
93	Case Category	Routine (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	(TBU-ABX-5TDH, 2024-07-26)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 30mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....30mg
	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 below 30C, protect from light and heat
	For generic drugs (me-too Status)	Calcort Tablet (Hoechst Marion Roussel)
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: T007, T008, T009 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted 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 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 30mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 30MG TABLET; Marathon Pharmaceuticals, LLC Northbrook, IL, 60062 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS. The case was deferred in 357th meeting. audit trail report/system log. The firm does not have audit trail report/system log for submitted stability studies for drug product.	
	Decision	
	Not Applicable	
94	Case Category	Routine (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	(MU4-61V-4ZYQ, 2024-07-26)

	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Safcort 18mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....18mg
	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 below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: T004, T005, T006 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted 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 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 18mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 18MG TABLET;Marathon Pharmaceuticals, LLC Northbrook, IL, 60062 U.S.A.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS. The case was deferred in 357th meeting. audit trail report/system log. The firm does not have audit trail report/system log for submitted stability studies for drug product.	
	Decision	
	Not Applicable	
95	Case Category	Routine (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	(494-TL5-XDNL, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 36mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....36mg
	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 below 30C, protect from light and heat
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED
	Detail of stability batches of drug product	Batches: T0010, T0011, T0012 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted 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 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Emflaza 36mg tablet by M/s PTC Therap, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 36MG TABLET
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS. The case was deferred in 357th meeting. audit trail report/system log. The firm does not have audit trail report/system log for submitted stability studies for drug product.	
	Decision	
	Not Applicable	
96	Case Category	Routine (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	(3G1-WDD-J8QZ, 2024-08-27)
	Detail of Fee Submitted	30000.0, 2024-07-10,
	The proposed proprietary name / brand name	**Safcort 6mg Tablet**
	Label Claim	Each tablet contains:- Deflazacort.....6mg
	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 below 30C, protect from light and heat
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s ANUH PHARMA LIMITED

	Detail of stability batches of drug product	06 months real time and 06 months accelerated stability data is submitted 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 15-04-2022 for 1.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	EMFLAZA 6MG TABLET USFDA Approved
	GMP status of the firm	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS.
	Evidence of approval of manufacturing facility	Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted.
	Evaluation Remarks	
	The firm shall submit applicable fee for correction of specifications for LOD from 0.1% to 1% for DS. The case was deferred in 357th meeting. audit trail report/system log. The firm does not have audit trail report/system log for submitted stability studies for drug product.	
	Decision	
	Not Applicable	
97	Case Category	Any Other (Farooq Aslam)
	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	(XE6-B54-3N3V, 2025-05-22)
	Detail of Fee Submitted	300000.0, 2025-03-10,
	The proposed proprietary name / brand name	**Amtrix 1G**
	Label Claim	Each vial contains: Ceftriaxone as sodium.....1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1'S ; 50'S AND/OR AS-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree celsius
	For generic drugs (me-too Status)	Oxidil by Sami Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., L-No.88, Yangzi Road, Economic and Technological Development Zone, Shijiazhuang City, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Report for PE studies against Rocephin by M/s Roche Products Limited (EU) is submitted.
	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 DML No. JI20150137 valid till 27-11-20230 is submitted. The manufacturing scope includes Cephalosporins.
	Details of Authorization Letter :	CoPP: Apostille copp no. Hebeu200250364 valid till 07-07-2027 is submitted. Ceftriaxone as sodium 1g is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 08-05-2028 is submitted. LOA: Copy of LOA is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA approved
	Evaluation Remarks	
	The case was deferred in 355th meeting for:	

Reason	Response
Submission of analytical method verification studies for drug substance.	The firm has stated that Ceftriaxone sodium for injection is produced by simple sterile filling of the substance without any chemical reaction during the manufacturing process, so the analytical method and validation between the API substance and FPP is the same.
Submission of notarized letter of authorization.	"We hereby undertake to submit the notarized letter of authorization by May 8, 2026"

	Decision	
	Approved as per import policy for inspection of manufacturer abroad. The firm shall submit notarized letter of authorization.	
98	Case Category	New License (Farooq Aslam)
	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	(VQM-778-PPN8, 2025-11-10)
	Detail of Fee Submitted	38700, 2025-09-05,
	The proposed proprietary name / brand name	**BETAPIME 1G INECTION**
	Label Claim	Each vial contains: Cefepime as Hydrochloride Monohydrate (with L-Arginine).....1000mg
	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)	Cefstar Injection 1000mg Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi Registration No: 030954
	Pharmacotherapeutic Group of (API)	Third generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kopran Research Laboratories Limited. Parijat House 1076,Dr. E. Moses Road, Worli, Mumbai-400 018,India

	Detail of stability batches of drug product	Batches: CMP19T, CMP20T, CMP21T (Batch size: 1000 vials) 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)	Loan letter from M/s Alton Pharmaceuticals for 10kg material is submitted. Clearnce certificate dated 01-11-2024 is submitted (M/s Alton Pharmaceuticals)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Cefstar 1000mg injection by M/s Barret Hodgson.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The data is not as per zone IV-A.
	The status in reference regulatory authorities	Regulatory Authority USFDA (Maxipime 1000mg Powder for Solution for Injection or Infusion, Hospira, Inc. Lake Forest, IL 60045 USA.)
	GMP status of the firm	New License (w.e.f. 02-06-2021)
	Evidence of approval of manufacturing facility	Dry vial injection section (Ceph) is approved.
	Evaluation Remarks	
	The case was deferred in 353rd meeting. The decision of the Board is as follows:	
	Decision: The Board was apprised the inconsistency between the date of submission of forced degradation studies and the timeline of the raised query. The Board considering the observation, directed the firm to submit clear justification and supporting evidence clarifying the chronology of submitted data.	
	The firm was asked to provide following clarification.	
	The final query regarding the submission of stability study of DS according to the conditions of zone IV-A, was forwarded on 11-12-2025 and the submitted chromatograms of degradation studies were acquired on 18-20th March, 2025, it the almost the 3rd month time point's testing. Clarification is required regarding performance of degradation studies before the query along with the supporting documents e.g. audit trail report, raw data sheets etc.	
	Response: The final query regarding the submission of stability study of DS according to the conditions of zone IV-A, was forwarded on 11-12-2025 and the submitted chromatograms of degradation studies were acquired on 18-20th March, 2025, it is to clarify that although it is not mandatory but we perform SIM studies (Degradation studies) on routine basis for all the products for which we perform stability studies and the same was performed for the product under consideration (Betapime 500mg & 1g Injection).	
	"our HPLC system is equipped with auto sampler and we normally perform the studies as a whole project taking advantage of auto sampling facility. Once the complete project is run, we process all the data of project at the same time. Moreover, as no excipients are involved in Cefepime injection and the same lot is used for both 500mg and 1g injections having same qualitative formulation, analyzed using the same stability indicating method results appear same and close to each other having same chromatographic profiles."	
	The firm has submitted Audit trail report motioning the SIM testing on 19-03-2025.	
	Decision	
	Deferred for verification of audit trail report from 18th to 20th March, 2025.	
99	Case Category	New License (Farooq Aslam)
	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	(L5E-6V5-B9L5, 2025-11-10)

Detail of Fee Submitted	38700, 2025-09-05,
The proposed proprietary name / brand name	**BETAPIME 500mg INECTION**
Label Claim	Each vial contains: Cefepime as Hydrochloride Monohydrate (with L-arginine) 500mg
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)	Cefstar Injection 500mg Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi Registration No: 0309543
Pharmacotherapeutic Group of (API)	Third generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Kopran Research Laboratories Limited. Parijat House 1076,Dr. E. Moses Road, Worli, Mumbai-400 018,India
Detail of stability batches of drug product	Batches: CMP16T, CMP17T, CMP18T (Batch size: 1000 vials) 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)	Loan letter from M/s Alton Pharmaceuticals for 10kg material is submitted. Clearnce certificate dated 01-11-2024 is submitted (M/s Alton Pharmaceuticals)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Cefstar 500mg injection by M/s Barret Hodgson.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The data is not as per zone IV-A.
The status in reference regulatory authorities	Regulatory Authority USFDA (Maxipime 500mg Powder for Solution for Injection or Infusion, Hospira, Inc. Lake Forest, IL 60045 USA.)
GMP status of the firm	New License (w.e.f. 02-06-2021)
Evidence of approval of manufacturing facility	Dry vial injection section (Ceph) is approved.
Evaluation Remarks	
The case was deferred in 353rd meeting. The decision of the Board is as follows:	
Decision: The Board was apprised the inconsistency between the date of submission of forced degradation studies and the timeline of the raised query. The Board considering the observation, directed the firm to submit clear justification and supporting evidence clarifying the chronology of submitted data.	
The firm was asked to provide following clarification.	
The final query regarding the submission of stability study of DS according to the conditions of zone IV-A, was forwarded on 11-12-2025 and the submitted chromatograms of degradation studies were acquired on 18-20th March, 2025, it the almost the 3rd month time point's testing. Clarification is required regarding performance of degradation studies before the query along with the supporting documents e.g. audit trail report, raw data sheets etc.	
Response: The final query regarding the submission of stability study of DS according to the conditions of zone IV-A, was forwarded on 11-12-2025 and the submitted chromatograms of degradation studies were acquired on 18-20th March, 2025, it is to clarify that although it is not mandatory but we perform SIM studies (Degradation studies) on routine basis for all the products for which we perform stability studies and the same was performed for the product under consideration (Betapime 500mg & 1g Injection).	
"our HPLC system is equipped with auto sampler and we normally perform the studies as a whole project taking advantage of auto sampling facility. Once the complete project is run, we process all the data of project at the same time. Moreover, as no excipients are involved in Cefepime injection	

	and the same lot is used for both 500mg and 1g injections having same qualitative formulation, analyzed using the same stability indicating method results appear same and close to each other having same chromatographic profiles."	
	The firm has submitted Audit trail report motioning the SIM testing on 19-03-2025.	
	Decision	
	Deferred for verification of audit trail report from 18th to 20th March, 2025.	
100	Case Category	Any Other (Farooq Aslam)
	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	(7HJ-7NY-J1TX, 2026-01-27)
	Detail of Fee Submitted	300000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Amtrix 500mg**
	Label Claim	Each vial contains: Ceftriaxone as Sodium.. 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1'S ; 50'S AND/OR AS-Controlled
	Shelf Life (Unit)	3 Year(s)the finished product should be stored in a dry place and not above 30°C
	For generic drugs (me-too Status)	generic
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., L-No.88, Yangzi Road, Economic and Technological Development Zone, Shijiazhuang City, China.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Report for PE studies against Rocephin by M/s Roche Products Limited (EU) is submitted.
	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 DML No. JI20150137 valid till 27-11-20230 is submitted. The manufacturing scope includes Cephalosporins.
	Details of Authorization Letter :	CoPP: Apostille copp no. Hebeu200250450 valid till 07-07-2027 is submitted. Ceftriaxone as sodium 0.5g is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL valid till 08-05-2028 is submitted. LOA: Copy of LOA is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	USFDA approved
	Evaluation Remarks	
	The application has been processed in compliance to the decision of DRAP Authority on priority. The case was deferred in 355th meeting for: 1. Submission of analytical method verification studies for drug substance. 2. Submission of notarized letter of authorization. The case was deferred in 355th meeting for:	

	Reason	Response
	Submission of analytical method verification studies for drug substance.	The firm has stated that Ceftriaxone sodium for injection is produced by simple sterile filling of the substance without any chemical reaction during the manufacturing process, so the analytical method and validation between the API substance and FPP is the same.
	Submission of notarized letter of authorization.	"We hereby undertake to submit the notarized letter of authorization by May 8, 2026"
	Decision	
	Approved as per import policy for inspection of manufacturer abroad. The firm shall submit notarized letter of authorization.	
101	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)**
	Application Form Dy. No / Tracking ID & date of submission	(MUQ-U5A-A59H, 2025-11-11)
	Detail of Fee Submitted	37000.0, 2025-05-07,
	The proposed proprietary name / brand name	**N-GIL 2.6MG TABLET**
	Label Claim	Each sustained release tablet contains: Glyceryl trinitrate (USP)...2.6mg
	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)Store at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Sustac SR 2.6mg Tablets By The Searle Company Limited
	Pharmacotherapeutic Group of (API)	VASODILATOR
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chin Chem
	Detail of stability batches of drug product	Batches: 212B24, 213B24, 214B24 3 batches having batch size of 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	...
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Sustac Tablet by M/s The Searle Company Limited Karachi.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of drug substance as per Zone IV-B 60 months real time and 06 months acc.
	The status in reference regulatory authorities	SUSTAC SR 2.6MG TABLETS By M/s CHEMIDEX PHARMA LTD MHRA Approved
	GMP status of the firm	Submitted copy of cGMP certificate of the firm based on inspection dated 21st Jan 2025
	Evidence of approval of manufacturing facility	Submitted copy of letter of renewal of DML dated 01-06-2021 specifying Tablet (General) section.

Evaluation Remarks

Observations	Response
Submission of dissolution testing in PE studies since the submitted justification is not acceptable as the dissolution media is different for dissolution testing and CDP recommended media.	PE and CDP studies have been performed against Sustac Tablet by M/s The Searle Company Limited Karachi.
You have used Diluted Nitroglycerine 2% w/w with Lactose, please provide any reference for the formulation specifically addition of 2% Lactose w/w.	USP describes the content of Nitroglycerine with a limit of NMT 10%.
Provide reference for adopting the dissolution specifications.	Submitted.
The firm was asked to provide import documents.	Initially the firm had submitted supply letter form M/s Dawn Impex 2kg diluted Nitroglycerine and clearance certificate from M/s Unimark Pharmaceuticals, but the batch number was different from the batch used for product development. The firm was asked to submit clarification and the firm replied that they had attached the documents from M/s Unimark mistakenly. Now the firm has submitted clearance certificate and form 6 from M/s Tabros Pharma.

The case was deferred in 353rd meeting. following is the decision of Registration Board:

In view of discrepancies in the submitted import documents and the involvement of an unauthorized importer i.e. M/s Dawn Impex, the Board decided to defer the case and directed the firm to submit detailed clarifications and supporting documents regarding the change of import documents.

Response: Now the firm has submitted Clearance certificate dated 27-03-2024 from M/s Tabros Pharma without responding to the direction of the Board for clarification regarding change oof import documents.

Decision

Deferred

For confirmation of provision of loan from M/s Tabros Pharma. The Board further directed the applicant to submit clarification regarding the borrowing of drug substance for product development.

102	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)**
	Application Form Dy. No / Tracking ID & date of submission	(HE8-9WQ-73U3, 2025-09-26)
	Detail of Fee Submitted	37000.0, 2025-05-07,
	The proposed proprietary name / brand name	**N-GIL 6.4MG TABLET**

Label Claim	Each sustained release tablet contains: Glyceryl trinitrate (as Diluted Nitroglycerine USP)...6.4mg
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)Store at 25°C. Excursions permitted between 15°C and 30°C.
For generic drugs (me-too Status)	Sustac SR 6.4mg Tablets By The Searle Company Limited
Pharmacotherapeutic Group of (API)	VASODILATOR
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Chin Chem
Detail of stability batches of drug product	Batches: 212B24, 213B24, 214B24 3 batches having batch size of 1200 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	The firm has not directly imported the raw material for product development; however the firm has submitted a letter from M/s Dawn Impex confirming the supply of 2kg diluted Nitroglycerine.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Sustac Tablet by M/s The Searle Company Limited Karachi.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted stability study data of 3 batches of drug substance as per Zone IV-B 60 months real time and 06 months acc.
The status in reference regulatory authorities	SUSTAC prolonged release 6.4MG TABLETS By M/s CHEMIDEX PHARMA LTD MHRA Approved
GMP status of the firm	Submitted copy of cGMP certificate of the firm based on inspection dated 21st Jan 2025
Evidence of approval of manufacturing facility	Submitted copy of letter of renewal of DML dated 01-06-2021 specifying Tablet (General) section.

Evaluation Remarks

Observations	Response
Submission of dissolution testing in PE studies since the submitted justification is not acceptable as the dissolution media is different for dissolution testing and CDP recommended media.	PE and CDP studies have been performed against Sustac Tablet by M/s The Searle Company Limited Karachi.
You have used Diluted Nitroglycerine 2% w/w with Lactose, please provide any reference for the formulation specifically addition of 2% Lactose w/w.	USP describes the content of Nitroglycerine with a limit of NMT 10%.
Provide reference for adopting the dissolution specifications.	Submitted.
The firm was asked to provide import documents.	Initially the firm had submitted supply letter form M/s Dawn Impex 2kg diluted Nitroglycerine and clearance certificate from M/s Unimark Pharmaceuticals, but the batch number was different from the batch used for product development. The firm was asked to submit clarification and the firm replied that they had

		attached the documents from M/s Unimark mistakenly. Now the firm has submitted clearance certificate and form 6 from M/s Tabros Pharma.

The case was deferred in 353rd meeting. following is the decision of Registration Board:

In view of discrepancies in the submitted import documents and the involvement of an unauthorized importer i.e. M/s Dawn Impex, the Board decided to defer the case and directed the firm to submit detailed clarifications and supporting documents regarding the change of import documents.

Response: Now the firm has submitted Clearance certificate dated 27-03-2024 from M/s Tabros Pharma without responding to the direction of the Board for clarification regarding change oof import documents.

Decision

Deferred

For confirmation of provision of loan from M/s Tabros Pharma. The Board further directed the applicant to submit clarification regarding the borrowing of drug substance for product development.

103	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar **(000995)**
	Application Form Dy. No / Tracking ID & date of submission	(7JP-YTZ-B565, 2024-11-08)
	Detail of Fee Submitted	75000.0, 18000.0 2024-09-02, 2024-10-17
	The proposed proprietary name / brand name	**KESTER**
	Label Claim	Each 1ml ampoule contains: KetoralacTromethamine USP 30mg
	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°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	NSAID's
	Name, address of Manufacturing site:	Biogen Life Sciences-M/s Biogen Life Sciences Address:8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Toradol 30mg/ml, USFDA Approved.
	Detail of previous approval	336th meeting Sr. No. 873

Evaluation Remarks

The applied product was approved in 336th meeting held on 4-6th June 2024 in favor of M/s Biogen LifeSciences. 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 asan 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	Routine (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(ZUG-HXG-AZX6, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Lipitor 80mg Tablet**
	Label Claim	Each film coated tablet contains: Atorvastatin (as the calcium trihydrate).....80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, 20s and 30s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Lipirex by Highnoon Laboratories Ltd
	Pharmacotherapeutic Group of (API)	Antihypertensive, Selective, competitive inhibitor of HMG-CoA reductase.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Up John Manufacturing Ireland Unlimited Company
	Detail of stability batches of drug product	03 batches : 1250 tablets each 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 20-10-2023 for 2.5kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Lipitor 80mg tablet by M/s Pfizer, US.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-06-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Form 6 dated 20-10-2023 for 2.5kg material is submitted.	
	Decision	
	Approved	
105	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(45Z-29E-79UA, 2026-03-26)
	Detail of Fee Submitted	38700, 2026-03-17,
	The proposed proprietary name / brand name	**Acedot 30mg Sachet**

	Label Claim	Each sachet contains: Racecadotril.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 16's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Cecado 30mg Sachet OBS AGP (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	AAntidiarrheals, Intestinal Anti-inflammatory/Anti-infective Agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Private Limited. Manufacturing Site Address: D-16, Phase-I, IDA-Jeedimetla, Hyderabad-500055 Telangana State
	Detail of stability batches of drug product	Batches TR-RASH-06, TR-RASH-07, TR-RASH-08, 500 sachet each. 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)	Clearance certificate dated 16-06-2025 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Recada sachet by M/s Sami Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.....
	The status in reference regulatory authorities	HIDRASEC CHILDREN 30 mg, Granules for oral suspension by Bioprojet Europe Ltd. (MHRA)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-04-2024.
	Evidence of approval of manufacturing facility	Sachet General Section (New) is approved.
	Evaluation Remarks	
	Initially the firm had submitted stability data of drug substance according to zone IV-A and during evaluation it was noted that the values of results of different parameters in zone IV-A data were exactly the same as submitted in data of zone II till 36 months.	
	The firm was asked to clarify.	
	The firm has submitted new data of zone IV-A and has not submitted any clarification.	
	Decision	
	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
106	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(VLV-YJZ-3XAQ, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-03-17,
	The proposed proprietary name / brand name	**Acedot 10mg sachet**

	Label Claim	Each sachet contains: Racecadotril.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 16's, 20's, 30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Cecada 10mg sachet of OBS AGP (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	AAntidiarrheals, Intestinal Anti-inflammatory/Anti-infective Agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Pvt Ltd
	Detail of stability batches of drug product	Stability Batches (TR-RASH-02, TR-RASH-03, TR-RASH-04) 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)	Clearance certificate dated 16-06-2025 for 2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Recada sachet by M/s Sami Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.....
	The status in reference regulatory authorities	HIDRASEC INFANTS 10mg Granules for oral suspension by bioprojet Europe (MHRA))
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-04-2024.
	Evidence of approval of manufacturing facility	Sachet General Section (New) is approved.
	Evaluation Remarks	
	Initially the firm had submitted stability data of drug substance according to zone IV-A and during evaluation it was noted that the values of results of different parameters in zone IV-A data were exactly the same as submitted in data of zone II till 36 months.	
	The firm was asked to clarify.	
	The firm has submitted new data of zone IV-A and has not submitted any clarification.	
	Decision	
	Rejected The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of edited stability data pertaining to the drug substance by the applicant, the Board decided to reject the case.	
107	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(QH8-GQ8-4JDM, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-02,
	The proposed proprietary name / brand name	**Biofos 3g Sachet**
	Label Claim	Each sachet contains: Fosfomycin Trometamol eq. to Fosfomycin.....3g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled

	Shelf Life (Unit)	2 Year(s)Protect from heat sunlight and moisture. Store below 30ºC
	For generic drugs (me-too Status)	Cynfo 3g Sachet, Sami Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	J01XX01 - Other antibacterial (Fosfomycin)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Northeast Pharmaceutical Group Co.,Ltd, Plot No. 29, Shenxiliu Dong Road, Economic Technology Development District, Shenyang.
	Detail of stability batches of drug product	03 batches : 200 Sachet each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 16-05-2025 for 20 KG material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies submitted against the comparator's product i.e. Focin Ultra 3g Sachet by M/s Tabros Pharma Pvt. Ltd.,
	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 zone IV-A.
	The status in reference regulatory authorities	Monuril 3g granules for oral solution by Zambon UK Limited - EMC MHRA UK
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 26-04-2024.
	Evidence of approval of manufacturing facility	Sachet General Section (NEW) is approved.
	Evaluation Remarks	
	Decision	
	Approved	
108	Case Category	Any Other (Farooq Aslam)
	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	(M3R-1HP-J8NY, 2026-02-16)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**Talda 20mg Tablets**
	Label Claim	Each film coated tablet contains: Tadalafil..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	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)	Fildil (Tadalafil) Tablets 5mg, 10mg & 20mg. Highnoon Laboratories Ltd. Reg. No. 127633, 127634 &127635
	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:	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	03 batches (Batch size: 1000 tablets) 06 months accelerated and -6 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 26-03-2025 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies are 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 the conditions of zone IV-A.
	The status in reference regulatory authorities	CIALIS (tadalafil) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Lilly USA, LLC Indianapolis, IN 46285, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP authority regarding ED drugs.	
	Decision	
	Approved	
109	Case Category	Any Other (Farooq Aslam)
	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	(MGU-JPT-Y9M6, 2026-02-16)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**Talda 10mg Tablets**
	Label Claim	Each film coated tablet contains: Tadalafil..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	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)	Fildil (Tadalafil) Tablets 5mg, 10mg & 20mg. Highnoon Laboratories Ltd. Reg. No. 127633, 127634 &127635
	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:	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	03 batches (Batch size: 1000 tablets) o6 months accelerated and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies are 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 the conditions of zone IV-A.
	The status in reference regulatory authorities	CIALIS (tadalafil) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Lilly USA, LLC Indianapolis, IN 46285, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP authority regarding ED drugs.	
	Decision	
	Approved	
110	Case Category	Any Other (Farooq Aslam)
	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	(VZ5-ZZJ-DBWN, 2026-02-16)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**Talda 5mg Tablets**
	Label Claim	Each film coated tablet contains: Tadalafil..... 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	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)	Fildil (Tadalafil) Tablets 5mg, 10mg & 20mg. Highnoon Laboratories Ltd. Reg. No. 127633, 127634 &127635
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction. ATC code: G04BE08. Tadalafil is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5)
	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	03 batches (Batch size: 1000 tablets) o6 months accelerated and 06 months real time according to zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 26-03-2025 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies are 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 the conditions of zone IV-A.
	The status in reference regulatory authorities	CIALIS (tadalafil) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Lilly USA, LLC Indianapolis, IN 46285, USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP authority regarding ED drugs.	
	Decision	
	Approved	
111	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	(J8Z-27Q-XRH2, 2026-03-02)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	**Consista 10mg Tablets**
	Label Claim	Each Film coated tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled-De-Controlled,12's-De-Controlled-De-Controlled,15's-DeControlled-De-Controlled,16's-De-Controlled-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)	Tadalis Tablet I0mg- Hilton Pharma (Pvt) Ltd
	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 batch numbers are: T-486, T-487, T-488 (1500 tablets each) 06 months accelerated and 06 months real time according 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	Food and Drug Regulatory Authority USA-Cialis 10mg Tablet-ELI LILLY AND CO
	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 on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
112	Case Category	New Section (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	(7D1-3U2-R1L7, 2025-10-28)
	Detail of Fee Submitted	75000, 2025-10-23,
	The proposed proprietary name / brand name	**Colene Capsules 0.6mg**
	Label Claim	Each Capsule Contains: Colchicine.....0.6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	could not be confirmed (0.6mg tablet by NabiQasim is registered)
	Pharmacotherapeutic Group of (API)	Colchicine is an alkaloid used to treat gout and Familial Mediterranean Fever as well as prevent major cardiovascular events.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	India Glycols Limited.
	Detail of stability batches of drug product	COC-01, COC-002, COC-003 Each of 1500 Capsules 06 months accelerated and 06 months real time stability data of 03 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 19-09-2024 for 10 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Mitigare 0.6mg Capsule by Hikma Specialty USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months and 48 months stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	

	New Section	
	Decision	
	Approved The Board decided that the firm shall submit: 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
113	Case Category	New Section (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	(E3B-REM-U8ET, 2025-10-28)
	Detail of Fee Submitted	38700, 2025-10-23,
	The proposed proprietary name / brand name	**Colene Tablets 0.5mg**
	Label Claim	Each Tablet Contains: Colchicine.....0.5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC at cool and dry place
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Colchicine is an alkaloid used to treat gout and Familial Mediterranean Fever as well as prevent major cardiovascular events.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	India Glycols Limited.
	Detail of stability batches of drug product	COT-001, COT-002 Each of 5000 Tablets 06 months accelerated and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 19-09-2024 for 10 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Colchicine Tablets by Lahore Chemical And Pharmaceutical Works (Pvt) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months and 48 months stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Tablet General Section is approved as new section.
	Evaluation Remarks	
	New Secction	
	Decision	

	Approved	
114	Case Category	New Section (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	(8MY-1WH-S51X, 2026-02-24)
	Detail of Fee Submitted	38700, 2025-12-30,
	The proposed proprietary name / brand name	**Rotril 100mg Capsule**
	Label Claim	Each Capsule Contains: Racecadotril.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's capsule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C, and protect from heat, light and moisture.
	For generic drugs (me-too Status)	Available (SAmi)
	Pharmacotherapeutic Group of (API)	Racecadotril is an anti-secretory enkephalinase inhibitor useful in the treatment of diarrhea.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Pvt. Ltd.
	Detail of stability batches of drug product	RAC-001, RAC-002, RAC-003 each of 1000 capsules 06 months accelerated and 06 months real time according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 27-10-2024 for 1.2kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Recada Capsule 100mg by Sami Pharmaceuticals Pakistan
	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	UK-MHRA aprroved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
115	Case Category	New Section (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	(TL8-SHT-X5HG, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-02,
	The proposed proprietary name / brand name	**Omenac MR Capsule 75mg/20mg**
	Label Claim	Each Modified Release Capsule Contains; Diclofenac Sodium (as 25mg gastro resistant and 50mg prolonged released pellets)

		..... 75mg Omeprazole (as gastro-resistant pellets)..... 20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x10's Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store the capsules below 30°C
	For generic drugs (me-too Status)	Duglob 75mg/20mg MR Capsule by M/s Global
	Pharmacotherapeutic Group of (API)	NSAID/PPI
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Surge Laboratories (Private) Limited,Surge Laboratories (Pvt) Ltd
	Detail of stability batches of drug product	DOC-001, DOC-002 Each of 5000 Batches 06 months accelerated and 06 months real time stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice no. 24101451-SG dated 28-10-2024 for 3kg diclofenac pellets and 5kg omeprazole pellets from M/s Surge Laboratories is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against the reference product i.e. Dicloduo Combi MR Capsule 75mg / 20mg by M/s Haupt Pharma Amarg Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Diclofenac Sodium pellets: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A. Omeprazole: 06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	EMA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
116	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	(XS9-A4Q-SQTA, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-11-19,
	The proposed proprietary name / brand name	**Permith**
	Label Claim	Each 100 gram of cream contain: Permethrin 5g
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30°C
	For generic drugs (me-too Status)	Lotrix cream by GSK
	Pharmacotherapeutic Group of (API)	Pyrethroids/antiparasitic
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	NGL Fine-Chem Limited. Unit no. 2, W-41/C, MIDC Tarapur Industrial Area, Boisar, District-Palghar 401506, Maharashtra, India
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size: 30g*67 tubes) 06 months accelerated and 12 months real time stability data according to zone IV-B.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 15-01-2025 for 1.6kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. ScabFree 5% w/w cream by M/s Atco
	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	Permethrin Cream 5% w/w by MHRA
	GMP status of the firm	NA
	Evidence of approval of manufacturing facility	NEW DML issued w.e.f. 27-10-2023. Cream/Ointment (General) Section is approved.
	Evaluation Remarks	
	New License	
	Decision	
	Approved	
117	Case Category	Routine (Farooq Aslam)
	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	(J5E-D45-V9QD, 2024-10-18)
	Detail of Fee Submitted	75000.0, 18030.0 2024-07-11, 2024-09-30
	The proposed proprietary name / brand name	**PHLORIL 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 Year30C
	For generic drugs (me-too Status)	ANAFORTAN PLUS(AGP Pakistan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	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	Spasfon Injection(Teva Sante, ANSM FRANCE APPROVED DRUG)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted approval letter No.F.119-PRVC/2024(PR-II) dated 16th May, 2024 for change of manufacturing site from M/s Swiss Pharma (contract manufacturer) to M/s Seraph Pharmaceuticals (self manufacturing facility) for the product Sefonic (Reg No. 110977). The contract manufacturer in the instant case is M/s Seraph Pharmaceuticals.	
	Decision	
	Approved	
118	Case Category	Routine (Farooq Aslam)
	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	(APR-BQ8-8GXP, 2024-09-13)
	Detail of Fee Submitted	30000.0, 2024-09-05,
	The proposed proprietary name / brand name	**Eprenol 50mg Tab**
	Label Claim	Each sugar coated tablet contains: Eperisone HCl.....50mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)At room temperature
	For generic drugs (me-too Status)	Perispa 50mg tab by M/s Platinum
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. SNA Healthcare Pvt. Ltd. Address: Plot No. N-213/3, MIDC Tarapur, Boisar 401506, Maharashtra, INDIA.
	Detail of stability batches of drug product	03 batches : 1000 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)	Loan letter from M/s Kanel Pharmaceuticals for 300 grams of material sated 05-03-2024 is submitted. Clearance certificate dated 29-11-2023 is submitted issued to M/s Kanel Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Perispa 50mg tablet by M/s Platinum.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Myonal tablet 50mg PMDA Japan approved
	GMP status of the firm	Last inspection report dated 28-10-2024 is submitted,
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Verification of loan letter is required.	
	Decision	

	Approved subject to verification of loan letter and pre-registration fee for change of title of marketing authorization holder.	
119	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	(DNS-23N-2ALG, 2025-04-11)
	Detail of Fee Submitted	75000.0, 2025-02-25,
	The proposed proprietary name / brand name	**FAMTROL FL**
	Label Claim	Each metered dose (ex-valve) contains: Fluticasone propionate---------- -- 50 mcg Formoterol fumarate dihydrate. ---------- 5mcg Deliverable dose: fluticasone propionate.....46mcg formoterol fumarate dihydrate.....5mcg
	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)Do not store above 25°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
	Detail of stability batches of drug product	Batches: 24Sb-359-01, 24Sb-360-02, 24Sb-361-03 (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 and 0.25kg Fluticasone propionate is submitted along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. FLutiform pressurized inhalational suspension by M/s Napp Pharmaceuticals Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Fluticasone propionate: 06 months accelerated and 60 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	

120	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	(ZTY-TY6-XA7L, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-02-25,
	The proposed proprietary name / brand name	**FAMTROL FL**
	Label Claim	Each metered dose (ex-valve) contains: Fluticasone propionate---------- -- 125 mcg Formoterol fumarate dihydrate. ---------- 5mcg Deliverable dose: fluticasone propionate.....115mcg formoterol fumarate dihydrate.....4.5mcg
	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)Do not store above 25°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
	Detail of stability batches of drug product	Batches: 24Sb-368-01, 24Sb-369-02, 24Sb-370-03 (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 and 0.25kg Fluticasone propionate is submitted along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. FLutiform pressurized inhalational suspension by M/s Napp Pharmaceuticals Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Fluticasone propionate: 06 months accelerated and 60 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	
121	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	(JSX-MX7-4JH1, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-02-25,
	The proposed proprietary name / brand name	**FAMTROL FL**
	Label Claim	Each metered dose (ex-valve) contains: Fluticasone propionate---------- -- 250 mcg Formoterol fumarate dihydrate. ------ ---------- 10mcg Deliverable dose: fluticasone propionate.....230mcg formoterol fumarate dihydrate.....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)Do not store above 25°C
	For generic drugs (me-too Status)	-
	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-373-01, 24Sb-374-02, 24Sb-375-03 (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 and 0.25kg Fluticasone propionate is submitted along with unattested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. FLutiform pressurized inhalational suspension by M/s Napp Pharmaceuticals Limited.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Formoterol fumarate dihydrate: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Fluticasone propionate: 06 months accelerated and 60 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	
122	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**

	Application Form Dy. No / Tracking ID & date of submission	(6BU-ZAT-9YES, 2024-11-19)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Sugamed 200mg/2ml injection**
	Label Claim	Each 2ml ampoule contains: Sugammadex sodium equivalent to Sugammadex 200mg
	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 30C
	For generic drugs (me-too Status)	Brand Name: Sugat 200mg/2ml injection Registration holder: Sami Pharmaceutical Pakistan
	Pharmacotherapeutic Group of (API)	Selective Relaxant Binding Agents (SRBAs) / modified -cyclodextrin used to reverse neuromuscular blockade induced by the aminosteroid muscle relaxants rocuronium and vecuronium / Antidot
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Shandong Chenghui Shuangda Pharmaceutical Co., Ltd. Address: Economic Development Zone, Pingyuan County, Dezhou City, Shandong, P.R.China
	Detail of stability batches of drug product	03 batches : 1000 ampoules each 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)	Clearance certificate dated 11-08-2023 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Bridion by M/s MSD Sub MERCK, US.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches 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 17-12-2023.
	Evidence of approval of manufacturing facility	Liquid injectable Ampoule (General) (Additional Section) is approved.
	Evaluation Remarks	
	Decision	
	Approved	
123	Case Category	Any Other (Farooq Aslam)
	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	(APS-A5H-U41D, 2026-03-21)
	Detail of Fee Submitted	300000.0, 2025-04-18,
	The proposed proprietary name / brand name	**Borteshil**

	Label Claim	Each single dose vial contains: Bortezomib.....3.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	01's-As per SRO
	Shelf Life (Unit)	2 Year(s)15°C - 30°C
	For generic drugs (me-too Status)	Bortesoh by AJM Pharma
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (ATC Code L01XG01)
	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	PE studies have been performed against the reference product Velcade 3.5mg.
	Name, address of Marketing Authorization Holder:	Shilpa Medicare Limited, Plot No. S-20 to S26, Pharmaceutical formulations SEZ, TSIIC, Green Industrial Park, Polepally, Jadcherla, Telangana, 509301, India, India
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 07-10-2026 is submitted.
	Details of Authorization Letter :	CoPP: Legalized CoPP No. 4312238/TS/2024 valid till 14-03-2026 is submitted. The applied product is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP as per submitted CoPP. LOA: Notarized LOA dated 08-09-2025 is submitted. DSL: DSL valid till 23-05-2029 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to zone II.
	The status in reference regulatory authorities	Velcade (Takeda Pharmaceuticals America, Inc) USFDA Approved
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding imported drug products. The Submitted CoPP is expired.	
	Decision	
	Approved as per policy of import for inspection of manufacturer abroad.	
124	Case Category	New Section (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	(RSD-53Z-9QVQ, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	**Cefim Tablets 400mg**
	Label Claim	Each film-coated tablet contains: Cefixime..... 400 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-Controlled,20's-Controlled,30's-Controlled,5's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from Sunlight.

	For generic drugs (me-too Status)	Cebosh 400mg Tablets by Bosch Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 1785 tablets each 06 months accelerated and 06 months real time stability data of according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice No. 2119 dated 25-03-2023 is submitted from M/s Pharmagen Limited Lahore.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed agianst the reference product i.e Suprax tablet by M/s Odan Laboratories Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 baches according to zone V-A.
	The status in reference regulatory authorities	Health Canada Approved - Suprax 400mg Tablets (Cefixime) by Odan Laboratories, Monteal, Canada
	GMP status of the firm	NEW Section approval letter issued on 14-11-2025 for Tablet Cephalosporin.
	Evidence of approval of manufacturing facility	NEW Section approval letter issued on 14-11-2025 for Tablet Cephalosporin.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
125	Case Category	New Section (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	(UP3-Q53-H6V8, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	**Cefim Tablets 200mg**
	Label Claim	Each Film coated tablet contains: Cefixime..... 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's -Controlled,20's-Controlled,30's-Controlled,5's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C. Protect from Sunlight.
	For generic drugs (me-too Status)	Cefiget 200mg Tablets by Getz Pharma Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 3571 tablets each 06 months accelerated and 06 months real time stability data of according to zone IV-A.
	Documents for the procurement of API with approval from DRAP	Invoice No. 2119 dated 25-03-2023 is submitted from M/s Pharmagen Limited Lahore.

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed agianst the reference product i.e Suprax tablet by M/s Odan Laboratories Canada.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 baches according to zone V-A.
	The status in reference regulatory authorities	CIMA Spain approved
	GMP status of the firm	NEW Section approval letter issued on 14-11-2025 for Tablet Cephalosporin.
	Evidence of approval of manufacturing facility	NEW Section approval letter issued on 14-11-2025 for Tablet Cephalosporin.
	Evaluation Remarks	
	New Section	
	Decision	
	Approved	
126	Case Category	New Section (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	(RJH-TLS-JGWD, 2026-04-09)
	Detail of Fee Submitted	75000, 2026-01-28,
	The proposed proprietary name / brand name	**Xanpo Capsule 125mg/30mg**
	Label Claim	Each Capsule contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....125mg Trospium chloride IR pellets equivalent to Trospium Chloride.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10’s capsule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizoph. Trospium cHLORIDE is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).renia.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
	Detail of stability batches of drug product	XTH-001, XTH-002, XTH-003 Each of 1000 capsules 06 months real time and 06 moth accelerated according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy Capsule 125mg/30mg (USFDA)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	
	The process of IR pellet manufacturing will be carried out in the same section using spheronizer.	
	Decision	
	Deferred The Board decided that the firm shall submit: 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
127	Case Category	New Section (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	(XTS-LP7-T8J1, 2026-04-09)
	Detail of Fee Submitted	75000, 2026-01-28,
	The proposed proprietary name / brand name	**Xanpo 100mg/20mg Capsule**
	Label Claim	Each Capsule contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....100mg Trospium chloride IR pellets equivalent to Trospium Chloride.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's capsule-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizophrenia.Trospium Chloride: Trospium Chloride is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
	Detail of stability batches of drug product	XTM-001, XTM-002, XTM-003 each of 1200 Capsules 06 months real time and 06 moth accelerated according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy Capsule 100mg/20mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
	Evaluation Remarks	
	The process of IR pellet manufacturing will be carried out in the same section using spheronizer.	
	Decision	
	Deferred The Board decided that the firm shall submit: 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
128	Case Category	Any Other (Farooq Aslam)
	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	(MZW-WQD-9HWE, 2025-09-30)
	Detail of Fee Submitted	300000.0, 2025-06-25,
	The proposed proprietary name / brand name	**BORTADE 3.5mg/Vial**
	Label Claim	Each Vial cotains: Bortezomib.... 3.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO

Shelf Life (Unit)	24 Month(s)Store below 30°C. Protect from light and moisture.
For generic drugs (me-too Status)	Bortezomib 3.5mg/Vial MAH: Himont Pharmaceuticals (Pvt)Ltd.
Pharmacotherapeutic Group of (API)	Other antineoplastic agents
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	A comparative analysis of Bortezomib for Injection (3.5 mg/vial) showed that the test product by Kindos Pharmaceuticals is comparable to the reference product by Millennium Pharmaceuticals. Both appeared as white lyophilized powder and met assay specifications (Kindos: 102.0%, Reference: 97.7%). Identification tests for the test product conformed by UV and HPLC. Overall, the test product meets pharmacopeial standards.
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):	....
Details of Authorization Letter :	CoPP: The firm has submitted CoPP No. TF2k-36x9 valid till 11-07-2027. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL is valid till 15-08-2029. LOA: LOA from Manjing King-Friend Biochemical Pharmaceutical Co., Ltd., grants distribution the rights on behalf of M/s Meitheal Pharmaceuticals Inc, USA (MAH abroad) to the applicant.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies of Bortezomib 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 , 75% ± 5% RH for 6 months) as per ICH guidelines.
The status in reference regulatory authorities	Velcade Bortezomib 3.5 mg/Vial Millennium Pharmaceuticals, USFDA Approved
Evaluation Remarks	
The application has been processed in compliance to the decision of DRAP Authority.	
The stability data of drug substance, the submitted real time stability data is at 25oC and accelerated stability data is at 40oC whereas the innovator has mentioned the storage conditions as -20oC . The fir was asked to submit clarification.	
Reply: Stability studies for Bortezomib API were performed in accordance with ICH Q1A(R2), under long-term conditions of 25°C±2°C/60%RH±5% and accelerated conditions of 40°C ±2°C/75%RH±5%. These are standard and widely accepted conditions for evaluating the intrinsic stability and degradation pathways of drug substances. The purpose of such studies is to assess the inherent stability of the API, not to replicate the innovator's storage conditions. The innovator's –20°C storage may be attributed to its specific manufacturing process, impurity profile or other product-specific factors.	
Decision	

	Deferred for further deliberations on the storage conditions of drug substance. The Board directed the firm to submit supporting documents.	
129	Case Category	New Molecule/Formulation (Farooq Aslam)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(3ZP-XMU-BJN9, 2024-07-05)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Anelta (lefamulin) Injection 150mg/15mL**
	Label Claim	Each vial contains 168 mg Lefamulin acetate equivalent to 150 mg Lefamulin.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	6's -As per SRO
	Shelf Life (Unit)	2 Year(s)2°C to 8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antibacterial for Community Acquired Bacterial Pneumonia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yibin Hongguang Pharmaceutical Co., Ltd. Luolong county Nanxi District, Yibin City, Sichuan Province, China, PC-644100
	Detail of stability batches of drug product	3 batches: 700 vials 06 months accelerated (25oC/60%RH) and 06 months real time (3-5oC) stability studies have been submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	06-03-2023: Drug Import License for 0.5Kg API submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	XENLETA Injection: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone II conditions
	The status in reference regulatory authorities	XENLETA Injection (USFDA Approved)
	GMP status of the firm	29-01-2024: GMP Certificate inspection date
	Evidence of approval of manufacturing facility	21-06-2021: DML renewal specifies sterile infusion general I section
	Evaluation Remarks	
	The case was deferred in 345th meeting. 1. Clarify where the applied product will be manufactured, considering the fact that the drug substance of the innovator's product is produced through a natural fermentation process. Furthermore also clarify using scientific evidence as well as definition from DRAP Act as well as LRA Rules, that the applied product does not fall under the definition of Biological Product.	
	Reply: Lefamulin is derived from fermentation, but its final form is chemically modified. It is a semi-synthetic drug. The firm has submitted summary of synthetic route of the process of manufacturing.	
	2. Specify the polymorphic form of the drug substance used in the manufacturing of stability batches.	
	Reply: Form B is used in manufacturing of stability batches.	
	3. Provide details about the absolute stereochemistry of the drug substance used in your studies, since the API manufacturer has not performed any specific test.	

	Reply: The firm has submitted XRD structure analysis spectrum.	
	4. The innovator's product is supplied as a 15ml vial containing the active drug along with a 2-port infusion bag containing 250ml of 10mM citrate-buffered saline. While in your application you have not provided any details of the citrate buffered saline either as separate 3.2.P part or either within the same module 3.2.P.	
	Reply: The firm has provided the details of accompanying diluent. The firm has submitted a separate application No. V6L-AU2-W4PW for registration of diluent. The firm has not submitted In-Use stability studies.	
	5. Provide detailed description of the finished pack in which both components will be present, where the infusion bag will be manufactured, details manufacturing and specification of the infusion bag along with its stability stuyd data.	
	Reply: Lefamulin concentrate and diluent will be supplied as a kit containing 1 vial of concentrate and a glass vial of diluent.	
	6. Provide compatibility studies of your product with the citrate-buffered saline and in-use stability studies.	
	Reply: Submitted.	
	7. Submit detailed pharmaceutical equivalence studies of the diluent along with innovator's product's diluent as well.	
	submitted.	
	8. Submit 6th month stability study data	
	Submitted.	
	9. Justify why terminal sterilization of the product is nt performed. Moreover justification is also required how the bioburden will be controlled in finished product since the product also use sodium chloride in which bioburden is not fully controlled.	
	Reply: The finished product is sensitive to heat as per provided EMA report. The firm has not responded to the query regarding NaCL for controlling bioburden.	
	10. Submit clearance certificte as evidence of import of API since you have only submitted Drug Import License. Moreover copy of commercial invoice which is not attested by I&E DRAP is not evidence of import of API. You are advised to either submit clearance certificate / AD attested invoice or traceable and verifiable copy of Goods Declaration.	
	Copy of GD and receipt of duty.	
	11. Submit API stability study data as per Zone IV-A conditions	
	06 months accelerated and 36 months real time stability according to zone IV-A is submitted.	
	Decision	
	Deferred The Board decided that the firm shall submit: 1. In-use stability studies of drug product with the recommended diluent. 2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. The Board further directed that the application of the diluent shall be presented in the next Board's meeting.	
130	Case Category	New Section (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	(37S-BHM-6U4A, 2026-04-09)
Detail of Fee Submitted	75000, 2026-01-28,
The proposed proprietary name / brand name	**Xanpo 50mg/20mg Capsule**
Label Claim	Each Capsule Contains: Xanomeline tartrate IR pellets equivalent to Xanomeline.....50mg Trospium chloride IR pellets equivalent to Trospium Chloride.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	3 x 10's capsule-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Xanomeline Tartrate: Xanomeline is a muscarinic agonist used in conjunction with trospium, a muscarinic antagonist, to treat schizophrenia. Trospium Chloride is an antimuscarinic agent used to treat the symptoms of overactive bladder (OAB).
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	SHANDONG RISEN-SUN PHARMACEUTICAL CO., LTD.,VIYASH LIFE SCIENCES PRIVATE LIMITED
Detail of stability batches of drug product	XTL-001, XTL-002, XTL-003 each of 1200 Capsules 06 months real time and 06 moth accelerated according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Xanomeline Tartrate: Form 6 dated 24-03-2025 is submitted for 2.15kg material. Trospium chloride: Form 6 dated 24-03-2025 for 400 grams of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Cobenfy 50mg/20mg Capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Xanomeline tartrate: 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. Trospium chloride: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A.
The status in reference regulatory authorities	US FDA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
Evidence of approval of manufacturing facility	Second Capsule General Section is approved as new section.
Evaluation Remarks	
The process of IR pellet manufacturing will be carried out in the same section using spheronizer.	
Decision	
Deferred	

	The Board decided that the firm shall submit: 1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. 2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
131	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(18G-PLQ-RX57, 2024-10-21)
	Detail of Fee Submitted	75000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Estadol Advance 500mg Tablet**
	Label Claim	Each film-coated tablet contains: Paracetamol .....500mg (As per Innovator's Specs.)
	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)	Antipyretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Limited
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by UK-MEHRA as Panadol Advance 500 mg Tablets (Haleon UK Trading Limited)
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General Antibiotic section submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved	
132	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**VEGA PHARMACEUTICALS PVT LTD** PLOT # 4, PHARMA CITY 30KM MULTAN ROAD LAHORE **(000542)**
	Application Form Dy. No / Tracking ID & date of submission	(ADL-WA2-RMHE, 2025-07-28)

	Detail of Fee Submitted	37000.0, 2025-07-02,
	The proposed proprietary name / brand name	**Olopat Forte 0.7% Eye Drops**
	Label Claim	Each mL contains: 7.76 mg of olopatadine hydrochloride equivalent to 7 mg olopatadine (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15 - 30°C, protect from light.
	For generic drugs (me-too Status)	Xepat OD by Sante (Private) Limited
	Pharmacotherapeutic Group of (API)	Antihistamines
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches OPA T1-24, OPA T2-24, OPA T3-24 each having batch size of 2000 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 29-09-2023 specifies import of 2kg of Olopatadine hydrochloride
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against PAZEO (Batch # PA25539) by Alcon Laboratories, Inc..
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of API OLO/18/001, OLO/18/002, OLO/18/003 as per Zone IV-A
	The status in reference regulatory authorities	Health Canada approved Pazeo opthalmic solution 0.7% w/v
	GMP status of the firm	Valid GMP certificate issued on the basis of inspection dated 08-05-2024
	Evidence of approval of manufacturing facility	Eye/Ear Drops & Nasal Spray Section (General) II-New issued on 3rd June 2025
	Evaluation Remarks	
	Decision	
	Approved	
133	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(GHD-22N-W96Q, 2024-07-03)
	Detail of Fee Submitted	75000.0, 2024-06-14,
	The proposed proprietary name / brand name	**Estadol 1000mg/100ml**
	Label Claim	Each 100mL vial contains: Acetaminophen.....1000 mg (As per Innovator's specs.)
	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 controlled room temperature 20°C to 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Citi Pharma Limited. 3km, Head Balloki Road, Bhai Pheru, Distt Kasur - Pakistan
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted / Loan Letter by M/s. Horizon
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in USFDA (OFIRMEV)(Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons).
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 07.04.25 for tablet section only
	Evidence of approval of manufacturing facility	CLB letter dated 30th April 2024 indicating Liquid Injectable ampoule/vial General/General antibiotic is submitted by firm.
	Evaluation Remarks	
	Decision	
	Approved	
134	Case Category	Routine (Haleema Sharif)
	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	(ZGJ-2X8-4ZD1, 2024-07-10)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Xfin 250mg un-coated Tablets**
	Label Claim	Each Un-Coated Tablet Contains; Terbinafine (as HCl).....250mg (USP Spec's)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Lamisil 250mg Tablets, Manufacturer: Novartis Pharma (Pakistan) Ltd.
	Pharmacotherapeutic Group of (API)	antifungal agents,
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter by M/s. Seraph submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	LAMISIL, EQ 250MG BASE **Federal Register determination that product was not discontinued

		or withdrawn for safety or effectiveness reasons**
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	CLB letter indicating tablet general section is submitted y firm.
	Evaluation Remarks	
	1. Audit trail report of 21 CFR compliant system is not submitted by firm. 2. Firm has neither submitted Link to verify the excipient of reference product nor drug excipient compatibility studies.	
	Decision	
	Deferred Registration Boad deferred the case for the following: 1. Audit trail report of 21 CFR compliant system is not submitted by firm. 2. Either Link to verify the excipient of reference product or drug excipient compatibility studies	
135	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Helix Pharma (Pvt)., Ltd.** Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 **(000030)**
	Application Form Dy. No / Tracking ID & date of submission	(LUQ-71Z-L97P, 2025-03-04)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Tedizol Tablets 200mg**
	Label Claim	Each Film coated tablet contains: Tedizolid Phosphate 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	6's & 12's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Oxazolidinone class of antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Optimus Drugs Private Limited
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import Submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	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 to the firm based on inspection conducted on 07.03.2024
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section is submitted by firm.
	Evaluation Remarks	

Query	Response
GMP certificate of API manufacturer other than export, and evidence that drug substance	Please find enclosed herewith the valid GMP of API manufacturer along with export NOC from

	is also used domestically in country of origin. Moreover, Tedizolid is not present in that uploaded certificate.	manufacturer. As per API manufacturer, this material is under patent in India hence, they are not selling it domestically and therefore not part of the GMP yet as well.
	Mention Retest period/shelf life of API.	Retest date = 1 Year
	Decision	
	Approved	
136	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**UniMark Pharmaceuticals Pvt. Ltd.** Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat **(000557)**
	Application Form Dy. No / Tracking ID & date of submission	(4SA-V85-Q67S, 2024-12-17)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	**Levomark 25mg Tablet**
	Label Claim	Each uncoated tablet contains Levosulpiride 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2*10s-As per SRO
	Shelf Life (Unit)	2 Year(s)15° to 30°C
	For generic drugs (me-too Status)	Sulvorid tablet of M/S High Q Pharma
	Pharmacotherapeutic Group of (API)	Atypical antipsychotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearence certificate submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	levosupliride tablet AIFA Italy Approved
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 14.12.22
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet general Sectio I & II submitted by firm
	Evaluation Remarks	
	Audit trail report of 21 CFR compliant system is not submitted by firm.	
	Decision	
	Deferred Registration Board deferred the case for submission of the following: Audit trail report of 21 CFR compliant system	
137	Case Category	Routine (Haleema Sharif)
	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	(H67-39X-LZZ5, 2026-02-04)
	Detail of Fee Submitted	38700, 2025-12-30,
	The proposed proprietary name / brand name	**Kembril 140mg Capsule**
	Label Claim	Each hard gelatin capsule contains: Ibrutinib.....140mg
	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
	For generic drugs (me-too Status)	Ibrutix Capsule 140mg (114232)- Himmel Pharmaceuticals (PVT.) LTD
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic group: Antineoplastic agents, protein kinase inhibitors ATC code: L01EL01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: E094, E095, E096 (Batch size: 1000 Capsules) 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-20D2F1) dated 27-05-2024 is submitted (0.5760 kg) along with other procurement documents.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Ibruxen 140mg Capsules of Everest Pharmaceuticals Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batches: VLS-IRB21001, VLS-IRB21002. VLS-IRB21003 Real time data till 36 months and Accelerated till 6 month time point as per zone IVA
	The status in reference regulatory authorities	IMBRUVICA 140 mg hard capsules (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	Capsule section (Anti-Cancer) Human
	Evaluation Remarks	

Query	Response of firm
Drug substance import documents like clearance certificate or DRAP attested invoice along with COA of imported lot of API	Import of API was granted on Form 6 for trial purpose. Please find attached Form 6

	Decision	
	Approved	
138	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Shazeb Pharmaceutical Industries Limited** Hazara Trunk road Sarai Gadaee District Haripur KPK Pakistan **(000380)**
	Application Form Dy. No / Tracking ID & date of submission	(8JT-Q1Y-WGGE, 2024-08-13)
	Detail of Fee Submitted	30000.0, 2024-06-24,

	The proposed proprietary name / brand name	**Zee-Paracel 1000mg/100ml Infusion**
	Label Claim	Each 100ml contains: Paracetamol ..... 1000mg (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x100ml-De-Controlled
	Shelf Life (Unit)	36 Year(s)Store below 30oC
	For generic drugs (me-too Status)	Panafin Infusion by Medipak Limited
	Pharmacotherapeutic Group of (API)	Antipyretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	loan letter & clearance certificate submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 30.05.2022
	Evidence of approval of manufacturing facility	CLB letter indicating liquid Injectable (LVP) submitted by firm
	Evaluation Remarks	
	The firm submitted the drug substance clearance certificate and API loan letter; however, the batch numbers mentioned on both documents were different. The firm was asked to clarify the discrepancy. In response, the firm submitted another API loan letter bearing the same batch number as mentioned on the clearance certificate on the same date. However, the COA of the imported lot has still not been submitted by the firm.	
	Decision	
	Deferred The Registration Board deferred the case for clarification from M/s. Bosch Pharmaceuticals, Karachi regarding the specific lot/batch of drug substance lent to M/s. Shazeb.	
139	Case Category	New Section (Haleema Sharif)
	Name, address of Applicant.	**VEGA PHARMACEUTICALS PVT LTD** PLOT # 4, PHARMA CITY 30KM MULTAN ROAD LAHORE **(000542)**
	Application Form Dy. No / Tracking ID & date of submission	(615-2G8-ASQ3, 2025-07-28)
	Detail of Fee Submitted	37000.0, 2025-07-14,
	The proposed proprietary name / brand name	**Olopat 0.6% w/v Nasal Spray**
	Label Claim	Each spray delivers : 665mcg Olopatadine hydrochloride in 100mg of solution equivalent to 600mcg Olopatadine (as base) from nasal applicator
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C; excursions permitted to 15-30°C
	For generic drugs (me-too Status)	OLONAS spray by Sante (Private) Limited

	Pharmacotherapeutic Group of (API)	Antihistamines
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches OPAn T1-24, OPAn T2-24, OPAn T3-24 each having batch size of 400 units
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-10-2023 specifies import of 2kg of Olopatadine hydrochloride
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Zolopat Nasal Spray (Batch # ZN0001) by Remington Pharmaceutical Industries (pvt) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of API OLO/18/001, OLO/18/002, OLO/18/003 as per Zone IV-A
	The status in reference regulatory authorities	USFDA Approved Patanase nasal spray by Alcon, Inc.
	GMP status of the firm	Valid GMP certificate issued on the basis of inspection dated 08-05-2024
	Evidence of approval of manufacturing facility	Eye/Ear Drops & Nasal Spray Section (General) II-New issued on 3rd June 2025
	Evaluation Remarks	
	Decision	
	Approved Approved with innovator's specification. 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.	
140	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(3YX-GGD-QZXT, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	**Hixib 90mg tablet**
	Label Claim	Each film coated tablet contains: Etoricoxib 90mg
	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 30C
	For generic drugs (me-too Status)	Starcox 90mg Tablets by Getz Pharma
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SEUTIC LABS PVT. LTD Plot No:4-P2, Sy. No.:1-29 Gadwanthi Village, Humnabad Industrial Area, Humnabad, Bidar district, Karnataka-5853 30, India.
	Detail of stability batches of drug product	Submitted for six months
	Documents for the procurement of API with approval from DRAP	Submitted

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 11.10.2022
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section submitted by firm.

Evaluation Remarks

Query	Response of firm
In Assay of drug substance wavelength is 235nm, In Assay of drug Product it is 280nm, In dissolution it is 284nm, Clarify the difference.	For the optimization of assay method, the available literature survey was performed and UV spectrum was taken to optimize the detection wavelength. In most of articles the for "RP-HPLC method for the analysis of Etoricoxib in tablet form" the wavelength of UV detector is 280nm. Therefore, the method was developed and validated using 280nm wavelength for the assay of product. Moreover, the method was validated and all the validation results were found to be complying to the specifications defined by ICH and USP guidelines for method validation. The dissolution was performed using UV spectrophotometric method. The wavelength of 284nm was selected because the sample showed maximum absorbance at this wavelength. The minor shift of maximum absorbance from 280nm (as shown in assay) to 284nm (as shown in dissolution) is due to the difference in the pH of the samples i.e, the in dissolution the sample and standard preparations were prepared in dissolution medium i.e. 0.1N HCl pH 1.2, while the assay preparation were prepared in mobile phase.

Decision

Approved

141	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(17U-1TX-YS7M, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-10-22,
	The proposed proprietary name / brand name	**Hixib 120mg tablet**
	Label Claim	Each film coated tablet contains: Etoricoxib 120mg
	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 30C
	For generic drugs (me-too Status)	Starcox 120mg Tablets by Getz Pharma
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SEUTIC LABS PVT. LTD Plot No:4-P2, Sy. No.:1-29 Gadwanthi Village, Humnabad Industrial Area, Humnabad, Bidar district, Karnataka-5853 30, India.
	Detail of stability batches of drug product	Submitted for 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in MHRA
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 11.10.2022
	Evidence of approval of manufacturing facility	CLB letter indicating tablet general section submitted by firm

Evaluation Remarks

Query	Response of firm
In Assay of drug substance wavelength is 235nm, In Assay of drug Product it is 280nm, In dissolution it is 284nm, Clarify the difference.	For the optimization of assay method, the available literature survey was performed and UV spectrum was taken to optimize the detection wavelength. In most of articles the for "RP-HPLC method for the analysis of Etoricoxib in tablet form" the wavelength of UV detector is 280nm. Therefore, the method was developed and validated using 280nm wavelength for the assay of product. Moreover, the method was validated and all the validation results were found to be complying to the specifications defined by ICH and USP guidelines for method validation. The dissolution was performed using UV spectrophotometric method. The wavelength of 284nm was selected because the sample showed maximum absorbance at this wavelength. The minor shift of maximum absorbance from 280nm (as shown in assay) to 284nm (as shown in dissolution) is due to the difference in the pH of the samples i.e, the in dissolution the sample and standard preparations were prepared in dissolution medium i.e. 0.1N HCl pH 1.2, while the assay preparation were prepared in mobile phase.

Decision

Approved

142	Case Category	Routine (Haleema Sharif)
	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	(SM2-UMZ-3ZZD, 2025-09-26)
	Detail of Fee Submitted	75000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Vewty Eye Drops**
	Label Claim	Each mL contains: Pilocarpine hydrochloride U.S.P. .....12.5 mg (equivalent to pilocarpine free-base 10.6 mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2.5ml-As per SRO,5ml-As per SRO
	Shelf Life (Unit)	2 Year(s) Storeat15°Cto25°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Parasympathomimetic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches manufactured each having 03 liters batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	learance certificate dated 27-05-2022 specifies 0.15Kg import of PILOCARPINE HCL

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Vuity Eye Drops (Batch No: T4 I 23), Exp date: 09/2023) of Allergen AbbVie USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 lots of Pilocarpine Hydrochloride were subjected to storage conditions as per Zone IV-A
	The status in reference regulatory authorities	AbbVie Inc. North Chicago,IL 60064 USA Allergan is an affiliate of AbbVie Inc. - https://www.accessdata.fda.gov/drugsatfda_docs/l
	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	
	Decision	
	Deferred The Registration Board deferred the case for the following: Evidence of approval of the applied formulation by reference regulatory authorities, as the submitted reference product **(VUITY)** at the applied strength has been discontinued by the USFDA.	
143	Case Category	Routine (Haleema Sharif)
	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	(4RH-UXU-HHBZ, 2024-08-26)
	Detail of Fee Submitted	30000.0, 2024-07-02,
	The proposed proprietary name / brand name	**Pirox Gel 0.5%**
	Label Claim	Each gram contains: Piroxicam.....5mg (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Pcam Gel 0.5%, Manufacturer: Martin Dow Pharmaceutical company
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in MHRA, Manxiflex 0.5% w/w Gel, Manufacturer: C.P.M. Contract Pharma GmbH (Registered in Germany)

	GMP status of the firm	Uploaded in dossier
	Evidence of approval of manufacturing facility	uploaded in dossier
	Evaluation Remarks	

Query	Response of firm
Test for residual solvents has not been performed by drug substance manufacturer, Justification is required, Test for residual solvents must be performed by as per ICH guideline.	Upon inquiry from API Manufacturer, it was confirmed that testing for residual solvents is routinely performed as part of in-process controls. The specifications have been developed in accordance with the BP (British Pharmacopoeia). As the BP does not mention residual solvent testing in the Monograph therefore this test is not reported in the Certificate of Analysis (CoA)

Decision

Approved

The Board approved the product with the condition that, during commercial manufacturing, the manufacturer shall ensure the use of drug substance batches/lots for which residual solvent testing has been performed and reported in compliance with ICH guidelines.

144	Case Category	Routine (Haleema Sharif)
	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	(X73-JTB-3BP1, 2024-10-30)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-10-08
	The proposed proprietary name / brand name	**Solaridin 10mg Tablets**
	Label Claim	Each film coated tablet contains: Loratadine.....10mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30ºC
	For generic drugs (me-too Status)	Softin 10mg, Manufacturer: Werrick Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti allergic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter with M/s. Global and Clarence certificate submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted for three batches
	The status in reference regulatory authorities	Histaclar 10 mg Film-coated Tablets, Company: McDermott Laboratories Ltd., T/A Gerard Laboratories, Ireland Approved
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	1. Valid GMP certificate of drug substance (as No date of issue mentioned on GMP certificate) and drug product manufacturer is required.	

	Decision	
	Approved Approved subject to submission of valid GMP certificate of drug substance manufacturer.	
145	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**USAWA PHARMACEUTICALS** 146 SPECIAL INDUSTRIAL ZONE **(000491)**
	Application Form Dy. No / Tracking ID & date of submission	(53H-E6X-WD2Q, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**Uszone 2gm Injection**
	Label Claim	Each vial contains: Cefoperazone sodium eq.to Cefoperazone.....1000mg Sulbactam (as Sodium).....1000mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1x1's-As per SRO
	Shelf Life (Unit)	2 Yearroom tempresure
	For generic drugs (me-too Status)	BIPED 2G Injection
	Pharmacotherapeutic Group of (API)	Therapeutic Goods
	Name, address of Manufacturing site:	Shawan Pharmmaceuticals-Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad-
	The status in reference regulatory authorities	Evidence attached in module 1
	Detail of previous approval	BIPED 2G Injection DRAP Meeting No.330th dated 24 to 26 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	
146	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Fedro Pharmaceutical Labs Pvt Ltd** 149 Industrial Estate Hayatabad Peshawar **(000238)**
	Application Form Dy. No / Tracking ID & date of submission	(DMZ-LLT-ZM9E, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-01-12,
	The proposed proprietary name / brand name	**Culis 20mg Tablet**
	Label Claim	Each film coated tablet contains: Tadalafil..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade

	For generic drugs (me-too Status)	Dalafil 20mg Tablet M/s Solaries Life Sciences Pvt Ltd. rawat Paksitan ,Reg. no. 132631
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) Inhibitors
	Name, address of Manufacturing site:	Solaris life Sciences (PVT) Ltd.-Plot No.08, Street no S-1 RCCI industrial Estate, Rawat Pakistan-
	The status in reference regulatory authorities	Cialis 20mg tablet, Registered in Food and Drug Administration (USFDA)
	Detail of previous approval	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	
147	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Fedro Pharmaceutical Labs Pvt Ltd** 149 Industrial Estate Hayatabad Peshawar **(000238)**
	Application Form Dy. No / Tracking ID & date of submission	(N8J-PNG-S3JG, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-01-13,
	The proposed proprietary name / brand name	**Culis 5mg Tablet**
	Label Claim	Each Film coated tablet Contains: Tadalafil..... 5mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade
	For generic drugs (me-too Status)	Dalafil 5mg Tablet M/s Solaries Life Sciences Pvt Ltd. rawat Paksitan ,Reg. no. 1326320
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) Inhibitors
	Name, address of Manufacturing site:	Solaris life Sciences (PVT) Ltd.-Plot No.08, Street no S-1 RCCI industrial Estate, Rawat Pakistan-
	The status in reference regulatory authorities	Cialis 5mg tablet, Registered in Food and Drug Administration (USFDA)
	Detail of previous approval	352 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	
148	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	(NPB-NNN-5QJD, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Cansa Tablet 2.5mg**
	Label Claim	Each film coated tablet contains: Letrozole.....2.5mg
	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. 08, Street No. S-1, RCCI, Industrial Estate,Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Fedro Pharmaceutical Labs Pvt Ltd** 149 Industrial Estate Hayatabad Peshawar **(000238)**
	Application Form Dy. No / Tracking ID & date of submission	(URB-ZLX-5GT6, 2026-03-02)
	Detail of Fee Submitted	97200, 2026-01-12,
	The proposed proprietary name / brand name	**Velif 20mg Tablet**
	Label Claim	Each film coated tablet contains: Verdenafil (as hydrochloride trihydrate) ..... 20mg (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 30 centigrade
	For generic drugs (me-too Status)	Verdena 20mg tablet M/s Solaris life Sciences Pvt Ltd. Rawat Pakistan .Reg.no 132427
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) Inhibitors
	Name, address of Manufacturing site:	Solaris life Sciences (PVT) Ltd.-Plot No.08, Street no S-1 RCCI industrial Estate, Rawat

		Pakistan-
	The status in reference regulatory authorities	Levitra 20mg Tablet .Mfg by Bayer healthcare United state US FDA Approved .
	Detail of previous approval	351 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	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(2G2-DY9-8TXT, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**LOTREX-T EYE DROPS**
	Label Claim	Each ml of ophthalmic suspension contains: Loteprednol Etabonate 5mg Tobramycin 3mg
	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)	LOTETOB OPTHALMIC SUSPENSION by Helix Pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 333 MoM
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, S.I.T.E., Super Highway, Karachi -PAKISTAN.-
	The status in reference regulatory authorities	Zylet Eye Drops US-FDA Approved
	Detail of previous approval	Lotinin E/D 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	
151	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	(7VE-7TH-WY9T, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**EXSET 4MG/5ML SYRUP**
	Label Claim	Each 5 ml of syrup contains: Ondansetron (as hydrochloride dihydrate) 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	OnseronSyrup4mg/5ml
	Pharmacotherapeutic Group of (API)	Anti-emetics and Anti-nauseants
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	ZofranSyrup4mg/5ml
	Detail of previous approval	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	
152	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**USAWA PHARMACEUTICALS** 146 SPECIAL INDUSTRIAL ZONE **(000491)**
	Application Form Dy. No / Tracking ID & date of submission	(GSS-W81-69RQ, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**Uszone 1gm Injection**
	Label Claim	Each vial contains: Cefoperazone sodium eq.to Cefoperazone 500mg Sulbactam (as Sodium) .....500mg Product complies JP Specification
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearroom tempresure
	For generic drugs (me-too Status)	BIPED 1G Injection
	Pharmacotherapeutic Group of (API)	Therapeutic Goods
	Name, address of Manufacturing site:	Shawan Pharmmaceuticals-Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad-
	The status in reference regulatory authorities	Evidence attached in module 1
	Detail of previous approval	BIPED 1G Injection DRAP Meeting No.330th dated 24 to 26 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	
153	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aulton Pharmaceuticals** Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000828)**
	Application Form Dy. No / Tracking ID & date of submission	(J1Q-82Z-5253, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-11,
	The proposed proprietary name / brand name	**EMLINO-M XR TABLET (Emp 10mg, Lin 5mg, Met 1000mg)**
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....10MG Linagliptin.....5MG (As immediate release coat) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Diampa LXR Tablets (Empagliflozin+Linagliptin+Metformin) 10mg+5mg+1000mg) Manufactured by Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	WELLMARK PHARMACEUTICALS PVT. LIMITED-PLOT NO. 122, PHASE-V, BLOCK-B, INDUSTRIAL ESTATE, HATTAR, KPK-
	The status in reference regulatory authorities	TRIJARDY™ XR TABLETS (extended-release tablets), Comapny: Boehringer Ingelheim Pharmaceuticals, Inc. (USFDA Approved) NDA: 212614
	Detail of previous approval	EMPEG-ML XR TABLET (10mg, 5mg, 1000mg) 340 Minutes of Meeting Pg: 951 (Registration Number: 123479)
	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.	**Aulton Pharmaceuticals** Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000828)**
	Application Form Dy. No / Tracking ID & date of submission	(MLZ-8AV-G7J4, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-11,
	The proposed proprietary name / brand name	**EMLINO-M XR TABLET (Emp 5mg, Lin 2.5mg, Met 1000mg)**
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....5MG Linagliptin.....2.5MG (As immediate release coat) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Diampa LXR Tablets (Empagliflozin+Linagliptin+Metformin) 5mg+2.5mg+1000mg) Manufactured by Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	WELLMARK PHARMACEUTICALS PVT. LIMITED-PLOT NO. 122, PHASE-V, BLOCK-B, INDUSTRIAL ESTATE, HATTAR, KPK-
	The status in reference regulatory authorities	TRIJARDY™ XR TABLETS (extended-release tablets), Comapny: Boehringer Ingelheim Pharmaceuticals, Inc. (USFDA Approved) NDA: 212614
	Detail of previous approval	EMPEG-ML XR TABLET (5mg, 2.5mg, 1000mg) 340 Minutes of Meeting Pg: 943 (Registration Number: 123478)
	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.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(P2T-9HX-EH5M, 2026-04-28)

	Detail of Fee Submitted	97200, 2026-03-09,
	The proposed proprietary name / brand name	**Urivent-D Capsule**
	Label Claim	Each Hard Gelatin Capsule Contains: Dutasteride (as Soft Gel Capsule) .....0.5mg Tamsulosin Hydrochloride (as Modified Release Pellets).....0.4mg (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 YearStore below 25 °C
	For generic drugs (me-too Status)	Maxflow-D Capsule
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-KM, Chak Beli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	UKMHRA
	Detail of previous approval	Dutaride-T Capsule , Minutes of 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	
156	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aulton Pharmaceuticals** Plot # 84/1,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000828)**
	Application Form Dy. No / Tracking ID & date of submission	(R68-79B-EVJ7, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-11,
	The proposed proprietary name / brand name	**EMLINO-M XR TABLET (Emp 12.5mg, Lin 2.5mg, Met 1000mg)**
	Label Claim	Each Film Coated Extended Release Tablet contains: Empagliflozin.....12.5MG Linagliptin.....2.5MG (As immediate release coat) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Diampa LXR Tablets (Empagliflozin+Linagliptin+Metformin) 12.5mg+2.5mg+1000mg) Manufactured by Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-Diabetic

	Name, address of Manufacturing site:	WELLMARK PHARMACEUTICALS PVT. LIMITED-PLOT NO. 122, PHASE-V, BLOCK-B, INDUSTRIAL ESTATE, HATTAR, KPK-
	The status in reference regulatory authorities	TRIJARDY™ XR TABLETS (extended-release tablets), Comapny: Boehringer Ingelheim Pharmaceuticals, Inc. (USFDA Approved) NDA: 212614
	Detail of previous approval	EMPEG-ML XR TABLET (12.5mg, 2.5mg, 1000mg) 340 Minutes of Meeting Pg: 954 (Registration Number: 1234
	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.	**Caliph Pharmaceuticals (Pvt) Ltd.** Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK **(000748)**
	Application Form Dy. No / Tracking ID & date of submission	(R9E-82Y-R97Q, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**TOCIN PLUS EYE DROPS**
	Label Claim	Each ml of Suspension Contains: Dexamethasone 1mg Tobramycin 3mg
	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)	TOBRADEX SUSPENSION by Novartis Pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 333 MoM
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, S.I.T.E., Super Highway, Karachi -PAKISTAN.-
	The status in reference regulatory authorities	TOBRADEX SUSPENSION MHRA Approved
	Detail of previous approval	Tobton-D Eye Drops 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	

158	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(X4N-E83-DBM9, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**TOBRACAL EYE DROPS**
	Label Claim	Each ml contains: Tobramycin 3mg
	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)	Tobnove E/D by Novex Pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 333 MoM
	Name, address of Manufacturing site:	Winthrox Laboratories Pvt. Ltd.-K-219-A, S.I.T.E., Super Highway, Karachi -PAKISTAN.-
	The status in reference regulatory authorities	Tobrex Ophthalmic Solution USFDA Approved
	Detail of previous approval	Tycin Eye Drops 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	
159	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	(XUH-H2U-BXW7, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**EXSET 8 mg Tablet**
	Label Claim	Each film coated tablet contains: Ondansetron (as hydrochloride dihydrate) 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Zofran Tablet 8mg
	Pharmacotherapeutic Group of (API)	Anti-emetics and Anti-nauseants
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	Zofran Tablet 8mg
	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	
160	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**GILLMAN PHARMACEUTICALS** 41/2-A, PHASE I & II, INDUSTRIAL ESTATE, HATTAR **(000683)**
	Application Form Dy. No / Tracking ID & date of submission	(Y6Z-MNM-TSDE, 2026-04-28)
	Detail of Fee Submitted	97200, 2026-02-12,
	The proposed proprietary name / brand name	**Forex 500mg/10ml Injection**
	Label Claim	Each 10ml contains: Iron as Ferric Carboxymaltose 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 25 degree celcius
	For generic drugs (me-too Status)	BOFERIN 500MG/10ML INJECTION (BOSCH PHARMACEUTICALS (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	Iron replacement products
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	FERINJECT (VIFOR PHARMA)
	Detail of previous approval	Fermed Injection 500mg/10ml (Meeting No. 352) (Case No. 51)
	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.	**UniMark Pharmaceuticals Pvt. Ltd.** Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat **(000557)**
	Application Form Dy. No / Tracking ID & date of submission	(XM2-ZD2-4U6B, 2026-04-29)

	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**Platogrel 90mg Tablet**
	Label Claim	Each film coated tablet contains Tecagrelor 90mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's, 14's and 20's -As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	Hitica 90mg Tablet by M/S Highnoon pharma
	Pharmacotherapeutic Group of (API)	antiplatelet agent
	Name, address of Manufacturing site:	Medizan Laboratories Pvt Ltd-Plot # 313, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Change in Manufacturing Site in PRVC meeting, registration certificate is attached below.
	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. The cross-referred product was approved in PRV vide tracking ID 4TB-Y9B-MSH1 dated 10-March 2026.	
	Decision	
	Approved	
162	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saaaf Pharmaceuticals** Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 **(000637)**
	Application Form Dy. No / Tracking ID & date of submission	(594-55T-NHQP, 2026-02-09)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	**Esoprox**
	Label Claim	Naproen-------375mg Esomeprazole as magnesium tri-hydrate-----20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28"s-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 c
	For generic drugs (me-too Status)	No
	Pharmacotherapeutic Group of (API)	Yes
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd- Plot # 313, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Yes
	Detail of previous approval	Esik 375mg/20mg MR Tablets
	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.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(X4W-RAD-QYUH, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Hiraxcen Tablet 20mg**
	Label Claim	Each uncoated tablet contains: Piroxicam-Beta-Cyclodextrin 191.2mg (eq. to Piroxicam.....20mg)
	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. 08, 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	
164	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	(XQ7-LJP-N6DM, 2026-02-09)
	Detail of Fee Submitted	97200, 2026-01-26,
	The proposed proprietary name / brand name	**Sezroxen 500mg/20mg Tablet**
	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	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. 08, Street No. S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	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	
165	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)**
	Application Form Dy. No / Tracking ID & date of submission	(1AE-2QT-A1UX, 2026-05-07)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Ontron 8mg Tablet**
	Label Claim	Each film coated tablet contains: Ondansetron as (Hydrochloride Dihydrate)..... 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	12's (2x6's) (1x12's)-Controlled,14's (1x14's) (2x7's)-Controlled,1x10's (10's)-Controlled,20's (2x10's)-Controlled,30's (3x10's) -Controlled,7's (1x7's)-Controlled
	Shelf Life (Unit)	2 YearStore at 25°C (Excursions permitted between 15°C - 30°C).
	For generic drugs (me-too Status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist(Antiemetic)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd-Plot No. 129, Sunder Industrial Estate Raiwand Road, Lahore.-
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	Detail of previous approval	Stawia 8mg Tablet approved in 326 Registration Board 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	
166	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(DU5-L7Q-MTAH, 2026-05-07)
	Detail of Fee Submitted	97200, 2026-03-14,
	The proposed proprietary name / brand name	**Tigec 50mg Injection IV**
	Label Claim	Each lyophilized vial contains: Tigecycline.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Tiganext by Bio-Next Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibacterial Agent
	Name, address of Manufacturing site:	Bio-Labs (Pvt.)Ltd.,-Plot No. 145, Kahuta Industrial Area, Islamabad-
	The status in reference regulatory authorities	Refer to 330th DRB Approval of Bio Labs Pvt Ltd.
	Detail of previous approval	UswaTig 50mg Injection, 330th 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	
167	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)**
	Application Form Dy. No / Tracking ID & date of submission	(198-E3A-ZDWT, 2026-04-20)
	Detail of Fee Submitted	97200, 2026-02-20,
	The proposed proprietary name / brand name	**MYNAP 500mg/20mg DR Tablet**
	Label Claim	Each Modified release Tablet contains: Naproxen .....500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate .....20mg (as

		Immediate Release Coat) (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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Glomov Tablet Global Pharma
	Pharmacotherapeutic Group of (API)	Nonnarcotic analgesic, antipyretic, anti-inflammatory plus Proton Pump Inhibitor
	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	https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/l UK - MHRA Reference: https://www.medicines.org.uk/emc/product/5743/s
	Detail of previous approval	Esonyp 20/500mg DR Tablet | Minutes of 324th 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	
168	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	(2LT-LRD-EVLL, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-02-24,
	The proposed proprietary name / brand name	**COXTO 90MG TABLET**
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib.....90mg (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 25c
	For generic drugs (me-too Status)	ETOXIB 90MG TABLET
	Pharmacotherapeutic Group of (API)	NSAID Selective inhibitor of cyclooxygenase-2 (COX-2)
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	OTORN TABLET, 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	
169	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(6JG-MNN-27LB, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**Sacuvex 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex).....49mg Valsartan (as sacubitril valsartan sodium salt complex)..... 51mg
	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)	Ubitril Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blockers (ARBs)
	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	Sacubex 100mg 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	
170	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Valor Pharmaceuticals** Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad **(000496)**
	Application Form Dy. No / Tracking ID & date of submission	(D5D-4S7-E6H9, 2026-04-22)
	Detail of Fee Submitted	97200, 9400 2026-01-02, 2026-04-15

	The proposed proprietary name / brand name	**Bactimox 400mg/250mg Solution for infusion**
	Label Claim	Each vial of 250ml Contains: Moxifloxacin (as hydrochloride).....400mg. (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 YearProtect from direct sunlight, dust and moisture.
	For generic drugs (me-too Status)	MOXIGEN 400mg/250ml Solution for Infusion
	Pharmacotherapeutic Group of (API)	fluoroquinolone antibiotic
	Name, address of Manufacturing site:	Biogen Life Sciences-M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	REGISTERED IN GERMANY
	Detail of previous approval	MOXIGEN 400mg/250ml Solution for Infusion (approved in M-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	
171	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 **(00096)**
	Application Form Dy. No / Tracking ID & date of submission	(DPX-TW2-N4YH, 2026-04-06)
	Detail of Fee Submitted	97200, 2025-10-28,
	The proposed proprietary name / brand name	**Xieso 40mg Injection I.V**
	Label Claim	Each vial contains: Esomeprazole sodium equ. to Esomeprazole ..... 40mg (Manufacturer's Specifications)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Koncept 40mg Injection Mcolson Reseach Lab. Rawat
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Swera Pharmaceuticals -Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	343 MINUTES OF MEETING 8th & 10th Nov,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	
172	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 **(00096)**
	Application Form Dy. No / Tracking ID & date of submission	(EQ6-83J-AMAV, 2026-04-06)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	**EREC 50mg Tablet**
	Label Claim	Each film coated Tablet contains: Sildenafil Citrate 70.225 mg eq. to sildenafil 50mg (USP Spec's.)
	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)	NA
	Pharmacotherapeutic Group of (API)	phosphodiesterase-5 inhibitor (PDE5-I)
	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 (Viagra tablets 50mg)
	Detail of previous approval	345 Meetings of Registration Board held on 19th to 21th Feb,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	
173	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	(GZX-VY2-YP6P, 2026-04-07)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	**KETAWEL LOTION**

	Label Claim	Each ml contains: Ketoconazole.....20 mg (w/v)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	20ml-As per SRO,30ml-As per SRO,60ml-As per SRO,90ml-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)	Imidazole antifungal class of medications
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Ketoconazole shampoo 2% by M/s Cosette, USFDA Approved.
	Detail of previous approval	KETOCONIZ 2% Lotion Minutes of 351st Meeting of Registration Board (23rd – 24th September, 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	
174	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	(LDH-ZN1-VB79, 2026-04-08)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Merosel 500mg Injection**
	Label Claim	Each vial contains: Meropenem trihydrate eq. to Meropenem...500mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 Degree Celsius
	For generic drugs (me-too Status)	M/s Barrett Hodgson Pakistan Pvt.Ltd Baripenem
	Pharmacotherapeutic Group of (API)	Carbapenem antibacterial
	Name, address of Manufacturing site:	M/S Biogen Pharmaceuticals-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	MHRA APPROVED
	Detail of previous approval	Merogen 312meeting
	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.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(MWE-EU1-TYQ9, 2026-04-08)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Isowel 20mg Soft Gel Capsule**
	Label Claim	Each Soft Gel Capsule Contain: Isotretinoin .....20mg (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 30 Degree Celsius
	For generic drugs (me-too Status)	BIOGEN LIFE SCIENCES Altrezam 20mg Capsule
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Name, address of Manufacturing site:	M/S Biogen Pharmaceuticals-: 8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Isotretinoin 20 mg soft capsules (MHRA Approved)
	Detail of previous approval	BIOTAN 20mg Capsule 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	
176	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(PE5-115-7DLE, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**Sacuvex 200mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex).....97mg Valsartan (as sacubitril valsartan sodium salt complex)..... 103mg
	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)	Ubitril Tablet by Weather Folds Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blockers (ARBs)
	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	Sacubex 50mg 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	
177	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	(S6G-BNE-VSXT, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Mersel 1gm Injection.**
	Label Claim	Each vial contains: Meropenem trihydrate eq. to Meropenem...1g (USP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree Celsius
	For generic drugs (me-too Status)	M/s Barrett Hodgson Pakistan Pvt.Ltd Baripenem
	Pharmacotherapeutic Group of (API)	Carbapenem antibacterial
	Name, address of Manufacturing site:	M/s Biogen Pharmaceuticals-8-KM Chakbeli Road Rawat Rawalpindi Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	312 meeting Merogen
	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.	**Fahmir Pharma (Pvt) Ltd** Main Mandiwala stop ,26km, lahore Jaranwala Road ,Tehsil Sharaqpur Sharif.District Sheikupura **(000880)**
	Application Form Dy. No / Tracking ID & date of submission	(STQ-W1D-QZ6U, 2026-04-28)
	Detail of Fee Submitted	97200, 2025-12-26,
	The proposed proprietary name / brand name	**OMIR 40 mg Dry Powder Injection**
	Label Claim	Each Vial contains: Pre-lyophillized Sterile Powder of Omperazole Sodium eq. to Omperazole ..... 40 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 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Teph 40 mg Injection by Sami Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	VARIANT PHARMACEUTICALS (PVT.) LTD-PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Minutes of 312th meeting of Registration Board by OMPEZOLE 40mg IV Injection
	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.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(V8H-LLX-JLYY, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**Sacuvex 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sacubitril (as sacubitril valsartan sodium salt complex).....24mg Valsartan (as sacubitril valsartan sodium salt complex)..... 26mg (As per *Innovator's Specifications)
	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)	Ubitril Tablet by Weather Folds Pharmaceuticals

	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blockers (ARBs)
	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	Sacubex 50mg 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	
180	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(YGT-Q66-92Q4, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**Norista 5mg Tablet**
	Label Claim	Each Uncoated Tablet Contains: Norethisterone (USP).....5mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Postpon-M Tablet by OBS Karachi
	Pharmacotherapeutic Group of (API)	Progestins
	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	Norista Tablet, DRB 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	
181	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 **(00096)**

	Application Form Dy. No / Tracking ID & date of submission	(Y4E-S31-6U83, 2026-04-07)
	Detail of Fee Submitted	97200, 7500 2025-12-18, 2026-03-17
	The proposed proprietary name / brand name	**Toysn Injection 4.5gm**
	Label Claim	Each vial contains: Piperacillin (as Sodium) 4g + Tazobactam (as Sodium) 0.5g USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year(s)30C+-
	For generic drugs (me-too Status)	Pipral-T 4.5gm Injection by Nimral Labortories
	Pharmacotherapeutic Group of (API)	Penicillin and beta-lactamase inhibitors
	Name, address of Manufacturing site:	RSK Pharmaceuticals -Plot # 13A, Street # N-5, Rawat Industrial Estate, Rawalpindi-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	350 minutes of Meeting of Reg. Board Held on 29th to 30th July 2025 (Talzon Injection 4.5gm))
	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.	**RELIZON PHARMACEUTICALS** PLOT NO 118 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE **(000875)**
	Application Form Dy. No / Tracking ID & date of submission	(MSB-H85-938J, 2026-05-08)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**Ferizon 500mg/10ml Injection**
	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-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	BOFERIN 500MG/10ML INJECTION (BOSCH PHARMACEUTICALS (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	Iron replacement products
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	FERINJECT INJECTION (VIFOR PHARMA)
	Detail of previous approval	Fermed Injection 500mg/10ml (Meeting No. 352) (Case No. 51)
	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.	**RELIZON PHARMACEUTICALS** PLOT NO 118 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE **(000875)**
	Application Form Dy. No / Tracking ID & date of submission	(6JW-6N6-ABDN, 2026-05-08)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**Ondizon 8mg/4ml Injection**
	Label Claim	Each 4ml contains: Ondansetron HCl Dihydrate eq. to Ondansetron 8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4ml x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	ONSERON 8MG/4ML INJECTION (INDUS PHARMACEUTICALS)
	Pharmacotherapeutic Group of (API)	Serotonin 5HT-3 receptor Antagonist
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	ONDANSETRON SANDOZ 8MG/4ML (Sandoz Canada Inc. 110 Rue de Lauzon Boucherville, Québec, Canada J4B 1E6)
	Detail of previous approval	Emetron Injection 8mg/4ml (Meeting No. 352) (Case No. 19)
	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.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(9H4-EPS-61Q3, 2026-05-08)
	Detail of Fee Submitted	97200, 2026-03-06,

	The proposed proprietary name / brand name	**Vozent**
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....10mg (As per Innovator's specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s ,2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore between 20°C and 25°C (68°F and 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Ami Lifesciences Private Limited. Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara Gujarat, INDIA.
	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	313
	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.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(BHG-RSN-PMXD, 2026-05-08)
	Detail of Fee Submitted	97200, 2026-03-06,
	The proposed proprietary name / brand name	**Vozent**
	Label Claim	Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....20mg (As per Innovator's specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s, 2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30ºC (59°F to 86ºF)
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Ami Lifesciences Private Limited. Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara Gujarat, INDIA
	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	313
	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	New Section (Incharge Evaluation Cell)
	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	(723-77R-W1Q1, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-04-07,
	The proposed proprietary name / brand name	**Cefadroxil DS 250mg/5ml Dry powder Suspension**
	Label Claim	Each 5ml contains (Reconstituted): Cefadroxil Monohydrate Eq. to Cefadroxil....250mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Neucef DS suspension (Sami Pharmaceuticals(Pvt.)Ltd)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API procured from Pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CEDROX Dry Suspension 125mg/5ml by Platinum Pharmaceuticals Batch No. 248 Mfg date 04/25
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions
	The status in reference regulatory authorities	DURACEF 250mg/5ml Dry suspension (CIMA Approved)
	GMP status of the firm	GMP certificate dated 01.07.2025
	Evidence of approval of manufacturing facility	DML renewed 19.06.2025
	Evaluation Remarks	
	The application fulfils codal formalities and is submitted for consideration of the Board.	
	Decision	
	Approved	
187	Case Category	New Section (Incharge Evaluation Cell)

	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	(3PT-MWG-53AN, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**SZOLE 40mg Dry injection**
	Label Claim	SZOLE 40MG DRY POWDER INJECTION Each vial contains Omeprazole sodium eq.to Omeprazole....40mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 25°C
	For generic drugs (me-too Status)	Acichek 40mg (Bio-Labs Pvt. limited)
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches on long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not Applicable. (Attached procurement data)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed against Acicheck 40 mg Injection Batch25E139
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches on long-term and accelerated conditions
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion (MHRA Approved)
	GMP status of the firm	Approval letter for Dry Powder Injection (General) New dated 25 June 2025
	Evidence of approval of manufacturing facility	Approval letter for Dry Powder Injection (General) New dated 25 June 2025
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
188	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Ipram International** Plot # 26, S S 3, National Industrial Zone Rawat. **(000551)**
	Application Form Dy. No / Tracking ID & date of submission	(5Y3-NWQ-7A2P, 2026-04-15)
	Detail of Fee Submitted	38700, 9400 2026-03-24, 2026-05-08
	The proposed proprietary name / brand name	**Ipramol Infusion 100ml**
	Label Claim	Each 100ml Vial Contains: Paracetamol.....1g (BP Spec's)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Xtramol 1g Infusion
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical industries
	Detail of stability batches of drug product	Data of three batches at long-term and accelerated conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Zenith Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Xtramol 1g Infusion of EG Pharma Batch No 109
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at long-term and accelerated conditions
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	DML 27.08.2024; Grant of Additional Sections dated 15.06.2025 (Liquid Injectable Vial)
	Evidence of approval of manufacturing facility	DML 27.08.2024; Grant of Additional Sections dated 15.06.2025 (Liquid Injectable Vial)
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
189	Case Category	New Section (Incharge Evaluation Cell)
	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	(SGV-ZMU-286R, 2026-04-08)
	Detail of Fee Submitted	38700, 2026-03-30,
	The proposed proprietary name / brand name	**Trigaba 75mg Capsule**
	Label Claim	Each Capsule Contains: Pregabalin....75mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Lyrica Capsules 75mg (AGP Limited)
	Pharmacotherapeutic Group of (API)	Almelo Pvt.Ltd, India
	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	Pregablin Tillomed Capsule 75mg (MHRA Approved)
	GMP status of the firm	Available; Attached
	Evidence of approval of manufacturing facility	Available; Attached
	Evaluation Remarks	

	The loan request is dated 18.06.2025 and the stability was initiated on 18.08.2025. However, the intimation of loan to DRAP was given on 03.09.2025. Product development was done on borrowed API. However, DRAP's notification No.14-1/2022-PEC dated 01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs).	
	Decision	
	Deferred	
190	Case Category	New Section (Incharge Evaluation Cell)
	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	(NNJ-NNN-VBWG, 2026-04-08)
	Detail of Fee Submitted	38700, 2026-03-30,
	The proposed proprietary name / brand name	**Trigaba 300mg Capsule**
	Label Claim	Each Capsule Contains: Pregabalin....300mg (BP Specs.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	14's -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Gablin capsule 300mg (CCL Pharmaceuticals Pvt. Ltd.)icals
	Pharmacotherapeutic Group of (API)	Almelo Pvt.Ltd, India
	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	Pregablin Tillomed Capsule 300mg (MHRA Approved)
	GMP status of the firm	Available; Attached
	Evidence of approval of manufacturing facility	Available; Attached
	Evaluation Remarks	
	The loan request is dated 18.06.2025 and the stability was initiated on 18.08.2025. However, the intimation of loan to DRAP was given on 03.09.2025. Product development was done on borrowed API. However, DRAP's notification No.14-1/2022-PEC dated 01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs).	
	Decision	
	Deferred	
191	Case Category	Any Other (Incharge Evaluation Cell)
	Name, address of Applicant.	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)**
	Application Form Dy. No / Tracking ID & date of submission	(XQX-X2U-SSBL, 2026-01-05)

	Detail of Fee Submitted	38700, 2025-10-09,
	The proposed proprietary name / brand name	**Vardafil**
	Label Claim	Each film-coaed tablet contains; Vardenafil as HCl trihydrate----------20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4,8 & 20-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Amsofil 20mg Tablet (Amson Pharma)
	Pharmacotherapeutic Group of (API)	Selective inhibitor of phosphodiesterase type 5 (PDE5)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited,
	Detail of stability batches of drug product	T25VL20-48, T25VL20-49, T25VL20-50,
	Documents for the procurement of API with approval from DRAP (in case of Import)	DIL-C-F781ED
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Levitra 20mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	001-VHT, 002-VHT , 003-VHT
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	GMP dated 17.11.2025
	Evidence of approval of manufacturing facility	Renewed DML dated 04.10.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
192	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(5D8-2PU-U9JE, 2025-01-15)
	Detail of Fee Submitted	93000.0, 9400 2025-01-13, 2026-04-16
	The proposed proprietary name / brand name	**VERASAF 20mg Tablets**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil..... 20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	Levitra
	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
	Detail of previous approval	
	Evaluation Remarks	

	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
193	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(QED-5X5-TT78, 2025-05-26)
	Detail of Fee Submitted	93000.0, 9400 2025-04-18, 2026-04-16
	The proposed proprietary name / brand name	**Verasaf 5mg Tablets**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil..... 5mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C in a cool dry place
	For generic drugs (me-too Status)	LEVITRA Tablets
	Pharmacotherapeutic Group of (API)	Written in Module-1
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
194	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**

	Application Form Dy. No / Tracking ID & date of submission	(GN7-HJ6-Y535, 2025-01-15)
	Detail of Fee Submitted	93000.0, 9400 2025-01-13, 2026-04-16
	The proposed proprietary name / brand name	**VERASAF 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil ..... 10mg (BP Specs))
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	LEVITRA
	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
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
195	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(7GL-JD4-HWPA, 2025-04-25)
	Detail of Fee Submitted	93000.0, 9400 2025-01-20, 2026-04-16
	The proposed proprietary name / brand name	**Safden 25mg Tablet**
	Label Claim	Safden 25mg Tablets Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	VIAGRA
	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

	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: 2EZ-N4V-TJM7. 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	
196	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(JPJ-63G-Y8VU, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	**Safden 50mg Tablet**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil ..... 50 mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	VIAGRA
	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
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: DV9-RME-6JB8. 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	

197	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(JXL-PRS-9JVA, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2025-01-13, 2026-04-16
	The proposed proprietary name / brand name	**Safden 100mg Tablets**
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil ..... 100 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	VIAGRA
	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
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. The cross-referred product was approved in PRV dated 30-January, 2026 vide application TID: 882-QQY-J4Y2. 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	
198	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Max Pharmaceuticals** Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 **(000671)**
	Application Form Dy. No / Tracking ID & date of submission	(2S2-ZUN-AYPW, 2025-04-22)
	Detail of Fee Submitted	93000.0, 9400 2025-01-29, 2026-04-20
	The proposed proprietary name / brand name	**Vergia**
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30˚C. Protect from light, moisture and heat.
	For generic drugs (me-too Status)	Viagra 100mg Tablet

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Grays Pharmaceuticals-Plot#2, Street N# N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	Pfizer Pharmaceuticals, USA
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
199	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	(RNH-B66-DUAT, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**DICOZE 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)	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	Sildenafil Tablet, USP 25mg (Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
200	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Max Pharmaceuticals** Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 **(000671)**
	Application Form Dy. No / Tracking ID & date of submission	(VA3-THA-QBST, 2025-04-22)
	Detail of Fee Submitted	93000.0, 9400 2025-01-29, 2026-04-20
	The proposed proprietary name / brand name	**Vergia**
	Label Claim	Each film coated tablet contains: Sildenafil (as Citrate).....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30˚C. Protect from light, moisture and heat..
	For generic drugs (me-too Status)	Viagra 50mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Grays Pharmaceuticals-Plot#2, Street N# N-3, National Industrial Zone Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	Pfizer Pharmaceuticals, USA
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
201	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	(WRE-R79-ZDSV, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**DICOZE 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 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	Sildenafil Tablet, USP 100mg (Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
202	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hudson Pharma (Pvt) Ltd** D-93, North Western Industrial Zone, Port Qasim Authority **(000842)**
	Application Form Dy. No / Tracking ID & date of submission	(2V4-ADL-RMTH, 2025-09-26)
	Detail of Fee Submitted	93000.0, 9400 2025-01-08, 2026-04-22
	The proposed proprietary name / brand name	**Posazol 40mg/ml Suspension**
	Label Claim	Each ml of oral suspension contains: Posaconazole.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Private Limited-Plot No. 129 – Sunder Industrial Estate Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Posaconazole 40mg/ml oral Suspension-M/s Thornton & Ross Ltd. (trading as STADA) Linthwaite, Huddersfield, HD7 5QH, UK-Registration number: NDC 0054-0449-49
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
203	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar **(000995)**
	Application Form Dy. No / Tracking ID & date of submission	(3E6-GAP-7TM7, 2024-08-19)
	Detail of Fee Submitted	75000.0, 9400 2024-07-31, 2026-05-05
	The proposed proprietary name / brand name	**Sterane 10mg Tablet**
	Label Claim	Sterane 10mg Tablet...each tablet contains dydrogestron .. 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20s-As per SRO
	Shelf Life (Unit)	2 YearAmbient
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Aries Pharmaceuticals (Pvt) LTD-1-w Industrial Estate Hayatabad Peshawar-
	The status in reference regulatory authorities	Available
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
204	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(6HY-DR2-DT8R, 2025-07-11)
	Detail of Fee Submitted	37000.0, 2025-03-24,
	The proposed proprietary name / brand name	**Difluzole**
	Label Claim	Each capsule contains Fluconazole.....150 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	4's & 1's-As per SRO

	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zolanix 150 mg Capsules, Batch No. MR7T
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	MHRA, UK
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
205	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(8T6-LPV-GY5Q, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Alopexa**
	Label Claim	Each mL contains Minoxidil....50 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	60 mL-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	D11AX01: Pyrimidine derivatives; alopecia
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Derma Techno Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Minoxin Topical Solution, Brookes Pharma Karachi, 133B24
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	US-FDA
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	

	The application fulfils codal formalities.	
	Decision	
	Approved	
206	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(71M-AAX-5QDV, 2025-07-11)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Piroxidol**
	Label Claim	Each tablet contains Piroxicam ....20 mg as Piroxicam Beta Cyclodextrin
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	M01AC01; non-steroidal anti-inflammatory drug (NSAID) within the oxicam group
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Medisave Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PIREXEN TABLET 20mg, SAFFRON
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	DML No. 000994 dated 09.05.2024
	The status in reference regulatory authorities	MHRA, UK
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
207	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(H8E-MUG-MDSN, 2025-04-18)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	**Hydrosone-C**
	Label Claim	Each gram contains Hydrocartisone (as Acetate)...10 mg + Clotrimazole...10 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5 g, 15 g, 30 g-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes

	Pharmacotherapeutic Group of (API)	Anti-inflammatory & Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches (300 tubes) at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	APIs on loan from Derma Techno Pakistan
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in module-III
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	MHRA, UK
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
208	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(HM5-2VV-2W6B, 2025-04-16)
	Detail of Fee Submitted	37000.0, 2025-01-06,
	The proposed proprietary name / brand name	**Ebasta**
	Label Claim	Each Tablet Contains Ebastine....10 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	ATC R06AX22; long-acting H1-receptor antagonist; antihistamines for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Mass Pharma Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	KESTIN TABLET 10mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	ANSM
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	Drug Substance Long term conditions edited	
	Decision	

	Rejected Registration Board rejected the application due to falsification of drug substance stability data by editing the long-term conditions	
209	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(L4M-RHY-9L25, 2026-02-03)
	Detail of Fee Submitted	38700, 2025-11-04,
	The proposed proprietary name / brand name	**Zynolid**
	Label Claim	Each film coated tablet contains Linezolid.....600 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Below 30 degree centigrade
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	oxazolidinone pharmacological class of antibiotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches (1000 tablets) at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Medisave
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Nezkil 600 mg tablets, B. T22922, Mfg, 12-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	FDA
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
210	Case Category	New License (Incharge Evaluation Cell)
	Name, address of Applicant.	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 **(000994)**
	Application Form Dy. No / Tracking ID & date of submission	(N37-2MG-524J, 2025-07-14)
	Detail of Fee Submitted	37000.0, 2025-06-23,
	The proposed proprietary name / brand name	**Pulmair**
	Label Claim	Each film coated tablet contains Montelukast....10 mg as Montelukast Sodium
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO

	Shelf Life (Unit)	24 Month(s)Below 30 degree
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonists (LTRAs)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of three batches (1500 tablets) at accelerated and long-term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	API on loan from Medidave Pharmaceuticals, Lahore
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Montika 10 mg, Batch EQM014, Mfg 09-2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of three batches at accelerated and long-term conditions
	The status in reference regulatory authorities	MHRA, UK
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	DML No. 000994 dated 09.05.2024
	Evaluation Remarks	
	The application fulfills codal formalities.	
	Decision	
	Approved	
211	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Werrick Pharmaceuticals** Plot No. 216 - 217, I-10/3, Industrial Area Islambad **(000340)**
	Application Form Dy. No / Tracking ID & date of submission	(NTB-M1R-67TE, 2025-10-03)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Werosin-D Capsules**
	Label Claim	Each hard gelatin Capsule Contains: Soft gelatin capsule of Dutasteride.....0.5mg, Tamsulosin HCl (as modified release pellets).....0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Tamsol-D Capsules by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Dutasteride: 5-alpha reductase inhibitors Tamsulosin HCl: alpha-adrenergic antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A,Vision Pharmaceuticals (Pvt.) ltd
	Detail of stability batches of drug product	Trial no 1 (Trial size: 1500 Capsules, Mfg Date: 09/2024, Exp Date: 09/2026) Trial no 2 (Trial size: 1500 Capsules, Mfg Date: 09/2024, Exp Date: 09/2026) Trial no 3 (Trial size: 1500 Capsules, Mfg Date: 09/2024, Exp Date: 09/2026) Stability Study Conditions: Accelerated: 40°C ± 2°C / 75% RH ± 5% RH (06 Months) Real Time: 30°C ± 2°C / 65% RH ± 5% RH (06 Months)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Dutasteride imported; from Dr. Reddy's, Telangana, India Clearance certificate dated 01

		June 2020 Tamsulosin HCL SR pellets 0.2% by Vision Pharmaceuticals Islamabad.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Duodart by Catalent/ GSK specs, Lot 5780736C Mfg 02/2024
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data of 3 batches
	The status in reference regulatory authorities	JALYN Capsules by GlaxoSmithKline
	GMP status of the firm	GMP Certified 22.08.2025
	Evidence of approval of manufacturing facility	Soft Gelatin Section in Renewal of DML dated 28 January 2026 Tracking ID: 7BB-6UT-WVWX
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
212	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	(RJS-6GD-XQ4S, 2025-12-10)
	Detail of Fee Submitted	75000.0, 2025-08-27,
	The proposed proprietary name / brand name	**Rimega 75mg Tablets**
	Label Claim	Rimegepant 75mg/Tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 7, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70,-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Rimegepant: It is a competitive antagonist of the human calcitonin gene-related peptide (CGRP) receptor.
	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 (in case of Import)	Attached in Module 3 in section 3.2.P.8
	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	NURTEC ODT (Rimegepant) orally disintegrating tablets, for sublingual or oral use Tablets: 75 mg Initial U.S. Approval: 2020 Manufactured for: Biohaven Pharmaceuticals, Inc. New Haven, CT 06510 USA
	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	
	Keeping in view that innovator used “Zydis” technology in which individual tablets are produced by lyophilizing an aqueous solution or suspension containing the active ingredient and excipients in a preformed blister, you have used a conventional method. The firm has replied interalia, "Technically we can manufacturer this product by formulating a compressed (Direct Compression Method)."	
	Decision	
	Deferred Registration Board deferred the application for the provision of the following: i. confirmation of using compressed (Direct Compression) method in the approved Rimegepant tablets by Reference Regulatory Authorities declared in the 275th meeting of the Registration Board ii. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. iii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP’s Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iv. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
213	Case Category	New Molecule/Formulation (Incharge Evaluation Cell)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)**
	Application Form Dy. No / Tracking ID & date of submission	(H9N-PTD-PL55, 2026-02-27)
	Detail of Fee Submitted	75000, 2025-12-08,
	The proposed proprietary name / brand name	**Rimepant OD Tablets 75mg**
	Label Claim	Each Oro-dispersible tablet contains: Rimegepant Sulfate as Rimegepant.....75mg
	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,7's-De-Controlled
	Shelf Life (Unit)	24 MonthDo not store above 30°C. Protect from sunlight and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Calcitonin gene-related peptide (CGRP) antagonists.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	-
	Detail of stability batches of drug product	Firm has submitted stability data of two batches of drug product on both real time and accelerated condition.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Form 6, Invoice, Airway Bill and GD as the evidence for documents of procurement.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence Study and Comparative Dissolution Profile against comparator product Nurtec ODT Tablets

		75mg by M/s Biohaven Pharmaceuticals Inc., USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability data of three batches of drug substance on both real time and accelerated condition.
	The status in reference regulatory authorities	Nurtec ODT Tablets 75mg by M/s Biohaven Pharmaceuticals Inc., USA
	GMP status of the firm	Valid GMP of FPP manufacturer is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted Valid Drug Manufacturing License (License No.: 000284) as the evidence of manufacturing facility.
	Evaluation Remarks	
	Keeping in view that innovator used “Zydis” technology in which individual tablets are produced by lyophilizing an aqueous solution or suspension containing the active ingredient and excipients in a preformed blister, you have used a conventional method. The firm has stated, "Alternatively, Getz Pharma has used conventional method for the manufacturer of Rimepant OD (Rimegepant) Tablets 75mg in accordance with Guidance Document for Submission of Application on Form 5-F (CTD) for Registration of Pharmaceutical Drug Products for Human Use which states: “Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product”. We are hereby enclosing Drug-Excipients compatibility study performed by Getz Pharma on Rimepant OD (Rimegepant) Tablets 75mg for your review."	
	Decision	
	Deferred Registration Board deferred the application for the provision of the following: i. confirmation of using conventional method in the approved Rimegepant tablets by Reference Regulatory Authorities declared in the 275th meeting of the Registration Board ii. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation. iii. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP’s Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 iv. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.	
214	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(1G2-VXX-TGT6, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Visunate-M 120mg Injection**
	Label Claim	Each vial contains: Artesunate.....120mg (Intl. Ph. Specifications)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1’s-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree

	For generic drugs (me-too Status)	Arcenate Injection 120mg Reg. no. 100929 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	artemisinin-based antimalarial agent
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd.-Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	Ph. Int Specifications
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2 nd Nov, 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	
215	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(28W-19U-L9PD, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**Co-Promy 375mg/20mg Tablet**
	Label Claim	Each Modified Release Tablet contains: Naproxen (as enteric coated core) .....375mg Esomeprazole as Magnesium Trihydrate (as immediate release coat) .....20mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Glomov Tablet by Global Pharma
	Pharmacotherapeutic Group of (API)	NSAID (Nonsteroidal Anti-inflammatory drug with PPI (Proton Pump Inhibitor)
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Naproxen and Esomeprazole Magnesium Tablet 375/20mg by ScieGen Pharmaceuticals,New York, USFDA Approved.
	Detail of previous approval	Napeso 375/20mg Tablet,340th
	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.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(9UE-PSA-RUS7, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**Carbo-Fe 750mg/15ml Injection**
	Label Claim	Each 15 ml contains: Ferric carboxymaltose eq. to elemental iron.....750mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15 mL x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Ferinject Injection by OBS Pharma
	Pharmacotherapeutic Group of (API)	Anti-anaemic preparation
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	INJECTAFER 750mg/15ml (50mg/ml) AM REGENT, North America,USA, USFDA Approved.
	Detail of previous approval	Feroxyma 750mg/15mL ,348
	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.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(GRZ-S25-N34V, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-04,
	The proposed proprietary name / brand name	**Latidine-C 5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Lafutidine.....5mg (As per JP Specifications)
	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,28's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Lafudin 5mg tablet by M/s NovaMed Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiulcer/H2 receptor Antagonist
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Taiho Pharmaceutical Co., Ltd.Japan (PROTECADIN® 5 mg Tablet)
	Detail of previous approval	Lafudin 5mg Tablet ,331st Minutes of 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	
218	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(RRG-3MG-47BS, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-04,
	The proposed proprietary name / brand name	**Latidine-C 10 mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Lafutidine.....10mg (As per JP Specifications)
	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,28's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Lafudin 10mg tablet by M/s NovaMed Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiulcer/H2 receptor Antagonist
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Lafutidine Tablets 10mg by Sawai Pharmaceutical, Japan, PMDA Approved.
	Detail of previous approval	Lafudin 10mg Tablet ,331st Minutes of 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	
219	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(UN6-6M7-LW91, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**Carbo-Fe 500mg/10ml Injection**
	Label Claim	Each 10ml contains: Ferric carboxymaltose eq. to elemental iron.....500mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL Vial in 1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Fercari Injection BY Hilton Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti-anaemic preparation
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	INJECTAFER 500mg/10ml (50mg/ml) AM REGENT, North America,USA, USFDA Approved.
	Detail of previous approval	Feroxyma 500mg/10mL ,293
	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.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(W3L-PM5-QJWJ, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**Co-Promy 500mg/20mg Tablet**
	Label Claim	Each Modified Release Tablet contains: Naproxen (as enteric coated core) .....375mg Esomeprazole as Magnesium Trihydrate (as

		immediate release coat) .....20mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Glomov Tablet by Global Pharma
	Pharmacotherapeutic Group of (API)	NSAID (Nonsteroidal Anti-inflammatory drug with PPI (Proton Pump Inhibitor)
	Name, address of Manufacturing site:	M/s NovaMed Pharmaceuticals (Pvt.) Limited-28 KM, Ferozepur Road, Lahore-
	The status in reference regulatory authorities	Naproxen and Esomeprazole Magnesium Tablet 500/20mg by ScieGen Pharmaceuticals, New York, USFDA Approved.
	Detail of previous approval	Napeso 500mg/20mg Tablet,340th Minutes of 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	
221	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	(E6S-5XS-XET3, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-27,
	The proposed proprietary name / brand name	**Avanza 50mg Tablets**
	Label Claim	Each tablet contains: Avanafil.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,2's-As per SRO,20's-As per SRO,30's-As per SRO,4's-As per SRO,50's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Avafil Tablet 50mg ; Registration No: 132886 ; Registration Date: 2025-12-24 ; Company Name: Getz Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	REZDIFFRA (Resmetirom) tablets, for oral use Tablets: 60 mg, 80 mg, and 100 mg Initial U.S. Approval: 2024 Company: Manufactured for and Distributed by: Madrigal Pharmaceuticals, Inc.

		West Conshohocken, PA https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.fda.gov
	Detail of previous approval	Avala 50mg Tablet ; Reg. # 132422 ; 351 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	
222	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	(PG5-QNZ-Q7PM, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-27,
	The proposed proprietary name / brand name	**Avanza 100mg Tablets**
	Label Claim	Each tablet contains: Avanafil.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,12's-As per SRO,2's-As per SRO,20's-As per SRO,30's-As per SRO,4's-As per SRO,50's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Avafil Tablet 100mg ; Registration No: 132888 ; Registration Date: 2025-12-24 ; Company Name: Getz Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd.-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	REZDIFFRA (Resmetirom) tablets, for oral use Tablets: 60 mg, 80 mg, and 100 mg Initial U.S. Approval: 2024 Company: Manufactured for and Distributed by: Madrigal Pharmaceuticals, Inc. West Conshohocken, PA https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.fda.gov
	Detail of previous approval	Avala 100mg Tablet ; Reg. # 132423 ; 351 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	
223	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(JDB-7WH-9L5W, 2025-12-05)
	Detail of Fee Submitted	97200, 9400 2025-11-05, 2026-05-11
	The proposed proprietary name / brand name	**Vydra Chewable Tablets 100mg**
	Label Claim	Each Chewable Tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per DPC/SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C Protect from heat, Light and Moisture
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Martin Dow Limited-Plot No. 37، Sector 19، Korangi Industrial Area، Karachi-
	The status in reference regulatory authorities	Direktan Chewable Tablets 100mg (Austria)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
224	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(MUX-5WG-H4GG, 2026-01-27)
	Detail of Fee Submitted	97200, 9400 2025-11-05, 2026-05-11
	The proposed proprietary name / brand name	**Vydra Chewable Tablets 50mg**
	Label Claim	Each Chewable Tablet contains: Sildenafil Citrate eq. to Sildenafil 50mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per DPC/SRO-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C Protect from heat, Light and Moisture
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Martin Dow Limited-Plot No. 37، Sector 19، Korangi Industrial Area، Karachi-
	The status in reference regulatory authorities	Direktan Chewable Tablets 50mg (Austria)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
225	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hudson Pharma (Pvt) Ltd** D-93, North Western Industrial Zone, Port Qasim Authority **(000842)**
	Application Form Dy. No / Tracking ID & date of submission	(J6W-ED9-5ZXD, 2025-05-12)
	Detail of Fee Submitted	93000.0, 9400 2025-01-08, 2026-04-22
	The proposed proprietary name / brand name	**Posazol 100mg DR Tablet**
	Label Claim	Each Delayed-Release Tablet contains: Posaconazole.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	24's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Private Limited-Plot No. 129 – Sunder Industrial Estate Raiwind Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	Posaconazole 100mg DR Tablet-M/S Merck Sharp & Dohme LLC (118446553)-Registration number: NDC 0254-2045-02
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
226	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	(7GW-LBT-G9WM, 2025-04-17)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**Jorox 2.5mg Tablet**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	:1x4's, 1x5's, 1x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30ºC
	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	Tadalafil Tablets, USP 2.5mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
227	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	(JA9-EA2-PXBA, 2025-04-17)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**Jorox 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)	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	Tadalafil Tablets, USP 5mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
228	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	(YUA-PVE-6ZZ9, 2025-04-17)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**Jorox 10mg Tablet**
	Label Claim	Each film-coated tablet contains Tadalafil, USP.....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 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-
	Name & address of API manufacturer	ULTRATECH INDIA LTD
	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	Tadalafil Tablets, USP 10mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	
229	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	(Z97-DRM-X6B3, 2025-04-17)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-04-16
	The proposed proprietary name / brand name	**Jorox 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)	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	Tadalafil Tablets, USP 20mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	Detail of previous approval	
	Evaluation Remarks	
	The applicant initially selected No in the data already approved column of the application. After submission of pre-registration variation fee, they have requested for consideration against the already approved cross-referred product. 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	

230	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(9R3-1R1-GZLH, 2026-04-28)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo Tablets 9mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: 9.194mg of Orforglipron Calcium eq. to Orforglipron.....9.0mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's Tablets-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Orforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	ORD-001, ORD-002, Each of 5000 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 Foundayo Tablets Approved by US FDA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Valid w.e.f 07-04-2025
	Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021
	Evaluation Remarks	
	The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.	
	Decision	
	Rejected The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons: a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk	

	of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death) c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP's guidelines d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug's US FDA approval in April 2026 e) applicant's failure to provide evidence demonstrating that the innovator product's approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities. f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025 g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant	
231	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(JH4-6Z1-T9U5, 2026-04-30)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo Tablets 0.8mg**
	Label Claim	Each Film Coated Tablet Contains: 0.817mg of Orforglipron Calcium eq. to Orforglipron.....0.8mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3x 10's Capsules in blister pack-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	rforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Two Batches, ORA-001, ORA-002 Each of 5000 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 Foundayo Tablets Approved by US FDA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
The status in reference regulatory authorities	US FDA
GMP status of the firm	Valid w.e.f 07-04-2025
Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021

Evaluation Remarks

The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.

Decision

Rejected

The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons:

a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy

b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death)

c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP’s guidelines

d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug’s US FDA approval in April 2026

e) applicant’s failure to provide evidence demonstrating that the innovator product’s approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities.

	f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025 g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant	
232	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(Q6H-QVG-SMH9, 2026-04-30)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo Tablets 2.5mg**
	Label Claim	Each Film Coated Tablet Contains: 2.554mg of Orforglipron Calcium eq. to Orforglipron.....2.5mg (As per Innovator's specifications)
	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 in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Orforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	ORB-001, ORB-002, Each of 5000 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 Foundayo Tablets Approved by US FDA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Valid w.e.f 07-04-2025
	Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021
	Evaluation Remarks	
	The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.	
	Decision	
	Rejected The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for	

registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons:

a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy

b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death)

c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP's guidelines

d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug's US FDA approval in April 2026

e) applicant's failure to provide evidence demonstrating that the innovator product's approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities.

f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025

g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant

233	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(R7H-RDN-4J5G, 2026-04-30)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo 17.2mg Tablet**
	Label Claim	Each film coated tablets contains: 17.57mg of Orforglipron Calcium eq. to 17.2mg Orforgliprone
	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 in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	Orforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
Detail of stability batches of drug product	ORF-001, ORF-002, Each of 5000 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 Foundayo Tablets Approved by US FDA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
The status in reference regulatory authorities	US FDA
GMP status of the firm	Valid w.e.f 07-04-2025
Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021

Evaluation Remarks

The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.

Decision

Rejected

The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons:

a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy

b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death)

c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP’s guidelines

d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug’s US FDA approval in April 2026

e) applicant's failure to provide evidence demonstrating that the innovator product's approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities.

f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025

g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant

234	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(R7P-VAV-YQ6X, 2026-04-30)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo Tablets 5.5mg**
	Label Claim	Each Film Coated Tablet Contains: 5.619mg of Orforglipron Calcium eq. to Orforglipron.....5.5mg (As per Innovator's specifications)
	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 in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Orforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	ORC-001, ORC-002, Each of 5000 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 Foundayo Tablets Approved by US FDA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	Valid w.e.f 07-04-2025
	Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021
	Evaluation Remarks	
	The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.	
	Decision	
	Rejected	

The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons:

a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy

b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death)

c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP's guidelines

d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug's US FDA approval in April 2026

e) applicant's failure to provide evidence demonstrating that the innovator product's approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities.

f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025

g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant

235	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(XSS-Y6G-TW48, 2026-04-30)
	Detail of Fee Submitted	75000, 2026-04-13,
	The proposed proprietary name / brand name	**Orfo Tablets 14.5mg Tablet**

Label Claim	Each Film Coated Tablet Contains: 14.81mg of Orforglipron Calcium eq. to Orforglipron.....14.5mg (As per Innovator's specifications)
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 in a dry place away from direct heat or sunlight.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Orforglipron is an oral, non-peptide glucagon-like peptide-1 receptor agonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
Detail of stability batches of drug product	ORE-001, ORE-002, Each of 5000 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 Foundayo Tablets Approved by US FDA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Conducted at Zone IV-a stability conditions
The status in reference regulatory authorities	US FDA
GMP status of the firm	Valid w.e.f 07-04-2025
Evidence of approval of manufacturing facility	DML # 000427 w.e.f 01-04-2021

Evaluation Remarks

The instant application is applied under New License category in accordance with decision of Registration Board taken in its 257th meeting for such applications. Orforglipron is a NCE which was approved by US FDA on 01 April 2026. However, the firm submitted data from stability batches of 2025.

Decision

Rejected

The Registration Board noted that the US FDA approval letter (NDA 220934) dated 01-04-2025 mentions that NDA for the use of Foundayo (orforglipron) tablets was filed on 20-01-2026 for use in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. In the instant application for registration of orforglipron tablets by the M/s Hamaz Pharmaceuticals (Pvt) Ltd. (DML No. 000427), the Board observed a serious discrepancy regarding authenticity and chronology of the product development and evidence for established safety, which can lead to harm to health. Therefore, keeping in view of the aforementioned critical issues and evolving pharmacovigilance system, the Board decided to reject the instant application on the basis of following reasons:

a) insufficient time for innovator drug to be in market regarding established safety as the US FDA has required 07 Postmarketing clinical studies for Foundayo (orforglipron) tablets due to serious risk of medullary thyroid cancer, and to identify unexpected serious risks of long-term use in pediatric patients with obesity, and exposure to orforglipron in pregnancy

b) request by US FDA in their approval letter for enhanced pharmacovigilance for Foundayo (orforglipron) tablets for a period of 5 years for domestic and foreign postmarketing cases of DILI attributable to orforglipron, resulting in jaundice, liver failure, liver transplant, or death and analysis providing an assessment of causality, with documentation of indication, temporal association, duration of therapy, associated signs and symptoms, relevant laboratory values (especially baseline and peak ALT, AST, and TB) and diagnostic tests, concomitant therapies, confounders, underlying

	risk factors, treatment given for the event, drug disposition (e.g., dechallenge/rechallenge), and outcome at the time of the report (including whether the patient was hospitalized, experienced liver failure, liver transplant, or death) c) inadequate Drug Substance Characterization, specifically absence of definitive structural elucidation data to confirm identity of drug substance in line with DRAP's guidelines d) scientifically unjustifiable product development timelines as stability batches were manufactured and stability studies were initiated almost six months prior to the reference drug's US FDA approval in April 2026 e) applicant's failure to provide evidence demonstrating that the innovator product's approved quality attributes, including product strengths, compositions, and finished product specifications, were authorized by the Reference Regulatory Authority (RRA) at the time the applicant had initiated stability studies and product development activities. f) lack of data integrity and submission of misleading information evidenced by the fact that Product Development protocol was issued on 08-04-2026 whereas the stability batches were manufactured in 2025 g) the firm failed to provide evidence that US FDA approved quality, safety and efficacy parameters of Orforglipron tablet dosage regimen in strengths 0.8, 2.5, 5.5, 9, 14.5, and 17.2mg were established and accessible on FDA website at the time of initiation of stability of the exact aforementioned strengths by the applicant	
236	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)**
	Application Form Dy. No / Tracking ID & date of submission	(E7R-EVJ-5AP3, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-11-07,
	The proposed proprietary name / brand name	**Vorizen Injection 200mg (Lyophilized Powder for solution for Infusion)**
	Label Claim	Each vial contains: Lyophilized Voriconazole 200mg
	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 15 to 30°C.
	For generic drugs (me-too Status)	Noric 200mg Lyophilized Powder for Infusion by MTI Medical Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Triazole and tetrazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Synergene Active Ingredients Pvt. Ltd., Plot No. 59/D, J.N. Pharma City, Parawada (V&M), Visakhapatnam District 531021, Andhra Pradesh, India.
	Detail of stability batches of drug product	TR-VOINJ-02 406 Vials 02-2024 02-2026 TR-VOINJ-03 406 Vials 02-2024 02-2026 TR-VOINJ-04 406 Vials 02-2024 02-2026
	Documents for the procurement of API with approval from DRAP (in case of Import)	No clearance certificate attached. No ADC attested commercial invoice Batch No VZP002062311 June 2023, Exp 2028 Form 6 attached.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product for PE studies Noric Lyophilized Powder for Infusion NR-013
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per zone IVa. Long term: 48 months
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate attached. Validity: 26-04-2028
	Evidence of approval of manufacturing facility	Additional Section dated November 2029 Lyophilization (general) section
	Evaluation Remarks	
	1.Innovator has stated voriconazole revealed no evidence of either polymorphism, yours form is I. We have been informed by M/s. Synergene Active Ingredients Private Limited that "PXRD analysis has been performed on three plant scale batches of Voriconazole drug substance (Batch No. SYNVZIV18004II, SYNVZIV18006II and SYNVZIV18007II) and 2 theta values comparison between literature # US 2009/0023922 A1 and three plant scale batches of Voriconazole drug substance , it is evident that the manufacturing process followed by Synergene Active Ingredients Private Limited for Voriconazole Drug Substance is consistently producing crystalline form-I reported in literature (patent ref. number US 2009/0023922 A1). 2.If sterility test is not performed that material cannot be declared as injectable grade. As per USP, Where the label states that Voriconazole is sterile, it meets the requirements. Response from API Manufacture: (Synergene Active Ingredients Private Limited) We have been informed by M/s. Synergene Active Ingredients Private Limited that they have confirmed that they supply Voriconazole Injectable Grade (Non-sterile) drug substance. 3 Compare your specs and test method with JP in a tabular format. The comparative table of Innovator Specifications and test method of Voriconazole Injection 200mg with JP Monograph 4Justify the stated 12.3 mL fill volume prior to lyophilization, and explain how it correlates with: 19 mL reconstitution volume 20 mL extractable final volume 13 mL overfill For Voriconazole Injection, 12.3 mL of the solution is filled prior to Lyophilization. This overfill is intended to compensate for process losses during Lyophilization and to ensure delivery of the complete labeled dose upon reconstitution. This approach is consistent with standard manufacturing practices for lyophilized injectables and aligns with the innovator product. As per innovator literature, Voriconazole is supplied in single-use vials. The vial contents are reconstituted with 19 mL of Water for Injection to obtain a clear solution containing 10 mg/mL of Voriconazole with an extractable volume of 20 ml. Similarly, practical evaluation of the developed product confirmed complete solubilization and an extractable volume of 20 mL, ensuring delivery of the intended dose. Assessor Concluding Remarks The applied product API is in crystalline Form I, whereas the innovator product API is reported to exhibit no evidence of polymorphism as per EPAR. The Certificate of Analysis and commercial invoice describe the API as "injectable grade"; however, the manufacturer has confirmed it is non-sterile injectable grade as no sterility testing has been performed. Extractable volume testing is not included in the specifications to justify the 0.3 mL overfill, whereas the innovator product employs a 1.13 mL overfill as per EPAR. Applicant has claimed Innovator specifications while applied product is present in JP.	
	Decision	
	Deferred The Registration Boad deferred the case for the submission of the following documents: • Evidence of approval of reference product using crystalline Form I of drug substance. • Performance of extractable volume test to justify 0.3 ml overfill, whereas the innovator product employs 1.13 mL overfill.	
237	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(TV8-ER8-R5R6, 2024-08-22)

	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Racetril**
	Label Claim	Each sachet contains: Racecadotril 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 10’s, 16’s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Racedo sachet 10mg, Highnoon laboratories
	Pharmacotherapeutic Group of (API)	antidiarrheals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Private Limited D-16 ,Phase-I ,IDA-Jeedimetla Hyderabad-500055 Telangana State
	Detail of stability batches of drug product	794DS01,794DS02,794DS03
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearence Certificate attached date of issue 10-10-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE performed with Hidrasec Sachet 10mg Granules for oral suspension (Abbott). SXN830
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of API as per Zone IV b.
	The status in reference regulatory authorities	MHRA Approved - HIDRASEC INFANTS 10 mg, Granules for oral suspension, Bioprojet Europe Ltd. IRELAND
	GMP status of the firm	GMP certificate expired on 22-05-2025
	Evidence of approval of manufacturing facility	Sachet section is available.
	Evaluation Remarks	
	Assessor Concluding Remarks A prominent peak is observed in sample chromatogram 794DS01 (Sample 7)10mg at a retention time of 2–3 minutes in only 10mg sachet. Applicant has stated it is due to syringe filter issue. Sequence audit trial to verify chromatograms sequence not submitted. Method audit trail show changes in injection volume and other parameters.	
	Decision	
	Deferred Deferred the case for submission of the following documents: • Sequence audit trail to verify submitted chromatograms like Racecadotril sachet 10mg B#794DS03 3 M Acc Test Sol. A, Date Acquired 4/28/2024 10:42:52 AM and sequence audit trail of 6 months. • Justification for change in injection volume and other parameters. • Valid GMP certificate of relevant section.	
238	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(4TR-WXY-P39N, 2024-08-15)
	Detail of Fee Submitted	30000.0, 2024-07-15,
	The proposed proprietary name / brand name	**Racetril**
	Label Claim	Each sachet contains: Racecadotril 30mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	7’s, 10’s, 16’s-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Racedo sachet 30mg, Highnoon laboratories
	Pharmacotherapeutic Group of (API)	antidiarrheals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Private Limited
	Detail of stability batches of drug product	795DS01, 1000 Sachet 795DS02, 1000 Sachet 795DS03, 1000 Sachet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate Dated 10-10-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hidrasec 30mg Granules for oral suspension (Abbott) SXE2758
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IV b.
	The status in reference regulatory authorities	MHRA Approved - HIDRASEC INFANTS 30 mg, Granules for oral suspension, Bioprojet Europe Ltd. IRELAND
	GMP status of the firm	GMP certificate is not valid.
	Evidence of approval of manufacturing facility	Sachet section is present.
	Evaluation Remarks	
	Assessor Concluding Remarks Sequence audit trial to verify chromatograms sequence not submitted. Method audit trail show changes in injection volume and other parameters.	
	Decision	
	Deferred Deferred the case for submission of the following documents: • Sequence audit trail to verify submitted chromatograms like Racecadotril sachet 30mg B#795DS03, Injection date 2024-01-19 02:04:09+05:00. • Justification for change in injection volume and other parameters. • Valid GMP certificate of relevant section.	
239	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(YMT-PML-1AU9, 2024-10-22)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-15, 2024-10-18
	The proposed proprietary name / brand name	**Racetril Capsule 100mg**
	Label Claim	Each capsule contains: Racecadotril BP ...100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Racedo Capsule 100mg, Highnoon laboratories
	Pharmacotherapeutic Group of (API)	antidiarrheals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SVK Laboratories Private Limited D-16 ,Phase-I ,IDA-Jeedimetla Hyderabad-500055 Telangana State
	Detail of stability batches of drug product	797DS01, 5000 Capsule 797DS02, 5000 Capsule

	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance Certificate Dated 10-10-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hidrasec Capsules 100mg (Abbott) SX614
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per zone IV B.
	The status in reference regulatory authorities	MHRA Approved - HIDRASEC 100 mg hard capsules Bioprojet Europe Ltd. IRELAND
	GMP status of the firm	GMP certificate expired on 22, May 2025.
	Evidence of approval of manufacturing facility	Capsule general section is present.
	Evaluation Remarks	
	Assessor Concluding Remarks Sequence audit trial to verify chromatograms sequence not submitted. Method audit trail show changes in injection volume and other parameters.	
	Decision	
	Deferred Deferred the case for submission of the following documents: • Sequence audit trail to verify submitted chromatograms like Racecadotril Capsule 100mg B#797DS02 3M ACC Test Sol. A, Date Acquired 4/28/2024 3:56:37AM. • Justification for change in injection volume and other parameters.	
240	Case Category	Routine (Iqra Aftab)
	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	(DZB-7Q4-ERNP, 2024-08-09)
	Detail of Fee Submitted	75000.0, 2024-07-09,
	The proposed proprietary name / brand name	**Vorcaz Tablet 100mg**
	Label Claim	Each Film Coated Tablet Contains: Voriconazole 100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 Protect from Light and Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	ANTIMYCOTICS FOR SYSTEMIC USE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Huahai Pharmaceutical Co., Ltd. (Xunqiao site) Manufacturing Site: Xunqiao, Linhai, Zhejiang 317024, C
	Detail of stability batches of drug product	23SB-704-01 :1500 Tablet 23SB-705-02:150 Tablet 23SB-706-03 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	CLEARANCE CERTIFICATE Computerized No: E-6729880624537 Date of issue: 21-Sep-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against Aristo 100mg Batch no 284569
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa.

	The status in reference regulatory authorities	Aristo Pharma GmbH (Germany)
	GMP status of the firm	Valid GMP certificate is required. GMP certificate Validity: 06-06-2025
	Evidence of approval of manufacturing facility	Section letter attached.
	Evaluation Remarks	
	The standard and batch numbers were not initially mentioned on the chromatograms. The applicant submitted revised chromatograms with addition of batch numbers in label column. The HPLC injections details does not mention batch numbers in the sample set sequence.	
	Decision	
	Deferred The Registration Board deferred the case for the submission of the following documents: • 21 CFR Part 11 compliance certificate. • Sequence audit trail including details of batch numbers of applied product in sample set sequence.	
241	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(55G-SSE-B9B7, 2024-07-16)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Voric 100mg Tablet**
	Label Claim	Each film coated tablet contains: Voriconazole.....100mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Triazole antifungal
	Name, address of Manufacturing site:	Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch size 1500 tablets 23SB-704-01 23SB-705-02 23SB-705-03
	Documents for the procurement of API with approval from DRAP (in case of Import)	CLEARANCE CERTIFICATE Computerized No: E-6729880624537
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference product for PE studies is Voriconazole Aristo 100mg Batch no 284569
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per Zone IV a.
	The status in reference regulatory authorities	Aristo Pharma GmbH (Germany)
	GMP status of the firm	M/s Genix Pharma GMP certificate validity 6-06-2026
	Evidence of approval of manufacturing facility	Tablet section revised letter attached of M/s Genix December 2023.
	Evaluation Remarks	

	The standard and batch numbers were not initially mentioned on the chromatograms. The applicant submitted revised chromatograms with addition of batch numbers in label column. The HPLC injections details do not mention batch numbers in the sample set sequence.	
	Decision	
	Deferred The Registration Board deferred the case for the submission of the following documents: • 21 CFR Part 11 compliance certificate. • Sequence audit trail including details of batch numbers of applied product in sample set sequence.	
242	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(R5E-49U-G34W, 2026-03-10)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	**Tranzacel 250mg Capsule**
	Label Claim	Each Capsules Contains: - Tranexamic Acid.....250mg (JP Specification)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30 Degree
	For generic drugs (me-too Status)	Btrol Capsules 250mg Bosch Pharmaceuticals (Pvt) Ltd. 030226
	Pharmacotherapeutic Group of (API)	Antifibrinolytic / Hemostatic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Bamboo Pharmaceuticals Co.,Ltd, No.9 Weiyi Road Hangzhouwan Economic Technology Development Zone, Shangyu District, Shaoxing City, Zhejiang Province, China
	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	Transamin 250mg Capsule PMDA Japan Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Query The same retention time has been reported for all chromatograms, which is scientifically implausible. Furthermore, the peaks observed in the chromatograms do not correspond to the retention times provided in the table. Response Your observation that identical retention times across all chromatograms are not scientifically justifiable, and we also understand the discrepancy noted between the peaks in the chromatograms and the retention times reported in the table. In response to your concerns, we will thoroughly review the analytical data and repeat the stability	

	studies to ensure accuracy, consistency, and full scientific validity. The revised chromatograms, along with corrected retention time tables and complete stability data, will be submitted for your re-evaluation	
	Decision	
	Rejected The Registration Board rejected the instant application as the majority of the submitted chromatograms showed identical retention times, and the peaks observed in the chromatograms did not correspond to the retention times provided in the table, raising serious concerns regarding the authenticity of the submitted stability data. Furthermore, the applicant also agreed that submitted data is not scientifically justifiable	
243	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(YAW-SPQ-1HLQ, 2026-03-10)
	Detail of Fee Submitted	38700, 2026-01-30,
	The proposed proprietary name / brand name	**Tranzacel 500mg Capsule**
	Label Claim	Each Capsules Contains: - Tranexamic Acid 500mg (JP Specification)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree Celsisu
	For generic drugs (me-too Status)	Btrol Capsules 500mg Bosch Pharmaceuticals (Pvt) Ltd. 030789
	Pharmacotherapeutic Group of (API)	Antifibrinolytic / Hemostatic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Bamboo Pharmaceuticals Co.,Ltd, No.9 Weiyi Road Hangzhouwan Economic Technology Development Zone, Shangyu District, Shaoxing City, Zhejiang Province, China
	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	Transmin 500mg Capsules PMDA Japan
	GMP status of the firm	VALID
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Query The same retention time has been reported for all chromatograms, which is scientifically implausible. Furthermore, the peaks observed in the chromatograms do not correspond to the retention times provided in the table. Response Your observation that identical retention times across all chromatograms are not scientifically justifiable, and we also understand the discrepancy noted between the peaks in the chromatograms and the retention times reported in the table. In response to your concerns, we will thoroughly review the analytical data and repeat the stability studies to ensure accuracy, consistency, and full scientific validity. The revised chromatograms, along with corrected retention time tables and complete stability data, will be submitted for your re-evaluation	

	Decision	
	Rejected The Registration Board rejected the instant application as the majority of the submitted chromatograms showed identical retention times, and the peaks observed in the chromatograms did not correspond to the retention times provided in the table, raising serious concerns regarding the authenticity of the submitted stability data. Furthermore, the applicant also agreed that submitted data is not scientifically justifiable	
244	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(SL5-VL1-2L3R, 2026-02-12)
	Detail of Fee Submitted	38700, 2025-12-30,
	The proposed proprietary name / brand name	**Diclosel 100mg SR Tablet**
	Label Claim	Each sustained release Tablet Contains: - Diclofenac Sodium 100mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree celsius
	For generic drugs (me-too Status)	Medifenac SR 100mg Tablet Mediate Pharmaceuticals, Karachi 048703
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory Drug.(NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Dongtai Pharmaceuticals co Ltd
	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	Approved by USFDA
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	Query The chromatograms of the 50 mg DR tablet and 100 mg SR tablet show the same retention time, differing only in the date. Response Your observation that identical retention times across all chromatograms are not scientifically justifiable, and we also understand the discrepancy noted between the peaks in the chromatograms and the retention times reported in the table. In response to your concerns, we will thoroughly review the analytical data and repeat the stability studies to ensure accuracy, consistency, and full scientific validity. The revised chromatograms, along with corrected retention timetables and complete stability data, will be submitted for your re-evaluation at the earliest.	
	Decision	
	Rejected The Registration Board rejected the instant application as the chromatograms of the 50 mg DR tablet and 100 mg SR tablet show the same retention time, differing only in the date., raising concerns	

	regarding the authenticity of the submitted stability data. Furthermore, the applicant also agreed that submitted data is not scientifically justifiable.	
245	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)**
	Application Form Dy. No / Tracking ID & date of submission	(GU1-E6G-ESSD, 2026-02-18)
	Detail of Fee Submitted	38700, 2025-12-30,
	The proposed proprietary name / brand name	**Linzwl 600mg Tablet**
	Label Claim	Each Film Coat Tablet contains: Linezolid...600mg USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14 s-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30 degree
	For generic drugs (me-too Status)	Ecasil 600mg tablet Manufacturer's Name: Sami Pharmaceuticals Pvt Ltd, Pakistan Registration No. 066904
	Pharmacotherapeutic Group of (API)	oxazolidinone
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Pure andc cure Health Care Pvt. Ltd
	Detail of stability batches of drug product	ATTACH
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attach
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attach
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attach
	The status in reference regulatory authorities	Linzolid 600mg film coated tablets/Pfizer Limited RRA: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attach
	Evaluation Remarks	
	The 3-month and 6-month data show the "same time" on chromatograms and "retention time" of API.	
	Decision	
	Rejected The Registration Board rejected the instant application as the chromatograms submitted for the 3 month and 6-month stability studies showed identical data acquisition times and drug substance retention times, raising concerns regarding the data authenticity of submitted stability data.	
246	Case Category	New Section (Iqra Aftab)
	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	(U3E-LBA-HR1P, 2025-11-07)
	Detail of Fee Submitted	75000, 2025-10-16,
	The proposed proprietary name / brand name	**Veneclax 10mg tablet**

Label Claim	Each Film coated Tablet Contains: Venetoclax 10mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-As per SRO,2's-As per SRO,30'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)	antineoplastic agents
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	NANTONG CHANYOO PHARMATECH CO., LTD NO.2 TONGHAI SI ROAD, YANGKOU CHEMICAL INDUSTRIAL PARK, RUDONG COASTAL ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU PROVINCE 226407
Detail of stability batches of drug product	Accelerated Stability: 40□2°C, RH 75□5% Long-term Stability: 30□2°C; RH 65□5% 24 months
Documents for the procurement of API with approval from DRAP (in case of Import)	FINAL CLEARANCE CERTIFICATE Computerized No: RO-A49769 Date of Issue: 25-02-2025 VENETOCLAX 000755 VCL. 702-240701 0.3000 Kilogram 05- 07- 2024 05- 07- 2027 NANTONG CHANYOO PHARMATECH CO., LTD NO.2 TONGHAI SI ROAD, YANGKOU CHEMICAL INDUSTRIAL PARK, RUDONG COASTAL ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU PROVINCE 226407, P.R.CHINA China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and CDP has been provided against Abbvie Healthcare India Batch No 127672
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided
The status in reference regulatory authorities	FOOD & DRUG ADMINISTRATION (FDA)
GMP status of the firm	New section Dated May 2024
Evidence of approval of manufacturing facility	New Section Tablet Cytotoxic Dated May 2024
Evaluation Remarks	
Concluding Remarks of Assessor Applicant has used amorphous form of API, instead of providing evidence for said form, they have submitted the innovator product PAR, which is based on the crystalline form of the API. The qualitative composition of the applied product cannot be considered comparable to that of the innovator, as the innovator utilizes the crystalline form while your product employs the amorphous form. Applicant has used calcium hydrogen phosphate anhydrous, whereas the innovator product contains calcium phosphate dibasic. Clarity and color, as well as microbiological quality, have only been included in the specifications; however, no revised Certificate of Analysis (CoA) has been submitted. Water content has been added to the specifications, but a revised CoA has not been provided. A clear snapshot showing the manufacturer details on the reference pack, as the batch number was torn as stated by applicant, is required. Repeated post-run reprocessing of integration and calibration parameters was observed. These modifications were made after data acquisition, which raises concerns regarding data integrity. Created by :M.Zaman Date Modified :9/11/2025 11:44:18 AM Modified by :M.Adnan	
Decision	
Deferred	

	The Registration Board deferred the case pending submission of the following documents: • Evidence of any reference product using the amorphous form of the API. • Clarification regarding the claim of qualitative similarity with the innovator product, whereas the innovator product contains the crystalline form of the API. • Performance and submission of test results for solution clarity, color, microbiological quality, and water content, along with a revised Certificate of Analysis. • Snapshot of the innovator product clearly indicating the manufacturer's information/batch No. • Scientific justification for the repeated post-run reprocessing of integration and calibration parameters.	
247	Case Category	Import (Muhammad Sarfraz Nawaz)
	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	(5PH-3W3-TNH4, 2024-08-21)
	Detail of Fee Submitted	150000.0, 150000.0 2023-10-30, 2024-06-07
	The proposed proprietary name / brand name	**letrogen**
	Label Claim	USED AS ANTINEOPLASTIC AGENT
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	3 YearStore below 30°C, protect from light and Moisture
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	GLOBELA PHARMA PVT LTD-Plot number:357 & 358,Road No.3,GIDC,Sachin,Surat-394230,Gujarat,India-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	M/s ABM HK ENTERPRISES (PVT) LTD, 2nd Floor, Plaza 60, Commercial Block-K, Phase-1,DHA, Lahore, Pakistan
	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	FDA
	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.	
248	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**

	Application Form Dy. No / Tracking ID & date of submission	(VWD-HAL-2MM9, 2025-03-12)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	**AMANTAFAS-98 ORAL POWDER**
	Label Claim	Each 100gm Contains: Amantadine HCl.....98gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10Kg-De-Controlled,20Kg-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 25C
	For generic drugs (me-too Status)	Amadine-98 Oral Powder (Reg no. 093841) Aptly Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate based on inspection dated 01-02-24
	Evidence of approval of manufacturing facility	Powder (General) section approval submitted
	Evaluation Remarks	
	Decision of 353rd meeting of Registration Board: Deferred for submission of target species. Updated status: Target Species: AMANTAFAS-98 Oral Powder is intended for use in poultry, including: Broiler chickens Layer chickens Breeder chickens The product is indicated for use in the prevention and control of Avian Influenza (AI) caused by susceptible strains of Influenza A virus	
	Decision	
	Rejected since the Sub-committee on Veterinary Drugs recommended restricting the use of Amantadine formulations to non-food-producing animals only while the firm has mentioned target species poultry including Broiler chicken, Layer chicken and Breeder chicken.	
249	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(9NX-6NU-PJTS, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEL-BROMOL-900 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....50 mg Menthol.....40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch BM 90 Liquid (121922)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML granted

	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
250	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(G7M-ES3-P878, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEL-BROMOL-300 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....10 mg Menthol.....20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch BM 30 Liquid (121920)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
251	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(XTV-UM3-DU84, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEL-BROMOL-600 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....20 mg Menthol.....40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch BM 60 Liquid (121921)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
252	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(184-P69-79EP, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLOSIN 72 ORAL POWDER**
	Label Claim	Each gram contains: Neomycin Sulphate.....720 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Neo-72 water soluble Powder (120876)
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML granted on 09-02-2026
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
253	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(2JY-3V2-Y7GT, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEL FEN 20 ORAL LIQUID**
	Label Claim	Each 100ml contains: Florfenicol.....20 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Fen 20% Liquid (121908)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML granted
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	Decision	
	Approved	
254	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(6TE-DP3-1J2D, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEBRO-1000 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	BRO-SAL 10% LIQUID (130113)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML granted
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
255	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(5AP-VWY-1LX7, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XANTADINE 10 ORAL POWDER**
	Label Claim	Each 100 gms contains: Amantadine HCl.....10%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ROLDINE 10% W/S POWDER (109104)
	Pharmacotherapeutic Group of (API)	Anti-viral
	Name, address of Manufacturing site:	--
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Target species: □ Calves, poultry□ Foals Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only.	

	Decision	
	Approved upto pack size of upto 100gm only for use in non-food producing animals.	
256	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(A1J-X6H-AYWB, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XANTADINE 1 ORAL POWDER**
	Label Claim	Each 100 grams contains: Amantadine HCl.....1gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ROLDINE 1% W/S POWDER (109105)
	Pharmacotherapeutic Group of (API)	Anti-viral
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Target species: □ Calves, poultry□ Foals Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only.	
	Decision	
	Approved upto pack size of upto 100gm only for use in non-food producing animals.	
257	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(MNG-UYL-21L1, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XANTADINE 98 ORAL POWDER**
	Label Claim	Each 100 grams contains: Amantadine HCl.....98 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ROLDINE 98 W/S POWDER (109103)
	Pharmacotherapeutic Group of (API)	Anti-viral
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	Target species: □ Calves, poultry□ Foals Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only.	
	Decision	
	Approved upto pack size of upto 100gm only for use in non-food producing animals.	
258	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(ARS-V4L-2G6B, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEBRO-500 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Brom 5% Oral Liquid (121915)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
259	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(ASA-ZWV-SPHJ, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLOSIN 100 ORAL POWDER**
	Label Claim	Each gm contains: Neomycin Sulphate.....1000 mg (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Arch Neo-100 water soluble Powder (120877)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the

		applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
260	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(B8N-S9V-UXMR, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA-ENROCIN-20 ORAL LIQUID**
	Label Claim	Each ML contains: Enrofloxacin.....200 mg Colistin Sulphate.....30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Enstin 20 Liquid (121918)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
261	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(BWB-JGL-NGLS, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYPRO 60 ORAL POWDER**
	Label Claim	EACH 100 GM POWDER CONTAINS:-Amprolium HCl.....60gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature

	For generic drugs (me-too Status)	AMPROSHELL 60% WATER SOLUBLE POWDER (075774)
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
262	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(PEW-3JW-A4D9, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA-ENROCIN-10 ORAL LIQUID**
	Label Claim	Each ML contains: Enrofloxacin.....100 mg Colistin Sulphate.....0.48 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Enstin 10 Liquid (121917)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
263	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(RNJ-STL-TTMH, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**OXYLANIX-100 ORAL LIQUID**
	Label Claim	Each 1000ml contains: Oxolinic acid.....100 gm (As per innovator’s specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled

	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	VETY-OXOL LIQUID (046668)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
264	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(WQJ-TVY-VHLT, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYPRO 90 ORAL POWDER**
	Label Claim	Each 100 gms contains: Amprolium HCl.....90 gms (USP specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	HARLIUM 90% W/S POWDER (109112)
	Pharmacotherapeutic Group of (API)	Coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
265	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(SJR-X6R-LMYG, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**N-RO 25% ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin 25gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	ENSTER 25 ORAL LIQUID (101503)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
266	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(QRW-ELQ-TH7W, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**N-RO 10% ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin 10gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	ENSTER 10 ORAL LIQUID (101500)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
267	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(ET6-4E6-SHWS, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**N-RO 20% ORAL LIQUID**

	Label Claim	Each 100ml contains: Enrofloxacin ..... 20gm (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	ENSTER 20 ORAL LIQUID (101501)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
268	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(NMU-56X-7JBB, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**RIL K ORAL LIQUID**
	Label Claim	Each 1000 ml contains: Toltrazuril.....25g Vitamin K3.....3g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Tolmars Liquid Registration No 075746
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
269	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**

	Application Form Dy. No / Tracking ID & date of submission	(Y36-SPV-ESD9, 2026-04-10)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**Enro Hexine 240 ORAL LIQUID**
	Label Claim	Each ml contains : Enrofloxacin ..... 100mg Guaifenesin ..... 40mg Aminophylline 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Carlos Flox AG Oral Liquid (109058)
	Pharmacotherapeutic Group of (API)	Antibiotic, expectorant, bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
270	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(L47-LS1-TRHV, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**BAKE COLIN 20 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin ..... 20gm Colistin sulphate 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Refloxtin-20 Oral Liquid (101430)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	

271	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(QMW-7B5-NYXS, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**BAKE COLIN 10 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin ..... 10gm Colistin sulphate 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Refloxtin-10 Oral Liquid (101429)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
272	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(QQG-3US-DM6A, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO COLLINE ORAL POWDER**
	Label Claim	Each 100 gm contains: Oxytetracycline HCl.....300 mg Neomycin Sulphate....150 mg Florfenicol.....100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Mycoline Oral Powder (120881)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	

	Approved	
273	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(TJ6-AND-R78Y, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO-QUINE-20 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Roxin 20 Liquid (122010)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
274	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(TMG-2H8-BDAG, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYPRO 50 ORAL POWDER**
	Label Claim	Each 100 gram contains: Amprolium HCl.....50 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	HARLIUM 50% W/S POWDER (109111)
	Pharmacotherapeutic Group of (API)	Coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	

	Approved	
275	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(ZQS-XVL-51LP, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEBRO-100 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....10 mg (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Arch Brom 1% Oral Liquid (121914)
	Pharmacotherapeutic Group of (API)	Mucolytic/expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
276	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(M81-TPR-YGRY, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**DAEK ORAL LIQUID**
	Label Claim	Each liter contains:- VITAMIN A.....25000000 IU. VITAMIN D3.....250000 IU. VITAMIN E.....15000 MG. VITAMIN K3.....2500 MG. (As per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	ADEK GOLD ORAL SOLUTION (063813)
	Pharmacotherapeutic Group of (API)	vitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML

	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
277	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(RNZ-B14-MH75, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**SEL E BAKE ORAL LIQUID**
	Label Claim	Each 100ml contains: Silymarin ..... 2100 mg Vitamin E ..... 1500 mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	HEPATOCARE LIQUID (062167)
	Pharmacotherapeutic Group of (API)	Hepatoprotective
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
278	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(TBA-7EM-V4SR, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**BARSA BAKE ORAL LIQUID**
	Label Claim	Each ml contains:- Trimethoprim.....80 mg Sulphadizaine.....400 mg. (As per innovator's specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the

		container tightly closed.
	For generic drugs (me-too Status)	Diatrim Oral Liquid. registration No 122008
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
279	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(ZRV-X97-3ZYV, 2026-04-24)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**OXCID ORAL LIQUID**
	Label Claim	Each ml contains: Oxolinic Acid 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	(117036) ACEOXOL ORAL SOLUTION of ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
280	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(X82-XUU-15UH, 2026-04-24)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**COTIL-P LIQUID**
	Label Claim	Each ml contains: Tilmicocin as phosphate.....250mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Condition

	For generic drugs (me-too Status)	TELSIN-P LIQUID INSHALL PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
281	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(VXU-EDV-8XTU, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**SPIROLIN ORAL POWDER**
	Label Claim	Each 100 gm contains: Lincomycin HCl 5 gm, Spectinomycin HCl 7.5 gm, Spiramycin Adipose 2.5 gm, Bromhexine HCl 0.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(101973) LSB ORAL POWDER of M/S. INSHAL PHARMACEUTICAL INDUSTRIES, RAWAT
	Pharmacotherapeutic Group of (API)	Antibiotic, mucolytic agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
282	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(VMP-ELL-XZN5, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 12/25 POWDER**
	Label Claim	Each gm contains: Tylosin Tartrate 100 mg, Doxycycline HCl 200 mg, Colistin Sulphate 25 mg, Bromhexine HCl 5 mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Fludoxyt-200 Powder (Reg. No. 103848) - Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
283	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(VHB-2LT-9BWL, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACELYTE POWDER**
	Label Claim	Each 100 gm contains: Paracetamol 2 gm, Vitamin C (Ascorbic Acid) 20 gm, Calcium Carbonate 4.5 gm, Potassium Chloride 4 gm, Magnesium Sulphate 3.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Spin-C Powder (Reg. No. 078239) - Leads Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Analgesic, vitamins, electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
284	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(UBQ-Z2Q-21VU, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-17,

	The proposed proprietary name / brand name	**ROFCOL 20/3 ORAL LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....20% Colistin sulphate 3%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(117019) ACMECOLIFLOX 20/3 ORAL LIQUID by M/S ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
285	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(U4G-9NY-QTR9, 2026-04-24)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**FECOL 25 ORAL LIQUID**
	Label Claim	Each ml contains: Florfenicol .....250mg Colistin sulphate.....0.5MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	(117029) FLOROCOL-25 ORAL LIQUID ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
286	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(S77-7WE-ZG8H, 2026-04-26)

	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE FLAG-114 LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....100mg Aminophylline .....40mg Guaiphenesin.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(122487) ENROHUB EXTRA ORAL LIQUID of M/S. AMAZON PHARMACEUTICAL (PVT.) LTD, AJK.
	Pharmacotherapeutic Group of (API)	Antibiotic, bronchodilator, expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
287	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(RR3-9N6-BSTH, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE FOX 20/5 POWDER**
	Label Claim	Each 100 gm contains: Calcium Fosfomycin.....20 gm Tylosin As Tartrate.....5 gm Fructose 1,6 Diphosphate.....18 gm Sodium Phosphate.....15 gm Magnesium Phosphate.....10 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	AAcmefos Water Soluble Powder (Reg. No. 116953) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Anti-diarrheal
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	

	upto 1Kg pack size.	
288	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(PE1-MS2-AE7G, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 12/48 POWDER**
	Label Claim	Each 1000 gm contains: Tylosin Tartrate 100 gm, Doxycycline HCl 200 gm, Colistin Sulphate 48 MIU, Bromhexine HCl 50 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Nobidoxine Oral Powder (Reg. No. 079117) - NOBLE PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
289	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(N92-MAN-WUXS, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACEFLAG LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....100mg Aminophylline .....100mg Guaiphenesin.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(049720) ENSOL-AG BY Biogen Pharma
	Pharmacotherapeutic Group of (API)	Antibiotic, bronchodilator, expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	

	Approved	
290	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(JRE-Q25-9GJX, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACEDINE 98 POWDER**
	Label Claim	Each 1000 gm contains: Amantadine HCl 980 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Amanta-98 Powder (Reg. No. 128562) - A&K Pharmaceutical
	Pharmacotherapeutic Group of (API)	Anti-viral
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Target Species:Broiler chickens, layer chickens, breeders, cats and dogs. Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only with a pack size upto 100gm.	
	Decision	
	Approved upto pack size of upto 100gm only for use in non-food producing animals.	
291	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(JHS-TVA-2457, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE-P FLOX ORAL LIQUID**
	Label Claim	Each ml contains: Pefloxacin methane sulfonate equivalent to pefloxacin.....100
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	PEFLO-10 ORAL LIQUID
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	Decision	
	Approved	
292	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(J98-8S9-U14Q, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**MYNOX 22/30 POWDER**
	Label Claim	Each 1000 gm contains: Neomycin Sulphate 250 gm, Oxytetracycline HCl 250 gm, Colistin Sulphate 300 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ONC FORTE POWDER (Reg. No. 078217) - NOBLE PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
293	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(J7Q-LTS-QJA9, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACELIUM 30 WATER SOLUBLE POWDER**
	Label Claim	Each gm contains: Amprolium HCl 300 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmepro-30 Water soluble Powder (Reg. No. 118475) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	Decision	
	Approved upto 1Kg pack size.	
294	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(DRZ-7H3-XVUE, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**MYNOX 22/24 POWDER**
	Label Claim	Each gm contains: Neomycin Sulphate 200 mg, Oxytetracycline HCl 200 mg, Colistin Sulphate 0.24 MIU,
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acme NOC 20/20/0.24 Water Soluble Powder (Reg. No. 117038) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
295	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(BEG-NSG-7E74, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE COX POWDER**
	Label Claim	Each 1000 gm contains: Sulphadimerazine 213 gm, Diaveridine 26 gm, Vitamin A 2,000,000 IU (=4 gm),Vitamin K3 4 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Coccidene AK Powder (Reg. No. 043148) - Leads Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic, antiprotozoal, vitamins

	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
296	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(ADL-RUJ-78GM, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE FON ORAL POWDER**
	Label Claim	Each gm contains: Neomycin Sulphate 150 mg, Oxytetracycline HCl 300 mg, Florfenicol 100 mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(125821) N-Florox Oral Powder of Ms RUTH PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
297	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(8ZD-XJN-25PW, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACEBRO 5 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(125830) Bromo Ruth 5% Oral Liquid of M/s. Ruth Pharmaceutical, Gujranwala.
	Pharmacotherapeutic Group of (API)	Mucolytic/ expectorant
	Name, address of Manufacturing site:	--

	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
298	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(7SJ-83X-4L2L, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 24/50 POWDER**
	Label Claim	Each 100 gm contains: Tylosin Tartrate 20 gm, Doxycycline HCl 40 gm, Colistin Sulphate 50 MIU, Bromhexine HCl 1 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Fludoxyt-400 Powder (Reg. No. 103851) - Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
299	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(7GS-WLX-JH72, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACEDINE 10 POWDER**
	Label Claim	Each 100 gm contains: Amantadine HCl 10 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Deen 10% Powder (Reg. No. 092183) - Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Anti-viral
	Name, address of Manufacturing site:	--

	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Target Species:Broiler chickens, layer chickens, breeders, cats and dogs. Based on international practices, the Sub-committee recommended restricting the use of Amantadine formulations to non-food-producing animals only with a pack size upto 100gm.	
	Decision	
	Approved upto pack size of upto 100gm only for use in non-food producing animals.	
300	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(6TL-RRT-416R, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 12/500 POWDER**
	Label Claim	Each 1000 gm contains: Tylosin Tartrate 100 gm, Doxycycline HCl 200 gm, Colistin Sulphate 500 MIU, Bromhexine HCl 5 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	B.G. Doxit Water Soluble Powder (Reg. No. 080147) - BIOGEN Pharma
	Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
301	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(4JZ-W6Y-MRDL, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 24/60 POWDER**
	Label Claim	Each 1000 gm contains: Tylosin Tartrate 200 gm, Doxycycline HCl 400 gm, Colistin Sulphate 60 gm, Bromhexine HCl 20 gm
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Nobi TDC 680 Oral Powder (Reg. No. 062127) - NOBLE PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
302	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(67Y-JU9-DHRA, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-17, 2026-05-10
	The proposed proprietary name / brand name	**ROFCOL 10/48 ORAL LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....100mg Colistin sulphate 0.48MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(125759) Acmecoliflox 10/48 Oral Liquid of M/s. Acme Pharmaceuticals, Rawat.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with following me-too product Acmecoliflox 10/48 Oral Liquid (125759) of M/s Acme pharmaceuticals along with submission of fee.	
	Decision	
	Approved	
303	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(49U-2SW-BRT9, 2026-05-05)
	Detail of Fee Submitted	38700, 2026-04-17,

	The proposed proprietary name / brand name	**MYNOX 23/50 POWDER**
	Label Claim	Each 100 gm contains: Neomycin Sulphate 25 gm, Oxytetracycline HCl 30 gm, Colistin Sulphate 50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Rena Mycin 300 Powder (Reg. No. 103863) - Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
304	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(394-PYZ-VLAM, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYCOLIN 24/100 POWDER**
	Label Claim	Each 100 gm contains: Tylosin Tartrate 20 gm Doxycycline HCl 40 gm Colistin Sulphate 100 MIU Bromhexine HCl 1 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Zyrox Bro Powder (Reg. No. 105039) - Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Antibiotics/ mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack size.	
305	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL

		ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(2ET-UY7-B46W, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**TYFLON SOLUTION**
	Label Claim	Each 100ml contains: Norfloxacin .....10% Colistin sulphate:.....250MIU Tylosin Tartrate.....5%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	NORCOTYL SOLUTION M/S BIOGEN PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
306	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(1U5-E2H-GVQU, 2026-05-03)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**TYCOLIN 12/450 POWDER**
	Label Claim	Each 1000 gm contains: Tylosin Tartrate 100gm, Doxycycline HCl 200gm, Colistin Sulphate 450 MIU, Bromhexine HCl 4gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Doxyline Water Soluble Powder (Reg. No. 075776)
	Pharmacotherapeutic Group of (API)	Antibiotic/mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	

	upto 1Kg pack size.	
307	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)**
	Application Form Dy. No / Tracking ID & date of submission	(472-VXV-DPSV, 2025-05-21)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Utrezol Bolus**
	Label Claim	Each bolus contains: Sulphanilamide .....1.92gm Sulphathiazole.....320mg Urea.....13.44gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25 Bolus-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 30
	For generic drugs (me-too Status)	Urosulpha Bolus (Reg No. 058938) of Ms Star laboratories
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	based on the stated observation their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	Tablet Bolus (Vet) section approval submitted
	Evaluation Remarks	
	Decision	
	Approved	
308	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(UXG-ANE-JVYD, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**MYNOX 22/25 POWDER**
	Label Claim	Each gm contains: Neomycin Sulphate 200 mg, Oxytetracycline HCl 200 mg, Colistin Sulphate 0.55 MIU,
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acme Noc 20/20/0.55 Water Soluble powder (Reg. No. 117040) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	Decision	
	Approved upto 1Kg pack sizes.	
309	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(6S8-AT2-RG74, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ACE FOX 20/10 WATER SOLUBLE POWDER**
	Label Claim	Each 100gm contains: Calcium Fosfomycin.....20 gm Tylosin As Tartrate.....10 gm Fructose 1,6 Diphosphate.....18 gm Sodium Phosphate.....15 gm Magnesium Sulphate.....10 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmefos Fort Water Soluble Powder (Reg. No. 116954) - BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has submitted revised master formula along with fee Rs. 9400/-	
	Decision	
	Approved upto 1Kg pack sizes.	
310	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(AUM-YAR-LESL, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-17, 2026-05-11
	The proposed proprietary name / brand name	**ROFOCOL 10/50 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....10gm Colistin sulphate 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature

	For generic drugs (me-too Status)	(075760) ENCO TIN LIQUID of M/S. INSHAL PHARMACEUTICAL INDUSTRIES, RAWAT.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with the following me-too product Enco tin Liquid (075760) of Ms Inshal pharmaceutical Industries along with submission of fee Rs. 9400/-	
	Decision	
	Approved	
311	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(3BA-S22-E8NW, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**ROFCOL 10/52 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....10gm Colistin sulphate 52MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(103846) TENO FLOX 52 LIQUID of M/S. INSHAL PHARMACEUTICAL INDUSTRIES, RAWAT.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved	
312	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(791-41V-N7AN, 2026-04-24)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**FECOL 23 LIQUID**
	Label Claim	Each 100ml contains: Florfenicol 23gm

		Colistin sulphate.....50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Listoflor Liquid (Reg. No. 078238) of M/s Leads Pharma
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with reference product Listoflor Liquid (Reg. No. 078238) of Ms. Leads pharma along with submission of fee Rs. 9400/-	
	Decision	
	Approved	
313	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(ZE1-UAD-DNPT, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**EN ACETYL ORAL LIQUID**
	Label Claim	Each 1000ml contains: Enrofloxacin .....100gm N-Acetyl L-Cysteine.....186gm Benzyl Alcohol .....20mg Propylene glycol.....100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	PENPROL SOLUTION by M/S LEADS PHARMA ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibiotic, anti-inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with reference product Penprol solution (Reg. No. 063718) of M/s Leads Pharma along with submission of fee Rs. 9400/-	
	Decision	
	Approved	
314	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**

	Application Form Dy. No / Tracking ID & date of submission	(1BD-MNU-WL7E, 2026-05-04)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACE FLUSH WATER SOLUBLE POWDER**
	Label Claim	Each gm contains: Hexamethylene Tetramine USP 955 mg, Vitamin B2 (Sodium Phosphate) 10 mg, Calcium Pantothenate BP 5 mg, Nicotinamide BP 25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Reanl-10 water soluble powder (Reg. No. 130396) - Acme Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-infective, vitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with reference product Reanl-10 Water soluble powder (Reg. No. 063718) of M/s Acme Pharmaceuticals. The firm shall submit fee Rs. 9400/- for pre-approval revision of formulation.	
	Decision	
	Approved upto 1Kg pack sizes. The firm shall submit fee Rs. 9400/- for pre-approval revision of formulation in line with reference product.	
315	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Werrick Pharmaceuticals** Plot No. 216 - 217, I-10/3, Industrial Area Islambad **(000340)**
	Application Form Dy. No / Tracking ID & date of submission	(V56-8YD-6J5R, 2024-09-30)
	Detail of Fee Submitted	37000.0, 276500 2024-09-24, 2026-05-05
	The proposed proprietary name / brand name	**Werosin 0.4mg Capsules**
	Label Claim	Each capsule contains: Tamsulosin Hydrochloride (as Modified Release Pellets).....0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Tamsolin Capsules 0.4mg Getz Pharma, Karachi-Pakistan
	Pharmacotherapeutic Group of (API)	Alpha adrenoceptor antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	3 batches of 500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested invoice submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE and CDP data against Tamsolin 0.4mg Capsules of Ms Getz
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV-A conditions
	The status in reference regulatory authorities	Flomax® (tamsulosin hydrochloride) Capsules, 0.4 mg FDA
	GMP status of the firm	GMP certificate valid till 26-01-2029
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
316	Case Category	Routine (Najia Saleem)
	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	(3UL-Y8N-G7JN, 2024-08-29)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Rinvok 45mg Tablet**
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib 45mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., 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)	Form-3 submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Rinvoq 45mg tablets (Batch No: M269K9)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	AbbVie Ltd, AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, SL6 4UB, UK, EMA Approved
	GMP status of the firm	GMP certificate based on evaluation conducted on 14-12-2023
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance.	
	Decision	

	Not Applicable	
317	Case Category	Routine (Najia Saleem)
	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	(8HA-N8D-S5SR, 2024-10-22)
	Detail of Fee Submitted	75000.0, 2024-09-18,
	The proposed proprietary name / brand name	**Rinvok Oral Solution**
	Label Claim	Each ml contains: Upadacitinib Hemihydrate Eq. to Upadacitinib.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 100ml. 120ml/A-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C, protect from light and heat
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	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	RINVOQ LQ ORAL SOLUTION;AbbVie Inc., North Chicago, IL 60064, USA, FDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance.	
	Decision	
	Not Applicable	
318	Case Category	Routine (Najia Saleem)
	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	(AB6-5Y6-248N, 2024-08-27)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Rinvok 30mg Tablet**
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib.....30mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	NOt submitted, the commercial invoice already submitted does not state the name of manufacturer/
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP data submitted against Rinvoq 30mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted from Chiral quest (DMF holder)
	The status in reference regulatory authorities	RINVOQ 30 mg prolonged-release tablets; AbbVie Ltd, UK
	GMP status of the firm	GMP certificate based on inspection conducted on 14-12-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance.	
	Decision	
	Not Applicable	
319	Case Category	Routine (Najia Saleem)
	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	(WPW-B8A-363E, 2024-08-12)
	Detail of Fee Submitted	75000.0, 2024-07-11,
	The proposed proprietary name / brand name	**Rinvok 7.5mg Tablet**
	Label Claim	Each film coated prolonged release tablet contains: Upadacitinib Hemihydrate eq. to Upadacitinib..... 7.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C, protect from light and heat
	For generic drugs (me-too Status)	Unijak of Ms Kaizen Pharma
	Pharmacotherapeutic Group of (API)	JAK inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches of 1500 tablets each
	Documents for the procurement of API with approval from DRAP	Not submitted

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Rinvoq 7.5mg tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	RINVOQ 7.5 mg tablets, AbbVie Ltd, JAPAN, PMDA Approved
	GMP status of the firm	GMP certificate submitted based on evaluation conducted on 14-12-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	The firm has informed that they have Waters HPLC system with Empower 2 software. The system is currently not 21CFR compliance.	
	Decision	
	Not Applicable	
320	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(R1A-G5X-E4SS, 2026-04-26)
	Detail of Fee Submitted	38700, 2026-04-20,
	The proposed proprietary name / brand name	**ACEBRO 10 ORAL LIQUID**
	Label Claim	Each ml contains: Bromhexine HCl.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml,m 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Bromohawk 100ml Liquid (Poultry)
	Pharmacotherapeutic Group of (API)	Mucolytic/ expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
321	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	**Snam Pharma** 61-G, Phase 1, Commercial Area, DHA, Lahore **(05-352-0058-036985D)**
	Application Form Dy. No / Tracking ID & date of submission	(DRY-ADP-11YR, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-28,
	The proposed proprietary name / brand name	**Ersoul**
	Label Claim	Ersoul Compound Nystatin Ointment 10g/tube Composition: 10g: Nystatin 1 million units +

		Neomycin Sulfate 35000 units + Permethrin 100mg + Triamcinolone Acetonide 10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10g/tube-De-Controlled
	Shelf Life (Unit)	36 Month(s)Store at no more than 25°C
	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.-No. 6 Liujing Road, Dongli District, Tianjin, Postal Code: 300300-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co. Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of apostille certified FSC and GMP certificates submitted
	Details of Authorization Letter :	Scanned copy of Apostille certified LOA submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Firm shall submit original notarized LOA and legalized FSC and GMP certificates along with fee for pre-approval revision of FPP specifications.	
	Decision	
	Approved The firm shall submit the following before issuance of registration letter. i. original notarized LOA and legalized Free sale and GMP certificates ii. fee for pre-approval revision of FPP specifications.	
322	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(LV2-AZD-RN1M, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ROFCOL 25/50 ORAL LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....250mg Colistin sulphate 0.5MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ACMECOLIFLOX 25/50 ORAL LIQUID by M/S ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	

	The firm has submitted correct/revised master formula along with fee for pre-approval revision.	
	Decision	
	Approved	
323	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(G83-91P-3GNT, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-17, 2026-05-11
	The proposed proprietary name / brand name	**ROFCOL 20/20 ORAL LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....20% Colistin sulphate 0.2MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ACMECOLIFLOX 20/20 LIQUID by M/S ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	new DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has submitted correct/revised master formula along with fee for pre-approval revision.	
	Decision	
	Approved	
324	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(BQD-23G-2G2N, 2026-04-26)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ROFCOL 20/50 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....20gm Colistin sulphate 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml,100ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Floxicol Oral Liquid (Reg. No. 058966) Biogen pharma
	Pharmacotherapeutic Group of (API)	Antibacterial

	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with me-too Floxicol Oral Liquid (Reg. No. 058966) of Biogen pharma along with submission of fee.	
	Decision	
	Approved	
325	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(1V7-P53-P7ZW, 2026-04-10)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**Enro Hexine 1000 ORAL LIQUID**
	Label Claim	Each 100ml contains Enrofloxacin ..... 10g Guaifenesin..... 10g Aminophylline ..... 4g (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Guasinrold Oral Liquid (109057)
	Pharmacotherapeutic Group of (API)	Antibiotic, expectorant, bronchodilators
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has submitted correct/revised master formula along with fee RS. 9400/- vide challan No. 8183479883 for pre-approval variation.	
	Decision	
	Approved	
326	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(UBB-JXB-9DA7, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ACELIUM 20 WATER SOLUBLE POWDER**

	Label Claim	Each gm contains: Amprolium HCl 200 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmepro-20 Water soluble Powder (Reg. No. 118474) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack sizes.	
327	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(YY9-P8T-9PEN, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ACELIUM 90 WATER SOLUBLE POWDER**
	Label Claim	Each gm contains: Amprolium HCl.....900 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmepro-90 water Soluble powder (Reg. No. 117043) - ACME Pharmaceuticals
	Pharmacotherapeutic Group of (API)	coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack sizes.	
328	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(ZZG-GBU-N3RT, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11

	The proposed proprietary name / brand name	**ACELIUM 50 WATER SOLUBLE POWDER**
	Label Claim	Each gm contains: Amprolium HCl 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmepro-50 Water Soluble Powder (Reg. No. 117042) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack sizes.	
329	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(M5V-7MZ-TNV2, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11
	The proposed proprietary name / brand name	**ACELIUM 60 WATER SOLUBLE POWDER**
	Label Claim	Each gm contains: Amprolium HCl 600 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Acmepro-60 Water Soluble Powder (Reg. No. 118476) - ACME PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack sizes.	
330	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)**
	Application Form Dy. No / Tracking ID & date of submission	(PYZ-51X-L712, 2026-05-04)
	Detail of Fee Submitted	38700, 9400 2026-04-20, 2026-05-11

	The proposed proprietary name / brand name	**ACELIUM 70 WATER SOLUBLE POWDER**
	Label Claim	Each 1000 gm contains: Amprolium HCl 700 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	(122375) PROMOZON 70% WATER SOLUBLE POWDER of M/S. AMAZON PHARMACEUTICAL (PVT.) LTD, AJK.
	Pharmacotherapeutic Group of (API)	Coccidiostat
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Decision	
	Approved upto 1Kg pack sizes.	
331	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	**AMSEZA PHARMA** Plot # 12, 01km Bangreel Road, T-Chowk, Rawat, Islamabad **(042684)**
	Application Form Dy. No / Tracking ID & date of submission	(35P-ABX-X3N2, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	**AMLINCO 40 Oral powder**
	Label Claim	Each 1000 gm powder contains: Lincomycin as HCl.....400gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10gm, 15 gm, 20 gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	LINCOSEL-40 ORAL POWDER (Reg No. 089826) SELMORE Pharmaceuticals Pvt.Ltd Lahore
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New Licence
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has revised formulation in line with reference product Lincosel-40 oral powder along with submission of fee Rs. 38700/- vide challan No. 53406967830The firm has also demanded following pack sizes in addition to the above-mentioned packs.30gm, 50gm, 100gm, 150gm 250gm, 500gm, 1000gm, 2500gm 5000gm, 10,000gm, 20,000gm, 25,000gm	
	Decision	
	Approved upto 1Kg pack sizes.	
332	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad

		Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(26U-V98-RTTM, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO FOS FORTE ORAL POWDER**
	Label Claim	Each100 gm powder contains: Fosfomycin Calcium.....20 gm Tylosin As Tartrate....10 gm Fructose 1,6 Diphosphate.....18 gm Sodium Phosphate.....15 gm Magnesium phosphate.....10 gm (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Fosy-tyl-200 Oral Powder (133484) BERACIN WATER SOLUBLE POWDER Reg# 103956 by M/S. D-HAANS PHARMACEUTICALS, PLOT NO. 9/A, INDUSTRIAL ESTATE, BHIMBER, AZAD KASHMIR.
	Pharmacotherapeutic Group of (API)	Antibactetrial,Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
333	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(3DN-ZGE-XWMN, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**RESPI XEL 40 ORAL POWDER**
	Label Claim	Each Gram Conatins: Doxycycline HCl.....400 mg Tylosin as Tartrate.....200 mg Colistin Sulphate.....0.5 MIU Bromhexine HCl.....10 mg (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	CRD Arch 40 Oral Powder (121993)

	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
334	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(3W9-XWN-YSA1, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA FUR 200 ORAL POWDER**
	Label Claim	Each100 gram contains, Furosemide (as monoethanolamine salt).....2 gm Sodium chloride.....3.5 gm Magnesium Sulphate.....3.5 gm Manganese Sulphate.....0.11 gm Calcium Carbonate.....4.5 gm Potassium chloride.....0.4 gm (As per innovators specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	GIPSOMIDE 20 W/S POWDER (109142)
	Pharmacotherapeutic Group of (API)	Diuretic,Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

335	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(82H-1S6-DHH7, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA FUR 250 ORAL POWDER**
	Label Claim	Each100 gram contains, Furosemide (as monoethanolamine salte).....2.5 gm Sodium chloride.....3.5 gm Magnesium Sulphate.....3.5 gm Manganese Sulphate.....0.1 gm Calcium Carbonate.....4.5 gm Potassium chloride.....0.4 gm (As per innovators specification).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	GIPSOMIDE 20 W/S POWDER (109142)
	Pharmacotherapeutic Group of (API)	Diuretic,Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
336	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(L49-4PJ-Y69A, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**RESPI XEL 20 ORAL POWDER**
	Label Claim	Each Gram Conatins: Doxycycline HCl.....200 mg Tylosin as Tartrate.....100 mg Colistin Sulphate.....0.5 MIU Bromhexine HCl.....5 mg (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE

	For generic drugs (me-too Status)	CRD Arch 20 Oral Powder (121994)
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
337	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(AMS-QP4-WG2A, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XE-LINC 4.4% ORAL POWDER**
	Label Claim	Each gram contains, Lincomycin as HCl.....44 mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Arch Linco 44 Powder (122003)
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
338	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**

	Application Form Dy. No / Tracking ID & date of submission	(G3E-HJG-8PWR, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XE-LINC 11 ORAL POWDER**
	Label Claim	Each gram contains, Lincomycin as HCl.....11 mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Arch Linco 11 Powder (122002)
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
339	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(NA8-UR9-P44A, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO COLLINE SUPER ORAL**
	Label Claim	Each gm contains: Oxytetracycline HCl.....300 mg Neomycin Sulphate....150 mg Florfenicol.....100 mg (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Mycoline Forte Oral Powder (120882)
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
340	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(SMR-L81-TYQP, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA PARA C ORAL POWDER**
	Label Claim	Each 100 gms contains: Paracetamol.... .....20 gm Vitamin C.....5 gm Potassium carbonate....12.5 gms Sodium bicarbonate.....12.5 gm Vitamin E..... 12.5 gm (As per Innovator,s specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	PARASCORBIC POWDER (087140)
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
341	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(WDT-Q31-5Q3U, 2026-02-20)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO FOS ORAL POWDER**
	Label Claim	Each100 gm powder contains: Fosfomycin Calcium.....20 gm Tylosin As Tartrate....5 gm Fructose 1,6 Diphosphate.....18 gm Sodium

		Phosphate.....15 gm Magnesium phosphate.....10 gm (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Fosy-tyl-100 Oral Powder (133485)
	Pharmacotherapeutic Group of (API)	Antibactetrial,Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
342	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(D78-2JJ-9DH9, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA COL 55 ORAL POWDER**
	Label Claim	Each kg contains: Colistin Sulphate.....550M IU (As per innovator’s specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	Arcol 55% Oral Powder (120886)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

343	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(H1S-2L5-EA6N, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA COL 60% ORAL POWDER**
	Label Claim	Each gm contains: Colistin Sulphate.....6,000,000 IU (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Arcol 60% Oral Powder (120885)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
344	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(S4N-68B-8B94, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA COL 48% ORAL POWDER**
	Label Claim	Each gm contains: Colistin Sulphate.....48,00,000 IU (As per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Arcol 48% Oral Powder (120884)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and

		equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
345	Case Category	New License (Sabahat Zehra)
	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	(D8X-VBS-X12T, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	**Niloxyclo plus Suspension**
	Label Claim	Each 100ml contains Oxyclozanide 3gm Levamisole HCl 1.5gm Cobalt sulphate 0.050gm Vitamin E 50mg (Manufacturer‘s Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 litre-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,250 ml-De-Controlled,500 ml-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)	Revozan CE Oral Suspension Registration no.133346 Registration Date: 30-12-2025 Company Name; Biorise Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
346	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	(P7A-ANT-S8L7, 2025-04-05)
	Detail of Fee Submitted	37000.0, 9400 2025-03-26, 2026-04-22
	The proposed proprietary name / brand name	**AXOCARB INJECTION**
	Label Claim	Each ml contains: Imidocarb Dipropionate .....120mg (Manufacturer’s Specification)

	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)	Imipro Injection (Reg. # 029610) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiprotozoal Agent
	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	
347	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	(SYU-ADL-UL32, 2025-04-05)
	Detail of Fee Submitted	37000.0, 9400 2025-03-26, 2026-04-22
	The proposed proprietary name / brand name	**AXOCARB INJECTION**
	Label Claim	Each ml contains: Imidocarb dipropionate 120mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ML-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)	Imipro Injection (Reg. # 029610) Selmore Pharma Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiprotozoal Agent
	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	
348	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**VETEC LABORATORIES** Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi **(000893)**
	Application Form Dy. No / Tracking ID & date of submission	(HJ6-GPJ-1YWW, 2025-03-20)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	**SECOUR TEC**
	Label Claim	Each ml contains: Sulphadiazine.....35.50mg Sulphadimidine.....28.40mg Neomycin sulphate.....1.80mg Hyoscine N butylbromide.....0.04mg Pectin.....7.10mg Kaolin.....103.30mg Vitamin B1.....0.15MG Vitamin B2.....0.22MG
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Scour-X oral suspension
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
349	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Mian Traders** Railways Road, Morre Eminabad **(09-341-0135-118497D)**
	Application Form Dy. No / Tracking ID & date of submission	(VL1-H5W-BH99, 2025-10-25)
	Detail of Fee Submitted	313500, 2025-10-22,
	The proposed proprietary name / brand name	**AMOXY 15%**
	Label Claim	Each !ml contains Amoxicillin trihydrate 150 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Pack 1 clear glass bottle of 100 ml.-De-Controlled
	Shelf Life (Unit)	-36 Year(s)Store in shade and dry place, temperature below 30oC.

	For generic drugs (me-too Status)	Novamox LA Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043135)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Asia Animal Pharmaceutical Co., Ltd-Address: 130, 1A National Road, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam. Phone: (+84) (0292) 3913347. Fax: (+84) (0292) 3913349-Vietnam
	Name, address of Marketing Authorization Holder:	MIAN TRADERS , RAILWAY ROAD,MORE EMINABAD, GUJRANWALA , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	
	Approved	
350	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(QAG-MRV-U14W, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE PREMIX ORAL POWDER**
	Label Claim	Each Kg powder contains: Procaine Penicillin ..... 12g Streptomycin Sulphate ..... 36g Zinc Bacitracin ..... 52g (As per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	PSB-100 W/S POWDER (013257)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
351	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(AVV-G12-4BBL, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKER MOX 600 W/S Powder**
	Label Claim	Each Gm Contain: Amoxicillin (As Trihydrate).....600mg (B.P Specification
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Moxter-60% w/s Powder (111480)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
352	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(B9U-DVG-Z4YQ, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKER MOX 700 W/S Powder**
	Label Claim	Each Gm Contain: Amoxicillin (As Trihydrate).....700mg (B.P Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Moxter-70% w/s Powder (111481)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
353	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(HN5-UNQ-JXS5, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**SPEC MOX L ORAL POWDER**
	Label Claim	Each 100Gm powder contains Lincomycin as HCL.....8.8Gm Spectinomycin Sulphate.....8.8Gm Amoxicillin as Trihydrate.....20Gm (As Per Innovator’s Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	TRI CIN 8.8 POWDER (122657)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	

	Approved	
354	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(U3N-TYP-MQXR, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**SPEC MOX 200 ORAL POWDER**
	Label Claim	Each 100Gm powder contains Spectinomycin Sulphate.....5Gm Lincomycin as HCl.....5Gm Amoxicillin as Trihydrate.....10Gm (As Per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	TRI CIN 5 POWDER (122656)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
355	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(WWJ-TBP-NAHU, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**PHENUMO GUARD ORAL POWDER**
	Label Claim	Each 1000g powder contains Amoxicillin Trihydrate ..... 100g Lincomycin HCl ..... 50g Colistin Sulphate

		..... 500MIU Bromhexine HCl ..... 5g (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	COLAB W/S POWDER (079839)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
356	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(XVH-DXV-GUT6, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**AMOXIN LSE ORAL POWDER**
	Label Claim	Each Gm powder contains: Amoxycillin As Trihydrate .....200mg Lincomycin HCL..... .....88mg Spectinomycin Sulphate .....88mg Vitamin E Acetate .....30mg (As Per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	LINTINO MOX 2000 W/S POWDER (109171)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	

	Decision	
	Approved	
357	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(Z33-WWX-ALU4, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**SPEC MOX FORT ORAL POWDER**
	Label Claim	Each 100Gm powder contains: Amoxicillin As Trihydrate.....20Gm Lincomycin HCL.....0.88Gm Spectinomycin 2 HCL.....0.88Gm (As Per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Harry Speclin 2/0.88/0.88 W/S POWDER (109166)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
358	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(ZN9-VQN-A8X2, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**SPEC MOX 400 ORAL POWDER**

	Label Claim	Each 100Gm powder contains Spectinomycin 2HCl.....8.8Gm Lincomycin HCl.....9Gm Amoxicillin as Trihydrate.....20Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	HARRY- SPECLIN 20/9/8.8 W/S POWDER (109165)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
359	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(DLN-VVW-4SNM, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**MOX CO 20% W/S POWDER**
	Label Claim	Each 100gm powder contains Amoxicillin as Trihydrate .....20 gm Colistin Sulphate .....80 MIU (As Per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mox-Colistin 80% W/S Powder (109161)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for

		manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
360	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(99W-G9P-4PYG, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**MOX CO 50% W/S POWDER**
	Label Claim	Each 100Gm powder contains Amoxicillin as Trihydrate .....50Gm Colistin Sulphate .....50MIU (As Per Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mox-Colistin 50% W/S Powder (109160)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
361	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(N7J-RJB-RYSJ, 2026-04-18)

	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**MOX CO W/S POWDER**
	Label Claim	Each 100Gm powder contains: Amoxicillin as Trihydrate .....15% Colistin Sulphate .....55MIU (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mox-Colistin 15/55 W/S Powder (109158)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
362	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(Z12-QHL-H7A6, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**MOX CO 15% W/S POWDER**
	Label Claim	Each 100 Gm powder contains Amoxicillin as Trihydrate .....15Gm Colistin Sulphate .....50MIU (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mox-Colistin 15/50 W/S Powder (109154)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for

		manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Preent
	Evaluation Remarks	
	Decision	
	Approved	
363	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(4YN-1SW-TLNE, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKER MOX 50% W/S Powder**
	Label Claim	Each 100g powder contains Amoxicillin As Trihydrate .....50gm (B.P Spec.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	AMOXYCYCLINE 50% W/S POWDER (109145)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
364	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(B5U-6Q5-3WRS, 2026-04-17)

	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE CRD 10/20 Oral Powder**
	Label Claim	Each Gm powder contains Doxycycline HCl ..... 200mg Tylosin as tartrate .....100mg Colistin sulphate ..... 0.50MIU Bromhexine HCl ..... 5mg (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	CRD Arch 20 Oral Powder (121994)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
365	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(MGA-ZLN-AU79, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE CRD 40/20 Oral Powder**
	Label Claim	Each Gm powder contains (As Per Innovators Spec.) Doxycycline HCl ..... 400mg Tylosin as tartrate .....200mg Colistin sulphate ..... 0.50MIU Bromhexine HCl ..... 10mg (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	CRD Arch 40 Oral Powder (121993)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
366	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(RJV-MAE-GP18, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAK CRD 500 Oral Powder**
	Label Claim	Each 100Gm powder contains: Doxycycline HCl ..... 20gm Tylosin tartrate ..... 10gm Colistin sulphate .....5MIU Bromhexine HCl ....0.2gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Strick CRD 50 W/S Powder (109129)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
367	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL

		INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(ZH4-GA2-X7S5, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAK CRD 71 Oral powder**
	Label Claim	Each 100Gm powder contains: Doxycycline HCl ..... 40gm Tylosin tartrate ..... 20gm Colistin sulphate .....100MIU Bromhexine HCl ....1gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Strick CRD 71 Oral Powder (109126)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved The Board referred the case of Colistin containing products for Sub-Committee on Veterinary Drugs for their opinion on use of Colistin in the Veterinary formulations.	
368	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(BGQ-TE8-7T1U, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Reno 2.5% Oral Powder**
	Label Claim	Each 100gm contains: Furosemide..... 2.5gm Sodium Chloride.....3.5gm Magnesium Sulphate.....3.5gm Manganese Sulphate.....0.1gm Calcium Carbonate.....4.5gm Potasium Chloride.....0.4gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled

	Shelf Life (Unit)	2 YearStore at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Gipsomide 25 Powder (109143)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
369	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(YVT-6NT-R9JR, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKER MOX 800 W/S Powder**
	Label Claim	Each 100Gm Contain: Amoxicillin As Trihydrate .....80Gm (As Per Innovator Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Amoxycycline 80% w/s Powder (109148)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

370	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(QSM-6AE-XHAU, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Mycine 500 Oral Powder**
	Label Claim	Each 100gm powder contain Oxytetracycline HCl.....20g. Colistin sulphate .....24MIU Neomycin Sulphate .....20g. (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Stiagulstin 24 w/s Powder (109134)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
371	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(PBJ-T2S-L2VQ, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**AUGMETO CURE ORAL POWDER**
	Label Claim	Each 100 gm contains:- Amoxicillin Trihydrate 20g eq.to Amoxicillin.....17.392 gm Colistin Sulphate.....4 gm Clavulanic acid as Potassium Clavulanate...4 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Callin 24 Powder (122267)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
372	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(P6A-DXZ-E1JT, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**DECO MOX 20% W/S ORAL POWDER**
	Label Claim	Each 1000Gm powder contains Amoxicillin as Trihydrate .....200gm Colistin Sulphate .....800MIU Dextrose Anhydrous QS.....1000Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Risto-Mox 20% Powder (122283)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	

	Approved	
373	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(LBT-NU2-JVWW, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**NEW MOX C ORAL POWDER**
	Label Claim	Each 100 Gm powder contains: Amoxicillin As Trihydrate .....10Gm Colistin Sulphate.....5Gm Neomycin Sulphate.....20Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mox Neo-C 350 W/S POWDER (109172)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
374	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(6GY-AP8-T79M, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**AUG BRO ORAL POWDER**
	Label Claim	Each 100Gm powder contains Amoxicillin As Trihydrate .....16Gm Clavulanic Acid as

		Potassium Clavulanate.....4Gm Bromhexine HCl.....0.5Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	MENTIN-MOX C W/S POWDER (109173)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
375	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(3UZ-MS5-G1J5, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Mycine 1000 Oral Powder**
	Label Claim	Each 100gm powder contains: Oxytetracycline HCl .....20gm Colistin sulphate .....55MIU Neomycin Sulphate .....20gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Stiagulstin 55 W/S Powder (109137)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present

	Evaluation Remarks	
	Decision	
	Approved	
376	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(4WP-96L-MA2Z, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Mycine 2000 Oral Powder**
	Label Claim	Each 100gm powder contains: Oxytetracycline HCl .....25gm Colistin sulphate .....30MIU Neomycin Sulphate .....25gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Stiagulstin 30 w/s Powder (109135)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
377	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(4SQ-ATN-DY51, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**DECO MOX 15% W/S ORAL POWDER**

	Label Claim	Each 1000Gm powder contains: Amoxicillin as Trihydrate .....150gm Colistin Sulphate .....500MIU Dextrose Anhydrous QS.....1000Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Risto-Mox 15% Powder (122282)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
378	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(39M-81Q-6GSU, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**DECO MOX 23% W/S ORAL POWDER**
	Label Claim	Each 1000Gm powder contains Amoxicillin as Trihydrate .....230gm Colistin Sulphate .....1000MIU Dextrose Anhydrous QS .....1000Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Risto-Mox 23% Powder (122284)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al

	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
379	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(GJD-47M-B8R8, 2026-04-18)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**DECO MOX 50% W/S ORAL POWDER**
	Label Claim	Each 100Gm powder contains Amoxicillin as Trihydrate .....50gm Colistin Sulphate .....50MIU Dextrose Anhydrous BP QS .....100Gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Risto-Mox 50% Powder (122285)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
380	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(YRD-8BS-J1RM, 2026-02-21)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XE-LINC 44 ORAL POWDER**

	Label Claim	Each 100 gram contains, Lincomycin HCl.....44 GM (As per innovator's specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)ROOM TEMPERATURE
	For generic drugs (me-too Status)	Licogrow-44 Oral Powder (080157)
	Pharmacotherapeutic Group of (API)	Antibactetrial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
381	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(DYQ-R6U-B138, 2026-02-23)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XYLO-QUINE-10 ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....10gm (As per innovator's specifications).
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ml, 150ml, 250ml, 500ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	Arch Roxin 10 Liquid (122009)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

382	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**FORZA ROMA PHARMACEUTICAL PVT LTD** PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD **(001020)**
	Application Form Dy. No / Tracking ID & date of submission	(EW2-5YR-PY6Z, 2026-03-23)
	Detail of Fee Submitted	38700, 2026-03-16,
	The proposed proprietary name / brand name	**TRISUL- F.R.**
	Label Claim	Each ml contains.....Trimethoprim 80 mg, Sulphadiazine 400 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 litre HDPE Bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Belo 30 degree
	For generic drugs (me-too Status)	Hilton Pharma Pvt Ltd Korangi Industrial Area
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
383	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Vetline International** 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore **(05-352-0066-040712D)**
	Application Form Dy. No / Tracking ID & date of submission	(JJJ-TQV-T491, 2025-08-20)
	Detail of Fee Submitted	313500.0, 2025-08-18,
	The proposed proprietary name / brand name	**ZOMO-AmpVan 2g**
	Label Claim	Composition: Ampicillin Sodium. Each bottle contains 2.0gm of Ampicillin (as Sodium)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x20-De-Controlled
	Shelf Life (Unit)	2 Year(s)Preserve in well-closed container, keep in a dry place at room temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Chengdu Zhongmu Biological Pharmaceutical Co., ltd-No. 699, The 3rd Chenglong Avenue, Economic Development District, Chengdu, No. 12 Xingguang Middle Road, Longquanyi District, Chengdu, Sichuan-China
	Name, address of Marketing Authorization Holder:	Chengdu Zhongmu Biological Pharmaceutical Co., ltd, No. 699, The 3rd Chenglong Avenue, Economic Development District, Chengdu, No.

		12 Xingguang Middle Road, Longquanyi District, Chengdu, Sichuan, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	
	Approved	
384	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Mian Traders** Railways Road, Morre Eminabad **(09-341-0135-118497D)**
	Application Form Dy. No / Tracking ID & date of submission	(BHW-GP7-63S8, 2025-08-26)
	Detail of Fee Submitted	300000.0, 13500 2025-01-28, 2026-04-29
	The proposed proprietary name / brand name	**SEPTRYL 120**
	Label Claim	Sulfamethoxazole 100 mg Trimethoprim 20 mg Excipient q.s 1 ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	36 Year(s)temperature below 30oC
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	ASIA ANIMAL, PHARMACEUTICAL CO., LTD -130, 1A NATIONAL ROAD, BALANG WARD, CAIRANG DISTRICT CANTHO CITY, VIETNAM-Vietnam
	Name, address of Marketing Authorization Holder:	MIAN TRADERS , RAILWAY ROAD, MORE EMINABAD, GUJRANWALA, PAKISTAN, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	
	Approved	
385	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(YMD-DAT-HS3B, 2026-02-19)

	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEALTH TIL 25% LIQUID**
	Label Claim	Each 100 ml Contains:- Tilmicosin as phosphate.....25 gm (as per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	14. Arch Til Liquid (122007)
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
386	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(3HX-2ZW-RSXR, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XE FLOX C 60 ORAL LIQUID**
	Label Claim	EACH 100ML CONTAINS: NORFLOXACIN .....20G COLISTIN SULPHATE...60MIU (as per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	NOR-C MAARSON LIQUID (071056)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present

	Evaluation Remarks	
	Decision	
	Approved	
387	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(DGY-QSY-57ZT, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XEA NORCIN ORAL LIQUID**
	Label Claim	Each 100 ml contains:- NORFLOXACIN .....20 gm Aminophyline .....8 gm Guaifenesin.....20 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	NOR+ AG SOLUTION (058968)
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
388	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(ZDS-M2N-J4GW, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**NOVA FEN 230 ORAL LIQUID**
	Label Claim	Each 1000 ml contains:- Florfenicol.....23 gm Colistin Sulphate.....50MIU (as per innovators specification)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	MAXIFLOR-PLUS LIQUID (075617)
	Pharmacotherapeutic Group of (API)	Amphenicol Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
389	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	**M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)**
	Application Form Dy. No / Tracking ID & date of submission	(NMR-XXQ-LXM4, 2026-02-19)
	Detail of Fee Submitted	38700, 2026-02-18,
	The proposed proprietary name / brand name	**XE FLOX C 50 ORAL LIQUID**
	Label Claim	EACH 100ML CONTAINS: NORFLOXACIN .....20G COLISTIN SULPHATE...50MIU (as per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	COLINOR ORAL LIQUID (071066)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

390	Case Category	New License (Sabahat Zehra)
	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	(Y45-BGJ-4D5G, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	**DIALYSIS W/S POWDER**
	Label Claim	Each 1000gm contains Furosemide 20gm Calcium carbonate 40gm Sodium chloride 35gm Magnesium sulphate 35gm (Manufacturer‘s Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	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)	Mag Flush Powder Registration no:103861 Registration Date:22-06-2020 Company Name:Inshal Pharmaceutical Industries.
	Pharmacotherapeutic Group of (API)	Diuretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
391	Case Category	New License (Sabahat Zehra)
	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	(EX3-WP4-ZDZY, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	**Coccibak powder**
	Label Claim	Each gm contains Amprolium HCl 166mg Sulfaquinoxaline 166mg Colistin sulphate 500,000IU Vitamin A 5,000IU Vitamin K3 05mg (Manufacturer‘s Specification)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 kg-De-Controlled,10 kg-De-Controlled,100 gm-De-Controlled,250 gm-De-Controlled,250 kg-De-Controlled,50 kg-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore at controlled room temperature.protect from heat,light and ,moisture

	For generic drugs (me-too Status)	Cocciplex forte w/s powder (Globel veterinary service)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
392	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Technovet Marketing** House No. 4, Street No. 1, Opposite bus stand Pull Wasil Road, Suraj Miani Multan **(04-361-0159-84737D)**
	Application Form Dy. No / Tracking ID & date of submission	(LQD-HTW-D3GU, 2025-08-04)
	Detail of Fee Submitted	300000.0, 2025-07-30,
	The proposed proprietary name / brand name	**VB-TICOSTIN**
	Label Claim	Each Ltrs contains : Tilmicosin Phosphate --------- 250g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 LTR -De-Controlled
	Shelf Life (Unit)	3 Year(s)store at temperature not exceeding 30C
	For generic drugs (me-too Status)	APOTIL ORAL SOLUTION BY SELMORE AGENCIES
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Name, address of Manufacturing site:	VIBO Co., LTD,-Lot No. 20 - Block G - Dl street - An Ha lndustrial zone, Pham Van Hai ward - Binh Chanh district - Ho Chi Minh city-Vietnam
	Name, address of Marketing Authorization Holder:	VIBO Co., LTD,, Lot No. 20 - Block G - Dl street - An Ha lndustrial zone, Pham Van Hai ward - Binh Chanh district - Ho Chi Minh city, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	
	Approved	
393	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	(1X6-5XM-5D5D, 2025-07-17)

	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Flush Nix Oral Powder**
	Label Claim	Each Kg contains: Furosemide 20gm Sodium Chloride 35gm Magnesium Sulphate 35gm Manganese Sulphate 1gm Calcium Carbonate 45gm Potassium Chloride 400mg
	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)	Neyphralyte Powder, Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071072)
	Pharmacotherapeutic Group of (API)	Diuretic
	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	
	Decision	
	Approved	
394	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	(9GQ-UHM-UB23, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Verme Plus Injection**
	Label Claim	Each ml contains: Ivermectin 10mg Clorsulon 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25°c - 30°c)
	For generic drugs (me-too Status)	Iverlon Injection (Reg. No: 088129, Mylab pvt ltd)
	Pharmacotherapeutic Group of (API)	antiparasitic agents
	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	
	Decision	
	Approved	
395	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	(BL7-ZGR-UX2B, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Verme Plus Injection**
	Label Claim	Each ml contains: Ivermectin 10mg Clorsulon 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (25°c - 30°c)
	For generic drugs (me-too Status)	Iverlon Injection (Reg. No: 088129, Mylab pvt ltd)
	Pharmacotherapeutic Group of (API)	antiparasitic agents
	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	
	Decision	
	Approved	
396	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	(P3M-6N1-JT5T, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**NICOX POWDER**
	Label Claim	Each kg contains: Sulfaquinoxaline 100gm Diaveridine 25gm Vit. A 1.25MIU Vit. K3 2.5gm
	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)	Diacox-S Oral Powder (Reg. No: 122049)
	Pharmacotherapeutic Group of (API)	Anticoccidials / Antiprotozoals Vitamin supplements
	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	
	Decision	
	Approved	
397	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	(MDM-5TL-3UGG, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	**Wormix Drench**
	Label Claim	Each 100ml contains: Albendazole 12.5gm Sodium Selenite 0.035gm Cobalt Sulphate 0.382gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Litre-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,250ml-De-Controlled,30ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)tore at room temperature (25°c - 30°c)
	For generic drugs (me-too Status)	ALBAZAK DS SUSPENSION (Reg. No: 046523, ZAKFAS PHARMACEUTICALS)
	Pharmacotherapeutic Group of (API)	Anthelmintic+ mineral supplement
	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	
	Decision	
	Approved	

398	Case Category	Routine (Sabahat Zehra)
	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	(GV6-2RZ-VJZQ, 2024-10-28)
	Detail of Fee Submitted	37000.0, 2024-10-14,
	The proposed proprietary name / brand name	**K-FLOX 400MG TABLET**
	Label Claim	Each film coated tablet contains: Moxifloxacin HCl eq. to Moxifloxacin.....400 mg. (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's, 10'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)	MOKSI 400mg Tablet (Abbott Laboratories (Pakistan) Limited) Reg. 067550
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	TRC-034, TRC-035, TRC-036
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Avelox 400mg Batch # ITA6258 by Bayers
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	LE-00510711/001/2018, LE-00510711/002/2018, LE-00510711/003/2018
	The status in reference regulatory authorities	Avelox 400mg film coated tablets, MHRA approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
399	Case Category	Routine (Sabahat Zehra)
	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	(151-9SS-JGXM, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	**Artepro 80mg + 480mg**
	Label Claim	Each tablet containsArtemether .....80mgLumefantrine.....

		Int. Specs
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	4s and 6s and 8s an-As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Artem DS 80mg/480mg Tablet
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VITAL LABORATORIES PVT LTD
	Detail of stability batches of drug product	T-302, T-307, T-303
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1931571416289
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Artem DS 80mg/480mg Tablet Batch # 147548
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Aetemether: ATMS 119003, ATMS 119004, ATMS 119005 Lumefantrine: LUM 114001, LUM 114002, LUM 114003
	The status in reference regulatory authorities	World Health Organization WHO
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
400	Case Category	Routine (Sabahat Zehra)
	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	(G8U-9RE-WNTB, 2024-10-21)
	Detail of Fee Submitted	37000.0, 2024-10-01,
	The proposed proprietary name / brand name	**Artepro 40mg + 240mg**
	Label Claim	Each tablet containsArtemether ... 40mgLumefantrine ... 240mgPh Int Specs
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	8s and 10s and 12s a-As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package.
	For generic drugs (me-too Status)	Qmetem DS 40mg/240mg Tablet
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	VITAL LABORATORIES PVT LTD
	Detail of stability batches of drug product	T-280, T-284, T-285
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-1931571416289

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Coartem 40/240mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	ATMS 119003, ATMS 119004, ATMS 119005
	The status in reference regulatory authorities	World Health Organization WHO
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
401	Case Category	Routine (Saima Hussain)
	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	(1H1-W9Y-H8RX, 2024-10-10)
	Detail of Fee Submitted	37000.0, 9400 2024-09-19, 2026-05-06
	The proposed proprietary name / brand name	**Defrox Tablet for Oral suspension**
	Label Claim	Each tablet contains: Deferasirox.....250mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 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)	Xefra Tablet 250mg by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Iron Chelation (ATC code: V03AC03)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Golden Drugs Private Limited (subsidiary of Bal Pharma Pvt Ltd.), C-155, Mewar Industrial Area Madri, Udaipur-313003, Rajasthan
	Detail of stability batches of drug product	Firm submitted stability data of three batches 1500 tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted Form-6.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has performed against the innovator brand EXJADE (deferasirox) tablets
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted stability data of drug substance as per zone-IV
	The status in reference regulatory authorities	EXJADE Tablet 250mg by Novartis Pharma Stein AG Stein, Switzerland
	GMP status of the firm	GMP Certificate dated 13th June,2023 is submitted
	Evidence of approval of manufacturing facility	Firm submitted tablet section approval letter dated 20th September,2021
	Evaluation Remarks	
	Decision	

	Approved	
402	Case Category	Contract Manufacturing (Saima Hussain)
	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	(Y17-Q6Y-URU2, 2024-06-21)
	Detail of Fee Submitted	75000.0, 2024-06-05,
	The proposed proprietary name / brand name	**Proxen**
	Label Claim	Composition: Each 5ml contains: Naproxen .....250mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml & 120ml-As per SRO
	Shelf Life (Unit)	24 Year(s)stored below 30°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	Martin Dow Marker Limited -7- Jail Road, Quetta, Pakistan-
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	Stability data of batches PDS-226-24, PDS-227-24, PDS-228-24 of batch size 5l 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 has performed against the reference product Naproxen Oral Suspension 250mg/5ml Manufactured By: Amneal Pharmaceuticals LLC
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone -IV is submitted by the firm.
	The status in reference regulatory authorities	Naproxen 50 mg/ml oral suspension by INFECTOPHARM (MHRA)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	GMP certificate of M/s. Martin Dow Marker dated 18th March 2024 mentioned that firm has oral liquid syrup section.

Evaluation Remarks

S. No	Query	Firm's Response
1.	Submit the Certificate of Analysis (CoA) / analytical reports for the excipients glycerin and sorbitol, including the results of impurity testing for ethylene glycol (EG) and diethylene glycol (DEG).	Firm submit the batch analysis report of both Tibet glycerine and sorbitol excipient performed by drug product which include test results of EG and DEG. Further, firm procured Tibet glycerine from Kohinor Soap& Detergents while the sorbitol has purchased from Habib rice products Ltd.
2.	As the formulation contains a preservative, preservative effectiveness testing (antimicrobial effectiveness testing) shall be performed in accordance with the relevant pharmacopeial recommendations,	The formulation of Naproxen Oral Suspension contains preservatives i.e., Methyl Paraben & Propyl Paraben, hence in accordance with the relevant pharmacopeial recommendations, we hereby undertake / commit to perform

		and the complete study report should be submitted.	Preservative Effectiveness Testing (PET) in the development batches and a complete study report including methodology, acceptance criteria, results and conclusions will be submitted to the esteemed authority for review & record. Signed undertaking / commitment is submitted.
	3.	The relative retention times (RRTs) for ethyl paraben and naproxen have not been reported in the system suitability results during assay method verification studies and during assay testing performed as part of stability studies. Provide the RRT values in accordance with USP recommendations, along with the revised system suitability data.	The revised system suitability data including RRTs for Ethyl Paraben and Naproxen has been documented in Method verification studies as well as Assay testing performed as part of stability studies. Assay results from prior stability testing remain valid; method performance continues to meet USP criteria.
	4.	Submit the updated stability data of the drug product, as only three months of stability data have been provided.	Stability Data of 6th month has been submitted.
	5.	Provide evidence confirming the availability of the reference product in a 120 mL pack size, including appropriate supporting material (e.g., labeling, SmPC, product photographs, or regulatory approval evidence)	The SRA Reference of the applied product in the same molecule, strength, dosage form, container closure system, indication and route of administration as required in the section 1.5.9 of CTD guidance document is attached for your reference. However, being a product of non-essential category, please note that the pack size of 120ml is required to meet the commercial demand in the local market. However, the reference product approved in MHRA is available in Pack sizes: 100 ml and 200 ml.
	Registration Board in its 353rd meeting deferred the application for submission of Certificates of Analysis (COAs) from the suppliers of excipient glycerin and sorbitol, including results of impurity testing for ethylene glycol (EG) and diethylene glycol (DEG). Firm submitted the COA from the suppliers of excipient glycerin and sorbitol, including results of impurity testing for ethylene glycol (EG) and diethylene glycol (DEG).		
	Decision		
	Approved		

403	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**FRONTIER DEXTROSE LIMITED** PLOT NO. 18/3 PHASE-1 INDUSTRIAL ESTATE HATTAR **(000633)**
	Application Form Dy. No / Tracking ID & date of submission	(XDA-JAN-3PZR, 2024-06-05)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	**Sterifluid NS ½ Infusion 1000ml**
	Label Claim	Each 100ml contains: Sodium chloride.....0.45gm Water for Injection.....Q.S.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree C
	For generic drugs (me-too Status)	Medisol ½ NS (Reg# 083359)

	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 - https://www.accessdata.fda.gov/scripts/cder/daf/in event=overview.process&ApplNo=018090
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

The firm has submitted same stability data for the 100 mL and 1000 mL volume size as that provided for the 500 mL, despite the fact that all three batches of each of these applied volumes possess different batch numbers and distinct manufacturing dates. This discrepancy raises serious concerns regarding the authenticity, reliability, and integrity of the submitted stability data.

Decision

Rejected

Registration Board was apprised that firm has submitted same stability data in the instant application Normal saline **(1000ml)** as submitted along with the Registration Application of Normal saline **(500ml)** volume size, despite the fact that all three batches of each of these applied volumes possess different batch numbers and distinct manufacturing dates. Details of the stability batches along with their manufacturing date of both 1000ml and 500ml is as under:

1000ml:

Batch no.	**Manufacturing Date**
579823	June,2023
581023	June,2023
581223	June,2023

500ml

Batch no.	**Manufacturing Date**
579723	May,2023
579323	May,2023
578923	May,2023

In the light of above facts, Board decided to reject the instant application.

404	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**FRONTIER DEXTROSE LIMITED** PLOT NO. 18/3 PHASE-1 INDUSTRIAL ESTATE HATTAR **(000633)**
	Application Form Dy. No / Tracking ID & date of submission	(7YR-LMT-LWN1, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-04-29,

The proposed proprietary name / brand name	**Sterifluid NS ½ Infusion 100ml**
Label Claim	Each 100ml contains: Sodium chloride.....0.45gm Water for Injection.....Q.S.
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	100ml-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree C
For generic drugs (me-too Status)	Medisol ½ NS (Reg# 106350)
Pharmacotherapeutic Group of (API)	Electrolytes
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Stability data of three stability batches of 4,000 bottles each is submitted
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 has performed against the comparator product competitor Product: Competitor Product: Nisf Normal Saline Injection 500 ml Manufacturer: Otsuka, Pakistan Ltd. F/4.9, H.I.T.E., Hub, Baluchistan.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted
The status in reference regulatory authorities	USFDA - https://www.accessdata.fda.gov/scripts/cder/daf/in event=overview.process&ApplNo=018090
GMP status of the firm	GMP certificate dated 15-12-2023 is submitted
Evidence of approval of manufacturing facility	GMP certificate dated 15-12-2023 mentioned that firm has Liquid Injectable Infusion LVP and SVP

Evaluation Remarks

The firm has submitted same stability data for the 100 mL and 1000 mL volume size as that provided for the 500 mL, despite the fact that all three batches of each of these applied volumes possess different batch numbers and distinct manufacturing dates. This discrepancy raises serious concerns regarding the authenticity, reliability, and integrity of the submitted stability data.

Decision

Rejected

Registration Board was apprised that firm has submitted same stability data in the instant application Normal saline (100ml) as submitted along with the Registration Application of Normal saline (500ml) volume size, despite the fact that all three batches of each of these applied volumes possess different batch numbers and distinct manufacturing dates. Details of the stability batches along with their manufacturing date of both 100ml and 500ml is as under:

100ml:

Batch no.	**Manufacturing date**
577823	27-05-2023
577423	26-05-2023
578523	28-05-2023

500ml:

Batch no.	**Manufacturing Date**

	579723	31-05-2023
	579323	30-05-2023
	578923	29-05-2023
	In the light of above facts, Board decided to reject the instant application.	
405	Case Category	Routine (Saima Hussain)
	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	(BQ3-DVW-2R9X, 2024-09-04)
	Detail of Fee Submitted	30000.0, 7000.0 2024-03-22, 2024-09-24
	The proposed proprietary name / brand name	**Friafen DS Suspension**
	Label Claim	Each 5ml contains: Ibuprofen..... 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (90ml)-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30ºC in dry cool environment
	For generic drugs (me-too Status)	Brufen 120ml by Abbot Laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt) Limited Address: 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station, 1 kilometer of Chundrai Road Lahore - Pakistan. Fax: +92 42 35802251 Tel : +92 42 3580192
	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	Ibuprofen 200 mg/5 ml Oral Suspension Aspire Pharma Ltd UK
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted chromatograms that belong to another company, as evidenced by the presence of that company's logo, identical analyst name, and the same peak morphology.	
	Decision	
	Rejected Registration Board decided to reject the instant on the basis that firm submitted the chromatograms that belongs to another company as evidenced by the presence of that company's logo and identical analyst name on the submitted chromatograms. Furthermore, the chromatograms submitted with the pharmaceutical equivalence report are identical to those submitted by M/s. Dr. Raza Pharma, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar, as part of the pharmaceutical equivalence report included in their Module III.	
406	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**

	Application Form Dy. No / Tracking ID & date of submission	(NUE-362-4R9E, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Provyl DS**
	Label Claim	Each 5mL Contains: Ibuprofen.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x120mL-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Brufen syrup 120ml (200mg/5mL)by Abbot Laboratories.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zenith Chemical Industries (Pvt.) Ltd
	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	Ibuprofen 200mg/5mL Oral Suspension (Pinewood Healthcare Ireland)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted chromatograms that belong to another company, as evidenced by the presence of that company's logo, identical analyst name, and the same peak morphology.	
	Decision	
	Rejected Registration Board decided to reject the instant on the basis that firm submitted the chromatograms that belongs to another company as evidenced by the presence of that company's logo and identical analyst name on the submitted chromatograms. Furthermore, the chromatograms submitted with the pharmaceutical equivalence report are identical to those submitted by M/s. Air Pharmaceuticals (Pvt.) Ltd, P74-75A Small Industrial Estate Kasur Pakistan, as part of the pharmaceutical equivalence report included in their Module III.	
407	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(X3V-LNW-GW6J, 2024-10-28)
	Detail of Fee Submitted	30000.0, 7000.0 2023-11-10, 2024-10-24
	The proposed proprietary name / brand name	**VONOPEP 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Vonaprazan Fumarate eq. to Vonaprazan.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x10's-De-Controlled,2x7's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree Centigrade.
	For generic drugs (me-too Status)	Vonozan 10mg Tablets

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JIANGXI SYNERGY PHARMACEUTICAL CO. LTD, CHINA.
	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	Takecab 10mg Tablets (PMDA JAPAN APPROVED)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same module-III including verification report of drug substance performed by drug product manufacturer, batch analysis report of drug substance, pharmaceutical development data and stability data of drug product as submitted by another firm for its approved product.	
	Decision	
	Rejected Registration Board decided to reject the instant application for submitting same data in module-III (including verification report of drug substance performed by drug product manufacturer, batch analysis report of drug substance, pharmaceutical development data and stability data of drug product) as submitted by another firm for its approved product.	
408	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(WPM-W9Q-3XA6, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Mylenol Duo**
	Label Claim	Each Film Coated Tablet contains: Paracetamol BP..... 500 mg Ibuprofen BP.....200 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 Tablets-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Provas Duo by Sami Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Pvt Ltd,Zenith Chemical Industries (Pvt.) Ltd
	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
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same analytical data of paracetamol drug substance that is submitted by another firm for the registration of a different formulation containing paracetamol and tramadol. Furthermore, the firm has submitted the same Comparative Dissolution Profile (CDP) data, analytical verification report of the drug product, and chromatograms exhibiting same peak areas as those submitted by the said firm for its applied formulation. Furthermore, the instant dossier was submitted on 05 November 2024, whereas the dossier of the other company was submitted on 10 September 2024.	
	Decision	
	Rejected Registration Board decided to reject the instant application, keeping in view that firm has submitted same analytical data of paracetamol drug substance (assay verification report and batch analysis report performed by drug product manufacturer) as submitted by another firm i.e. M/s. Reign Pharmaceuticals PCSIR - KLC (Pvt.) Ltd. TBIC Building – I, PCSIR Laboratories Complex, Shahrah – e – Dr. Salim – uz – Zaman Siddiqui, Off University Road, Karachi – 75280, for the registration of a different formulation containing paracetamol and tramadol. Furthermore, the firm has submitted the same Comparative Dissolution Profile (CDP) data, analytical verification report of the drug product, and chromatograms exhibiting same peak areas as those submitted by the said firm for its applied formulation.	
409	Case Category	Routine (Saima Hussain)
	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	(R41-5GD-X68G, 2024-10-17)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Vonasia 10mg tablet**
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-Free of Cost
	Shelf Life (Unit)	2 YearStore below 30C at cool and dry place
	For generic drugs (me-too Status)	Voniza 10mg Tablet of 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	TAKECAB 10mg Tablet of M/s Takeda

	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted same chromatograms in section 3.2.P.8.3 (along with stability data) as those submitted by another firm in its submitted Registration application.	
	Decision	
	Rejected Registration Board decided to reject the instant application keeping in view that, firm has submitted same chromatograms (mentioning same retention time, peak area, tailing factor, resolution and theoretical plate counts) along with the stability data of drug product as submitted by another firm i.e. Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan In addition, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by the said firm.	
410	Case Category	Routine (Saima Hussain)
	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	(9VN-JPA-N9P1, 2024-10-17)
	Detail of Fee Submitted	37000.0, 2024-10-03,
	The proposed proprietary name / brand name	**Vonasia 20mg tablet**
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C at cool and dry place
	For generic drugs (me-too Status)	Voniza 20mg Tablet of 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	TAKECAB 20mg Tablet of M/s Takeda
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms in section 3.2.P.8.3, as those submitted by another firm in its registration application. Furthermore, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by the same firm.	
	Decision	
	Rejected	

	Registration Board decided to reject the instant application keeping in view that, firm has submitted same chromatograms (mentioning same retention time, peak area, tailing factor, resolution and theoretical plate counts) along with the stability data of drug product as submitted by another firm i.e. M/s. Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar, Pakistan. In addition, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by the said firm.	
411	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Polyfine Chempharma** 51 Industrial Estate Hayatabad Peshawar, Pakistan **(000216)**
	Application Form Dy. No / Tracking ID & date of submission	(TES-3AX-BPM6, 2024-07-05)
	Detail of Fee Submitted	30000.0, 2024-05-21,
	The proposed proprietary name / brand name	**VONOFINE 20MG TABLET**
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....20mg
	Reference to Finished product specifications	
	Proposed Pack Size	28's/14's,-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Condition
	For generic drugs (me-too Status)	Brand Name: Voniza 20mg Tablet of Registration holder: M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SHANDONG CHENHUISHUANGDA PHARMACEUTICALCO.,LTD. Economic Development Zone, Pingyuan County, Dezhou, Shandong, China.
	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	Brand Name TAKECAB 20mg Tablet of Manufactured by M/s Takeda Marketing Authorization holder: M/s Takeda Regulatory Authority: (PMDA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms in section 3.2.P.8.3, as those submitted by another firm along with its registration application. Furthermore, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by that same firm.	
	Decision	
	Rejected Registration Board decided to reject the instant application keeping in view that, firm has submitted same chromatograms (mentioning same retention time, peak area, tailing factor, resolution and theoretical plate counts) along with the stability data of drug product as submitted by another firm i.e. Med Asia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate (SIZ) Risalpur. In	

	addition, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by the said firm.	
412	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Polyfine Chempharma** 51 Industrial Estate Hayatabad Peshawar, Pakistan **(000216)**
	Application Form Dy. No / Tracking ID & date of submission	(NXL-GET-TL2X, 2024-12-26)
	Detail of Fee Submitted	30000.0, 7000.0 2024-05-21, 2024-12-16
	The proposed proprietary name / brand name	**VONOFINE 10MG TABLET**
	Label Claim	Each film coated tablet contains: Vonoprazan as fumarate.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28's/14's,-As per SRO
	Shelf Life (Unit)	3 Year(s)room condition
	For generic drugs (me-too Status)	Brand Name: Voniza 10mg Tablet of Registration holder: M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	potassium-competitive acid blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SHANDONG CHENHUISHUANGDA PHARMACEUTICALCO.,LTD. Economic Development Zone, Pingyuan County, Dezhou, Shandong, China.
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Brand Name TAKECAB 10mg Tablet of Manufactured by M/s Takeda Marketing Authorization holder: M/s Takeda Regulatory Authority: (PMDA Approved)
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 26.05.2023
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section submitted by firm
	Evaluation Remarks	
	The firm has submitted same chromatograms in section 3.2.P.8.3, as those submitted by another firm along with its registration application.	
	Decision	
	Rejected Registration Board decided to reject the instant application keeping in view that, firm has submitted same chromatograms (mentioning same retention time, peak area, tailing factor, resolution and theoretical plate counts) along with the stability data of drug product as submitted by another firm i.e. Med Asia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate (SIZ) Risalpur. In addition, the assay results of all time points under both accelerated and long-term stability conditions of drug product are also exactly same to the assay results submitted by the said firm.	
413	Case Category	New License (Saima Hussain)

	Name, address of Applicant.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. **(000985)**
	Application Form Dy. No / Tracking ID & date of submission	(W2T-UR8-454G, 2024-10-21)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-06, 2024-10-10
	The proposed proprietary name / brand name	**Miflocin**
	Label Claim	Each 100ml Vial Contains: Ciprofloxacin as Lactate...200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100mlx1's-As per SRO
	Shelf Life (Unit)	2 Year15-30 degree Celsius
	For generic drugs (me-too Status)	Novidat Infusion 200mg/100ml by Sami Pharmaceuticals, Karachi Pakistan
	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	MHRA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted the same batch analysis report of the drug substance by the drug product manufacturer, as well as same pharmaceutical development data and stability data to those submitted by another firm along with its registration application.	
	Decision	
	Rejected Registration Board decided to reject the instant application keeping in view that firm has submitted same batch analysis report of the drug substance by the drug product manufacturer, as well as same pharmaceutical development and stability data as submitted by another firm i.e. M/s. MAFINS PHARMA plot no A-5 S.I.T.E super highway industrial area Karachi, whose registration application has under evaluation.	
414	Case Category	Routine (Saima Hussain)
	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	(6WR-BQU-RSD5, 2024-07-04)
	Detail of Fee Submitted	75000.0, 2024-05-30,
	The proposed proprietary name / brand name	**R2 Best 20mg Tablets**
	Label Claim	Each film-coated tablet contains.....20mg Finerenone
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10s 20s & 30s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	NOT APPLICABLE SINCE THIS IS A NEW DRUG"
	Pharmacotherapeutic Group of (API)	Selective Non-Steroidal Mineralocorticoid Receptor (MR) Antagonist.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Stability data of three batches 1500 tablet each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted the Form -6 only
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP have performed against the innovator product Kerendia Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted stability data as per zone-IV condition.
	The status in reference regulatory authorities	Kerendia 20mg Tablets by (M/s. Bayer Healthcare) (FDA Approved)
	GMP status of the firm	Firm submitted GMP certificate dated 05th August,2022.
	Evidence of approval of manufacturing facility	GMP certificate dated 5th August,2022 mentioned that firm has tablet(general) section
	Evaluation Remarks	
	Decision	
	Approved	
415	Case Category	Routine (Saima Hussain)
	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	(NWL-E3H-1YXJ, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-05-30,
	The proposed proprietary name / brand name	**R2 Best 10mg Tablets**
	Label Claim	Each film-coated tablet contains.....10mg Finerenone
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s 20s & 30s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade
	For generic drugs (me-too Status)	NOT APPLICABLE SINCE THIS IS A NEW DRUG"
	Pharmacotherapeutic Group of (API)	Selective Non-Steroidal Mineralocorticoid Receptor (MR) Antagonist.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical CO., Ltd.
	Detail of stability batches of drug product	Stability data of three batches 1500 tablet each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP	Firm submitted the Form -6 only

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and CDP have performed against the innovator product Kerendia Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm submitted stability data as per zone-IV condition.
	The status in reference regulatory authorities	Kerendia 10mg Tablets by (M/s. Bayer Healthcare) (FDA Approved)
	GMP status of the firm	Firm submitted GMP certificate dated 05th August,2022.
	Evidence of approval of manufacturing facility	GMP certificate dated 5th August,2022 mentioned that firm has tablet(general) section
	Evaluation Remarks	
	Decision	
	Approved	
416	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan **(000840)**
	Application Form Dy. No / Tracking ID & date of submission	(WMX-AH8-RABT, 2024-10-10)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-07, 2024-09-23
	The proposed proprietary name / brand name	**Systrears Lubricant Eye Drop (0.4 % Polyethylene Glycol 400 and 0.3% Propylene Glycol Lubricant Eye Drop)**
	Label Claim	Each mL contains:Polyethylene glycol 400 ----------4mgPropylene glycol ----------3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Systane Alcon Laboratories, Inc.
	Pharmacotherapeutic Group of (API)	Lubricant eye drop.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Eapearl Chemical,Shandong Shida Shenghua Chemical
	Detail of stability batches of drug product	3 batches of 1500 units each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Systane drops
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	The status in reference regulatory authorities	ALCON LABORATORIES, INC FORWORTH USA is available as OTC drug, on Dailymed of USA
	GMP status of the firm	GMP certificate issued dated 19-04-2019.

	Evidence of approval of manufacturing facility	Firm has been granted additional section of "Eye Drop (General)" vide letter no. F.1-75/2011-Lic (Vol-I) issued by Secretary CLB dated 14-10-2020.
	Evaluation Remarks	
	Your instant application has been evaluated and found deficient for following observations: Observations Valid DML/GMP certificate of drug substance manufacturers shall be submitted. Clarification shall be submitted for the method applied for the Assay test of propylene glycol. Analytical method verification studies of drug substances and drug product shall be submitted from the drug product manufacturer. • Batch manufacturing record of stability batches shall be submitted • Documents confirming procurement of drug substance shall be submitted You are therefore advised to submit response to above cited observations at earliest for further processing of the case. Registration Board in its 344th meeting deferred the case for submission of above cited shortcomings. However, it is found that firm has submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application.	
	Decision	
	Rejected Registration Board decided to reject the instant application on the basis that firm submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application.	
417	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(6QX-87V-4ZJS, 2024-10-28)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-26, 2024-10-24
	The proposed proprietary name / brand name	**Dexolna**
	Label Claim	Each Capsule contains: Dual delayed release dexlansoprazole Pellets eq to Dexlansoprazole .....60mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Delanzo DDR Capsules by Sami Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	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 production batches having 840 capsule batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 60 mg capsules by Sami"

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.3-3/94-Lic (Vol-II) dated 2-10-2019 mentioning capsule section
	Evaluation Remarks	
	Firm has same assay verification data of drug substance by drug product manufacturer, pharmaceutical development data and stability data as submitted by another firm along with their registration application.	
	Decision	
	Rejected Registration decided to reject the instant application keeping in view that firm submitting the same Module-III (assay verification data of drug substance by drug product manufacturer, pharmaceutical development data and stability data) as submitted by another firm i.e. M/s. Invictus Pharmaceuticals Plot No. 21&26, Street No. NS-2, (W-5), RCCI, Rawat along with their registration application which is still not evaluated yet.	
418	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(UEH-PN2-JPD2, 2024-09-03)
	Detail of Fee Submitted	30000.0, 2024-07-26,
	The proposed proprietary name / brand name	**Dexolna**
	Label Claim	Each Capsule contains: Dual delayed release dexlansoprazole Pellets eq to Dexlansoprazole .....30mg (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Delanzo DDR Capsules by Sami Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	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 production batches having 840 capsule batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 30 mg capsules by Sami"
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.3-3/94-Lic (Vol-II) dated 2-10-2019 mentioning capsule section
	Evaluation Remarks	

	Firm has same assay verification data of drug substance by drug product manufacturer, pharmaceutical development data and stability data as submitted by another firm along with their registration application.	
	Decision	
	Rejected Registration decided to reject the instant application keeping in view that firm submitting the same Module-III (assay verification data of drug substance by drug product manufacturer, pharmaceutical development data and stability data) as submitted by another firm i.e. M/s. Invictus Pharmaceuticals Plot No. 21&26, Street No. NS-2, (W-5), RCCI, Rawat along with their registration application which is still not evaluated yet.	
419	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(5L7-YM6-Y6HT, 2024-10-18)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-24, 2024-09-18
	The proposed proprietary name / brand name	**Dariblex PR Tablet 15mg**
	Label Claim	Each Prolonged release film-coated tablet contains: Darifenacin (as Hydrobromide).....15mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 28's, 30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Urological, drugs for urinary frequency and Incontinence. ATC Code: G04BD10
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MSN Pharmachem Private Limited
	Detail of stability batches of drug product	Stability data of 2 trial batches 767DS01 and 767DS02 of batch size 5000 tablets each is submitted
	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 and CDP have performed against the innovator product EMSELEX Prolonged Release Tablets 15mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
	The status in reference regulatory authorities	EMA & MHRA Approved (Emselex 15 mg prolonged-release tablets is registered and being marketed by pharmaand GmbH, Austria, manufactured by DREHM Pharma GmbH, Austria).
	GMP status of the firm	GMP certificate dated 26th July,2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 26th July,2023 mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	

	Approved Firm shall submit requisite pre-registration variation fee as per the latest SRO.	
420	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(1TW-LLV-D5QS, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Dariblex PR Tablet 7.5mg**
	Label Claim	Each Prolonged release film-coated tablet contains: Darifenacin (as Hydrobromide).....7.5mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 28's, 30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Urological, drugs for urinary frequency and Incontinence. ATC Code: G04BD10
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	MSN Pharmachem Private Limited
	Detail of stability batches of drug product	Stability data of 2 trial batches 768DS01 and 768DS02 of batch size 5000 tablets each is submitted
	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 and CDP have performed against the innovator product EMSELEX Prolonged Release Tablets 7.5mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm.
	The status in reference regulatory authorities	EMA & MHRA Approved (Emselex 7.5 mg prolonged-release tablets is registered and being marketed by pharmaand GmbH, Austria, manufactured by DREHM Pharma GmbH, Austria).
	GMP status of the firm	GMP certificate dated 26th July,2023 is submitted
	Evidence of approval of manufacturing facility	GMP certificate dated 26th July,2023 mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit requisite pre-registration variation fee as per the latest SRO.	
421	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	**Sohail Corporation** plot # 7, SR-5, Serai Quarters (Techno City), WH-42, Karachi Pakistan. **(238)**

Application Form Dy. No / Tracking ID & date of submission	(623-RHQ-DETM, 2026-02-19)
Detail of Fee Submitted	313500, 2025-11-20,
The proposed proprietary name / brand name	**25% Dextrose Injection 20ml**
Label Claim	Each 20ml ampoule contains: Dextrose....5gm (25% W/V) USP
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	50ampoules/box-Controlled
Shelf Life (Unit)	36 MonthStore at 20°C to 25°C (68°F to 77°F)
For generic drugs (me-too Status)	Manufacturer/Registration holder: M/s; Mehran International located at JM-498/D, Hume Road, Quaideen Colony, Opposite World Map, Near 3 Star Hall, Karachi-Pakistan. • Brand name: 25% Dextrose In
Pharmacotherapeutic Group of (API)	Electrolytes with carbohydrates.
Name, address of Manufacturing site:	Shandong Hualu Pharmaceutical Co., Ltd.-No.1 Hualu Road, Zhenxing Street, Chiping District, Liaocheng City, Shandong Province.-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	Valid Pharmaceutical Equivalence attached in Module 3
Name, address of Marketing Authorization Holder:	M/s; Sohail Corporation, Address: Plot no 7, (Serai Quarters) SR-5, Techno City, Warehouse No 42, 6th Floor, Karachi. , Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Valid GMP Inspection Report of Manufacturer issued by Shandong Provincial Drug Supervision and Administration Bureau attached herewith
Details of Authorization Letter :	GMP certificate of Drug Substance attached in Module 3 (3.2.S.2.1 Manufacture)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	The stability studies of 3 batches of Dextrose was carried out separately (API) including accelerated test and long-term test according to the storage condition and testing frequency required in ICH guidance and attached in Module 3 (3.2.S.7.3 Stability Data).
The status in reference regulatory authorities	USFDA Approved

Evaluation Remarks

Provide evidence of availability of the applied formulation in the approved reference regulatory authorities. The reference product given in Module -I is available as 2.5 g/10 mL and contains glucose monohydrate, whereas the proposed (applied) formulation is presented in a 20 mL ampoule containing 5 g of dextrose, formulated using glucose anhydrous. These differences in strength presentation and the form of glucose (monohydrate vs. anhydrous) should be justified with supporting evidence from the approved reference regulatory authorities. Firm in their reply stated that, we would like to clarify that our applied product is comparable to the RRA-approved product, with the only difference being the fill volume. The reference product is presented in 10 mL, whereas our applied product is in 20 mL; however, the strength and concentration remain identical (25% w/v). The label claim in both cases is the same, i.e., each 1 mL contains 250 mg of glucose, confirming equivalence in strength and therapeutic effect. Regarding the difference between glucose monohydrate and glucose anhydrous, it is submitted that both forms are covered under the compendial methods of the United States Pharmacopeia (USP).This strength Dextrose 5g/20mL is regular strength in China market,and it has been used more than 30 years in China, and through check our NMPA database, there are 66 manufacturer got this registration letter, and 27 manufacturers sold their Dextrose 5g/20mL in China market very well, such as famous company Kelun pharma and SHIJIANGZHUANG NO.4 pharma and Hualu pharma and Zhejiang Tianrui pharma all have this strength Dextrose 5g/20mL.Lots of Chinese people be treated by Dextrose

	5g/20mL, and there is no Serious adverse reaction reports, our NMPA did not note this Dextrose 5g/20mL cannot be sold in China market. So, this strength Dextrose 5g/20mL safety has been verified through actual usage.	
	Decision	
	Deferred Deferred for submission of evidence of availability of the applied formulation (Each 20ml ampoule contains: Dextrose....5gm (25% W/V)) in the approved reference regulatory authorities/agencies.	
422	Case Category	Contract Manufacturing (Saima Hussain)
	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	(4D1-RY2-Z3J4, 2024-07-31)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**FINRO 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Finerenone.....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 Year20-25C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	Firm informed that Finerenone 10mg tablet of M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar has already been approved in 353rd meeting of Registration Board, so the case is considered under cross-referenced contract manufacturing category.	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as per the latest SRO.	
423	Case Category	Routine (Saima Hussain)
	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	(EL3-38A-3MSZ, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2023-12-29,
	The proposed proprietary name / brand name	**Lithcell 400mg tablets**
	Label Claim	Lithcell 400mg tablets Film coated Tablets Lithium Carbonate.....400mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)25
	For generic drugs (me-too Status)	Neurolith 400mg tablet (Adamjee Pharmaceuticals (Pvt.) Ltd)080873
	Pharmacotherapeutic Group of (API)	Antipsychotic WHO ATC Code: N05AL05

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	stability data submitted T1LCK23 T2LCK23 T3LCK23 Batch size 1000 Tablets 1000 Tablets 1000 Tablets Manufacturing Date 10-2023 10-2023 10-2023 Date of Initiation 10-2023 10-2023 10-2023
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from M/s. Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the comparator brand Neurolith SR 400mg tablet Each film coated tablet contains: Lithium Carbonate……400 mg Mfg. date: 01/23 Exp date: 07/25 Manufactured by: Adamjee Pharmaceuticals (Pvt.) Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition
	The status in reference regulatory authorities	FDA approved Lithium Carbonate …..400 mg tablets Milpharm Limited, Ares, Odyssey Business Park, West
	GMP status of the firm	GMP inspection dated 28-10-2024 is submitted by the firm
	Evidence of approval of manufacturing facility	GMP inspection dated 28-10-2024 mentioned that firm has tablet (general section
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit requisite pre-registration variation fee as per the latest SRO.	
424	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	**Axis Pharmaceuticals (Pvt) Ltd** 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad **(000667)**
	Application Form Dy. No / Tracking ID & date of submission	(5QJ-A9G-2ABY, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-04-03,
	The proposed proprietary name / brand name	**Axamol Extend Tablet 665 mg**
	Label Claim	Each modified release Tablet contains: Paracetamol... 665 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-As per SRO
	Shelf Life (Unit)	2 Year(s)25-30 °C
	For generic drugs (me-too Status)	Panadol Extend Tablet
	Pharmacotherapeutic Group of (API)	Pain Management.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of 2 batches 5000 tablets each is submitted
	Documents for the procurement of API with approval from DRAP	API procured from M/s. Pharmagen(locally procured)

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the Panadol Modified release 665mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted
	The status in reference regulatory authorities	TGA Australia
	GMP status of the firm	GMP certificate dated 20-06-2022 submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate dated 20-06-2022 mentioned that firm has tablet (general) section
	Evaluation Remarks	
	Decision	
	Approved Firm shall submit fee for pre-registration variation as per the latest SRO.	
425	Case Category	Routine (Saima Hussain)
	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	(3GE-DNG-RM4B, 2024-04-23)
	Detail of Fee Submitted	75000.0, 2024-04-03,
	The proposed proprietary name / brand name	**Mesazine**
	Label Claim	Each tablet contains: Mesalazine 1g
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	7s, 10s, 14s, 20s, 2-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 25°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Intestinal anti-inflammatory agent (ATC code: A07EC02)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hengkang Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	Stability data of batches 23SB-422-01 (1500 tablets),23SB-423-02 (1500 tablets),23SB-424-03 (1500 tablets).
	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 and CDP have performed against the Pentasa 1g Prolong Release Tablet (B# 0635064) FERRING IRELAND LTD United Drug House, Magna Drive, Magna Business Park, Citywest Road Dublin 24, Ireland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV condition is submitted by the firm
	The status in reference regulatory authorities	Pentasa 1 g prolonged-release tablets, Ferring Ireland Ltd
	GMP status of the firm	
	Evidence of approval of manufacturing facility	GMP certificate dated 13th June,2023 mentioned that firm has tablet (general) section.
	Evaluation Remarks	

	Registration Board in its 357th meeting deferred the instant case for submission of evidence of reference product approved in RRA, that is manufactured by simple blending of the active pharmaceutical ingredient (API) with ethyl cellulose (polymer), rather than through the preparation of ethyl cellulose–coated granules prior to compression into tablets, as recommended by the innovator product Pentasa 1 g prolonged-release tablet. Firm in their reply stated that, The proposed formulation utilizes a wet granulation process, which plays a critical role in achieving a controlled release profile comparable to the reference product. During wet granulation, ethyl cellulose is dispersed in the granulating fluid, enabling intimate and uniform coating/embedding of mesalazine particles. This process results in the formation of densified granules, where ethyl cellulose is not merely blended but partially envelops the drug particles, forming a continuous or semi-continuous matrix. Ethyl cellulose, due to its hydrophobic and water-insoluble nature, functions as a rate-controlling polymer. Upon exposure to dissolution media: Rapid penetration of aqueous medium is restricted. Drug release occurs primarily via diffusion through the polymer matrix.	
	Decision	
	Deferred Registration Board directed the applicant to submit the samples of the trial batches along with the innovator product to the Central Drug Testing Laboratory, Karachi, for performing the quality testing (on all the parameters that are part of finished product specification) and comparative dissolution profiling of both the tested and innovator product. Accordingly, submit the analytical and Comparative dissolution profiling report issued by the CDL of both tested and innovator product, to establish the pharmaceutical equivalence between the two products.	
426	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(U9S-MLE-YM8P, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Dine 1% W/S Powder**
	Label Claim	Each 100gm powder contains: Amantadine HCl BP..... 1.0gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Roldine 1% W/S POWDER (109105)
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has mentioned target species as: Target Species: □ Poultry □ Calves □ Goats & sheep	
	Decision	
	Rejected Rejected. **Recommendations of Sub-Committee:** After deliberation, the sub-committee on veterinary Drugs recommended that Amantadine be banned for use in food producing animals due to concern about	

	drug resistance and food safety.	
427	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(TPP-8M5-6YBV, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Dine 10% W/S Powder**
	Label Claim	Each 100gm powder contains: Amantadine HCl BP ..... 10G (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Roldine 10% W/S POWDER (109104)
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm mentioned: Target Species: □ Poultry □ Calves □ Goats & sheep	
	Decision	
	Rejected Rejected. **Recommendations of Sub-Committee:** After deliberation, the sub-committee on veterinary Drugs recommended that Amantadine be banned for use in food producing animals due to concern about drug resistance and food safety.	
428	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(BAY-452-9UP8, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Dine 98% W/S Powder**
	Label Claim	Each 100gm powder contains: Amantadine HCl ..... 98gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Roldine 98 W/S POWDER (109103)

	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm mentioned: Target Species: □ Poultry □ Calves □ Goats & sheep	
	Decision	
	Rejected Rejected. Recommendations of Sub-Committee: After deliberation, the sub-committee on veterinary Drugs recommended that Amantadine be banned for use in food producing animals due to concern about drug resistance and food safety.	
429	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(QU2-3SY-LUXZ, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**AKE STREP 20 ORAL POWDER**
	Label Claim	Each gm powder contains Doxycycline HCl BP..... 200mg Tylosin as tartrate BP..... 100mg Dihydrostreptomycin USP .....20mg Bromhexine HCL BP..... 5mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	STREP DOX 20 POWDER (122004)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
430	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(8HQ-NTJ-YMW7, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,

	The proposed proprietary name / brand name	**BAKE C 100% ORAL POWDER**
	Label Claim	Each 100gm contains Vitamin - C BP.....100 GM (As Per Innovators' spec
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	SANNAVIT C-100 W/S POWDER (025368)
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
431	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(ABN-GDT-7ZVB, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE CTC 20% ORAL POWDER**
	Label Claim	Each 100Gm powder contains Chlortetracycline HCL USP..... 20gm (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Harry Cycline 20 W/S Powder (109120)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
432	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(Q6S-P3B-Q4TQ, 2026-04-13)

	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE CTC 25% ORAL POWDER**
	Label Claim	Each Gm powder contains Chlortetracycline HCL USP..... 250mg (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Harry Cycline 25 W/S Powder (109254)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
433	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(5NL-87J-D4B9, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE DOX 50% W/S POWDER**
	Label Claim	Each Gm powder contains Doxycycline As Hyclate BP..... 500mg (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arch Dox 50% W/S Powder (122349)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
434	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**

	Application Form Dy. No / Tracking ID & date of submission	(HAA-5TR-R5W8, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE DOX 80% W/S POWDER**
	Label Claim	Each gm Water Soluble powder contains Doxycycline Hyclate BP..... 923.32mg (EQ to 800mg Doxycycline) (As Per Innovators Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Dox Rold 800 W/S Powder (109113)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
435	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(GWN-6B5-21D5, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bake Fos 500 W/S Powder**
	Label Claim	Each 100gm powder contains: Fosfomycin Calcium BP..... 20gm Tylosin as Tartarate BP.....10 gm Fructose 1,6 diphosphate .....18 gm Sodium Phosphate.....15 gm Magnesium Phosphate .....10 gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	FOMYSTER POWDER (117263)
	Pharmacotherapeutic Group of (API)	Antibactetrial, Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
436	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(5BQ-UNA-Q6L5, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE FOS 1000 W/S POWDER**
	Label Claim	Each 100gm powder contains: Fosfomycin Calcium BP..... 20gm Tylosin Tartarate BP.....5gm Fructose 1,6 diphosphate .....18gm Sodium Phosphate.....15gm Magnesium Phosphate .....10gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Fosy-Tyl-100 Oral Powder (133485)
	Pharmacotherapeutic Group of (API)	Antibactetrial,Electolytes Replinisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
437	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(8TQ-Z3D-665W, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE OXY 10% W/S POWDER**
	Label Claim	Each 100 Gm Powder contains Oxytetracycline Hcl BP..... 10g As Per BP Specs
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Hans-Cycline 10% Powder (102219)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--

	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
438	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(LW3-J45-9N15, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE STREP 40 ORAL POWDER**
	Label Claim	Each gm powder contains Doxycycline HCl BP..... 200mg Tylosin as tartrate BP..... 100mg Dihydrostreptomycin USP .....40mg Bromhexine HCL BP..... 5mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	STREP DOX 40 POWDER (122005)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
439	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(MRT-HEA-6PJG, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**Bake Thunds Drench**
	Label Claim	Each 100ml contains: Triclabendazole .....12gm Ivermectin USP..... .....0.2gm Albendazole BP.....10gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Mecben Drench (121897)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
440	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(EW5-A1E-P5T1, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Reno 2% Oral Powder**
	Label Claim	Each 100gm contains: Furosemide BP.....2gm Sodium Chloride.....3.5gm Magnesium Sulphate.....3.5gm Manganese Sulphate BP.....0.1gm Calcium Carbonate.....4.5gm Potasium Chloride.....0.4g (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Gipsomide 20 Powder (109142)
	Pharmacotherapeutic Group of (API)	Diuretic, Electrolytes Replenisher
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
441	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(DQ3-X5W-H1BD, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-09,

	The proposed proprietary name / brand name	**Bak Tin 48 Oral Powder**
	Label Claim	Each gm powder contains Colistin Sulphate BP..... 48,00,000IU (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arcol 48% Oral Powder (120884)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
442	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(Y7H-PHY-1332, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Tin 50 Oral Powder**
	Label Claim	Each gm powder contains Colistin Sulphate BP..... 5000000IU (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Colizoc water soluble Powder (080942)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
443	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(DZ2-6SQ-7L4Y, 2026-04-15)

	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Tin 55 Oral Powder**
	Label Claim	Each Kg powder contains: Colistin Sulphate BP..... 550MIU (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arcol 55% Oral Powder (120886)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
444	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(4GB-LL9-5W1Q, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Bak Tin 60 Oral Powder**
	Label Claim	Each Gm powder contains: Colistin Sulphate BP..... 6,000,000 IU (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arcol 60% Oral Powder (120885)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
445	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**

	Application Form Dy. No / Tracking ID & date of submission	(1SH-SLN-VDSU, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**LINCO BAKE 1.1 ORAL POWDER**
	Label Claim	Each Gm powder contains Lincomycin As HCL USP ..... 11mg (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arch Linco 11 (122002)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
446	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(UP4-1DX-G72M, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**LINCO BAKE 4.4 ORAL POWDER**
	Label Claim	Each Gm powder contains Lincomycin As HCL ..... 44mg (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arch Linco 44 (122003)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
447	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**

	Application Form Dy. No / Tracking ID & date of submission	(PJW-X4H-DLX9, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**LINCO BAKE 44 W/S POWDER**
	Label Claim	Each 1000Gm powder contains Lincomycin As Hcl USP..... 440gm (USP Spec.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Lincoruth 44% Oral Powder (125824)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
448	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(SGN-D3Z-UDSU, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**NEO BAK 70% W/S Powder**
	Label Claim	Each 100Gm Powder contains: Neomycin Sulphate BP..... 70gm (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Neomycin Sulphate 70% POWDER (075694)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
449	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL

		INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(P2V-YXU-2TM5, 2026-04-15)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**NEO BAK 72% W/S Powder**
	Label Claim	Each Gm Powder contains: Neomycin Sulphate BP..... 720mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arch Neo 72 W/S Oral Powder (120876)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
450	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(EDM-ZXY-AVGS, 2026-04-16)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**NEO BAK 100% W/S Powder**
	Label Claim	Each Gm contains: Neomycin Sulphate ..... 1000mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Arch Neo 100 W/S Oral Powder (120877)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
451	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL

		INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(B2U-ZLY-4BPP, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**TYLO BAKE 50% W/S POWDER**
	Label Claim	Each 1000gm powder contains Tylosin Tartrate BP..... 500gm (As Per Innovator's Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Z-TARTRATE WATER SOLUBLE POWDER (099413)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
452	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(JQZ-34B-4LAT, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**TYLO BAKE 98% ORAL POWDER**
	Label Claim	Each 100gm powder contains Tylosin Tartrate ..... 98gm (As Per Innovator's Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Amsetyl-98 Oral W/S Powder (101999)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
453	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(N5T-SWT-WUZT, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**TYLO BAKE 100% W/S POWDER**
	Label Claim	Each 100gm powder contains Tylosin Tartrate BP..... 100gm (As Per Innovator Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Tylolina 100% Powder(069624)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
454	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(W88-YGJ-897Y, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**BOLT WORM DRENCH**
	Label Claim	Each ml contains: Oxyclozanide BP..... 62.5 mg Oxfendazole BP..... 22.65 mg Cobalt Sulphate ..... 1.67 mg Sodium Selenite ..... 0.5 mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	CLOFEN DRENCH (121892)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
455	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(LZP-DNT-X2PS, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**E-Lycte-C ORAL POWDER**
	Label Claim	Each 1000G contains:- Vitamin-c BP.....200gm Asprin BP.....67gm Potassium chloride.....3gm Sodium citrate.....7gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Spro-C W/S POWDER (074092)
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
456	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(UN5-1DJ-XQQS, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Flor Bake 1000 Oral Powder**
	Label Claim	Each 100gm powder contains: Oxytetracycline Hcl BP..... 300mg Florfenicol ..... 100mg Neomycin sulphate BP..... 150mg (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.

	For generic drugs (me-too Status)	Rabix w/s oral Powder (109138)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
457	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(WEP-45T-WL67, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Flor Bake 2000 Oral powder**
	Label Claim	Each Gm powder contains: Oxytetracycline Hcl BP..... 300mg Florfenicol ..... 100mg Neomycin sulphate BP..... 150mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Rabix Forte w/s oral Powder(109139)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
458	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(5TE-ZW2-ZGDA, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**Nilora Drench 100 Oral Suspension**
	Label Claim	Each 100ml contains: Levamisole HCL BP..... 1.5g Oxyclozanide BP..... 3.0g (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Nilzan Drench (002105)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
459	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(12P-PGB-89R4, 2026-04-16)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**PARA BAK C W/S Powder**
	Label Claim	Each 100gm powder contains: Vitamin-C BP.....5g Paracetamol BP.....20.0g Potassium Carbonate.....12.5g Sodium Bicarbonate.....12.5g Vitamin E.....12.5g (As Per Innovators' spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Parold C W/S Powder (109123)
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
460	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(AM5-BP1-Z53P, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**Rhithro Bake Oral Powder**

	Label Claim	Each 1000Gm Contains: Erythromycin Thiocyanate.....100 Gm Oxytetracycline HCL BP..... 200 Gm Neomycine Sulphate BP.....100 Gm (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	NEO-MIX POWDER (075712)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
461	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(1XB-DDT-EH89, 2026-04-12)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**SPIRO BAKE ORAL POWDER**
	Label Claim	Each 100gm contains: Lincomycin as HCl BP.....5gm Spectinomycin HCl BP.....7.5gm Spiramycin Adipate BP.....2.5gm Bromhexine HCl.....0.5gm (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	SPIRO SPEC POWDER Reg #
	Pharmacotherapeutic Group of (API)	Anti-bacterial, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
462	Case Category	New Section (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	(G7P-BHE-WP2Q, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Bronco Mox W/S POWDER**
	Label Claim	Each 1000g powder contains Amoxicillin Trihydrate BP..... 100g Lincomycin HCl BP ..... 50g Colistin Sulphate BP..... 500MIU Bromhexine HCl BP..... 5g (As Per Innovator 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)at Room Temperature
	For generic drugs (me-too Status)	COLAB W/S POWDER (079839)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
463	Case Category	New Section (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	(QEQ-ZU7-S5ZR, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Ford Mox C 15% POWDER**
	Label Claim	Each 100gm powder contains Amoxicillin As Trihydarte BP..... 15g Colistin sulphate BP..... 50MIU (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)at Room Temperature
	For generic drugs (me-too Status)	AMOXTIN-P WATER SOLUBLE POWDER (058994)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
464	Case Category	New Section (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	(HX2-9NB-8AXZ, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Ford Tin 15% POWDER**
	Label Claim	Each 1000gm powder contains Amoxicillin As Trihydarte ..... 15% Colistin sulphate ..... 550MIU (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)at Room Temperature
	For generic drugs (me-too Status)	Fullmox Oral Powder (087192)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
465	Case Category	New Section (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	(6SH-4ZH-MUU7, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**FORD Tin 20% W/S POWDER**
	Label Claim	Each 100gm powder contains Amoxicillin Trihydarte ..... 20G Colistin sulphate ..... 80MIU (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)at Room Temperature
	For generic drugs (me-too Status)	Colimoxin Forte Oral Dry Powder (080961)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
466	Case Category	New Section (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	(RWZ-UDL-9D6G, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Ford Tin 50% POWDER**
	Label Claim	Each 100gm powder contains: Amoxicillin Trihydrate BP..... 50G Colistin sulphate BP..... 50MIU (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)at Room Temperature
	For generic drugs (me-too Status)	ATC-Forte Oral Water Soluble Powder (081695)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
467	Case Category	New Section (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	(Y25-W9P-JRYP, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Lin Spec E W/S POWDER**
	Label Claim	Each gm powder contains Amoxicillin Trihydrate Eq To Amoxicillin Base BP..... 200mg Lincomycin HCl Eq To Lincomycin BP..... 88mg Spectinomycin Sulphate EQ TO BASE BP..... 88mg Vitamin E Acetate BP..... 30mg (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)at Room Temperature
	For generic drugs (me-too Status)	Lincomoxel Plus Oral Powder (080960)

	Pharmacotherapeutic Group of (API)	Antibacteria
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
468	Case Category	New Section (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	(9RN-7S5-S6DN, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**NC-MOX 35 W/S POWDER**
	Label Claim	Each Kg powder contains Amoxicillin as Trihydrate BP..... 100g Colistin sulphate BP..... 50g Neomycin Sulphate BP..... 200g (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)at Room Temperature
	For generic drugs (me-too Status)	NEO AC W/S POWDER (079844)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
469	Case Category	New Section (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	(8U3-MEN-LLQ4, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**OXFO MOX 50% W/S POWDER**
	Label Claim	Each 1000gm powder contains Amoxicillin as Trihydarte BP..... 500g (BP Specification.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature

	For generic drugs (me-too Status)	AMOXI-50 WATER SOLUBLE (063848)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
470	Case Category	New Section (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	(424-R6S-893J, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**OXFO MOX 70% W/S POWDER**
	Label Claim	Each 100gm powder contains AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN BASE BP.....70G (BP Specification.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	PRIMOX W/S POWDER (074032)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
471	Case Category	New Section (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	(T3N-MVS-ZHMD, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**OXFO MOX 600 W/S POWDER**
	Label Claim	Each gm powder contains Amoxicillin Trihydrate eq to Amoxicillin BP..... 600mg (BP Specification.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	TRIGER W/S POWDER (080958)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
472	Case Category	New Section (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	(JRJ-W64-U9HZ, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**OXFO MOX 800 W/S POWDER**
	Label Claim	Each gm powder contains Amoxicillin Trihydrate 800mg eq to Amoxicillin Base BP.....918.23mg (BP Specification.)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)at Room Temperature
	For generic drugs (me-too Status)	DOKAMOX-80% W/S POWDER (082505)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
473	Case Category	New Section (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	(L71-34D-VAH2, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**OXFORD PRE MIX W/S POWDER**
	Label Claim	Each Kg powder contains Procaine Penicillin BP..... 12g Streptomycin Sulphate BP..... 36g Zinc Bacitracin BP..... 52g (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)at Room Temperature
	For generic drugs (me-too Status)	SPZ-100 Powder (072671)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
474	Case Category	New Section (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	(2YQ-574-SVED, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**SPIN C Ford 500 W/S POWDER**
	Label Claim	Each 100gm powder contains Lincomycin HCl BP..... 8.8g Spectinomycin HCL BP..... 8.8g Amoxicillin Trihydrate BP..... 20g (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)at Room Temperature
	For generic drugs (me-too Status)	AMOXPECLIN W/S POWDER (102086)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
475	Case Category	New Section (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	(UW3-659-DMXW, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Spin C Ford 1000 W/S POWDER**
	Label Claim	Each 100gm powder contains Lincomycin HCl BP..... 9g Spectinomycin 2HCL

		BP..... 8.8g Amoxicillin Trihydrate BP..... 20g (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)at Room Temperature
	For generic drugs (me-too Status)	LINCO SPEC-A W/S POWDER (073942)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
476	Case Category	New Section (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	(1RH-ZYP-E63M, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Spin C Ford Fort W/S POWDER**
	Label Claim	Each 1000gm powder contains Lincomycin HCl BP..... 8.8g Spectinomycin 2HCL BP..... 8.8g Amoxicillin Trihydrate BP..... 20g (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)at Room Temperature
	For generic drugs (me-too Status)	LINCOSAC-200 W/S POWDER (081696)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
477	Case Category	New Section (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	(PYJ-9UT-34XR, 2026-01-06)

	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Troz-C 23% W/S POWDER**
	Label Claim	Each 1000gm powder contains Amoxicillin As Trihydrate BP..... 230G Colistin sulphate BP..... 1000MIU Dextrose Anhydrous qs..... 1000g (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)at Room Temperature
	For generic drugs (me-too Status)	SENACILIN W/S POWDER (079845)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
478	Case Category	New Section (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	(1AL-E3Z-AP4P, 2026-01-06)
	Detail of Fee Submitted	38700, 2025-12-31,
	The proposed proprietary name / brand name	**Troz-C 50% W/S POWDER**
	Label Claim	Each 100gm powder contains Amoxicillin Trihydrate BP.....,,,,,.... 50G Colistin sulphate BP..... 50MIU Dextrose Anhydrous qs..... 100g (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)at Room Temperature
	For generic drugs (me-too Status)	EUROMOX-50 W/S POWDER (080156)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted Penicillin Oral Powder Section dated 14.11.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
479	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(9XD-EPN-ZWQD, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**PROLIUM BAK 90% W/S Powder**
	Label Claim	Each Gm contains Amprolium HCl ..... 900mg (USP Spec)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Ampro Arch 90% Oral Powder (121907)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the inspection findings, the facility has established the basic infrastructure, documentation system, quality management framework, and utility setup required for manufacturing Veterinary Oral Liquid and Oral Dry Powder (General) dosage forms. Al
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
480	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**PRIX PHARMACEUTICA** 26 - ABBOT ROAD, LAHORE **(034401D)**
	Application Form Dy. No / Tracking ID & date of submission	(G62-X6R-N9SN, 2025-12-01)
	Detail of Fee Submitted	313500, 2025-11-28,
	The proposed proprietary name / brand name	**TOLOMEC PLUS SOLUTION FOR INJECTION 500ML**
	Label Claim	EACH ML CONTAINS:- IVERMECTIN E.U.P ..... 10MG, CLORSULON U.S.P. 100MG
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500 ML-De-Controlled
	Shelf Life (Unit)	5 Year(s)BELOW 30 0C
	For generic drugs (me-too Status)	IVERMECTIN 1% , CLORSOLON 10 % INJECTION REG. NO.099466 BY MEHRAN INTERNATIONAL. KARACHI
	Pharmacotherapeutic Group of (API)	Endectocides
	Name, address of Manufacturing site:	FATRO S.P.A. -VIA EMILIA 285 - 40064 OZZANO DELL EMILIA (BO) ITALY-Italy
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
481	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(SEV-HQE-PSX7, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**PROLIUM BAK 50% W/S Powder**
	Label Claim	Each Gm contains: Amprolium HCL USP..... 500mg (USP Spec)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Ampro Arch 50% Powder (121906)
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
482	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(WSA-ASB-7NLE, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**PROLIUM BAK 60% W/S Powder**
	Label Claim	Each 100GM contains: Amprolium HCl USP..... 60GM (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	AMPROL 600 W/S powder (084943)
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.03.2026.
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
483	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(U85-D71-L2WE, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-04-09,
	The proposed proprietary name / brand name	**BAKE OXY 95% W/S POWDER**
	Label Claim	Each Gm powder contains Oxytetracycline Hcl BP..... 950mg (As Per Innovator Spec)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100g, 250g, 500g, 1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	Amsox-95% Oral W/S POWDER (101993)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm was granted DML dated 25.3.2026.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
484	Case Category	Import (Sara Mehreen)
	Name, address of Applicant.	**AL ASAR ENTERPRISES** GULSHAN E GULAB COLONY BEHIND ABDULLAH HEART CARE HOSPITAL, NEAR PULWASAL SURAJ MIANI ROAD MULTAN **(04-361-0159-96972D)**
	Application Form Dy. No / Tracking ID & date of submission	(J13-EJZ-ZJUW, 2025-11-18)
	Detail of Fee Submitted	313500, 2025-11-11,
	The proposed proprietary name / brand name	**VIME-COLISTIN**
	Label Claim	Each Gram Contains: Colistin Sulfate ..... 5,000,000 IU
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1kg-De-Controlled
	Shelf Life (Unit)	3 Year(s)Store in a dry place, below 30OC. Protected from light and moisture.
	For generic drugs (me-too Status)	Acme Col -60 Water Soluble Powder (Reg. # 116967)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	Vemedim Animal Health-Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District,

		Hau Giang Province,-Vietnam
	Name, address of Marketing Authorization Holder:	AL-ASAR ENTERPRISES, Gulshan E Gulab Colony, Behind Abdullah Heart Care Hospital, House No. 12, Near Pull Wasil Chowk, Suraj Miani Road, Multan - Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Firm provided copy of GMP certificate issued by Ministry of Agriculture & Rural Development, Vietnam.
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Free Sale Certificate mentions that " be permitted for free sale in Viet Nam and oversea markets". Moreover, Free Sale Certificate is issued by Provincial Peoples Committee rather than Department of Animal health, Vietnam. Firm was asked for clarification & they replied as "In line with recent administrative innovations to streamline and shorten procedures for exporters, the Government of Vietnam has delegated the authority to issue CFSs to the Provincial People's Committees for products manufactured within their respective jurisdictions. Consequently, the CFS for Colistin was issued by the Can Tho City People's Committee". Submitted for consideration of the Board, please.	
	Decision	
	Deferred Deferred for confirmation of Free Sale Status in country of origin and issuing authority of FSC.	
485	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)**
	Application Form Dy. No / Tracking ID & date of submission	(U42-YUD-AG1T, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	**Pacionden 4mg/5ml Syrup**
	Label Claim	Each 5ml contains Ondansetron Hydrochloride eq.to Ondansetron.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	Onseron 4mg/5ml Syrup by Indus Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Lifesciences Pvt. Ltd.-Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230 Gujrat, 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	MHRA-Ondansetron 4mg/5ml Syrup by Focus Pharmamaceuticals Ltd, Dashwood House, 69

		Old Broad Street, London, EC2M 1QS, UK
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	I am writing on behalf of Pacific Pharmaceuticals Ltd. to formally request the withdrawal of this application (U42-YUD-AG1T) currently under your evaluation.	
	Decision	
	Rejected The Registration Board acceded to request of firm for the withdrawal of this application (U42-YUD-AG1T).	
486	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Hicon Pharmaceuticals** 131- Industrial estate Hayatabad **(000583)**
	Application Form Dy. No / Tracking ID & date of submission	(SS1-24Q-DW3H, 2024-09-27)
	Detail of Fee Submitted	37000.0, 2024-09-23,
	The proposed proprietary name / brand name	**Diclocon SR 100mg Tablet**
	Label Claim	Each sustained release tablet contains; Diclofenac Sodium 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree
	For generic drugs (me-too Status)	diclox 100mg sr tablet by winsfield pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	aarti drugs limited 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	diclofena sodium sr tablet usfda approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
487	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	**Focus & Rulz Pharmaceuticals (Pvt) Ltd** 44 - Industrial Triangle, Kahuta Road **(000628)**
	Application Form Dy. No / Tracking ID & date of submission	(9HV-XT2-X266, 2024-10-23)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-24, 2024-10-04
	The proposed proprietary name / brand name	**Omper 40mg Capsule**

	Label Claim	Each delayed release capsule contains: Omeprazole as enteric coated pellets 8.5% w/w omeprazole - 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 x 7's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25° C.
	For generic drugs (me-too Status)	Risek 40mg Capsule
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Saakh Pharm (Pvt) Ltd
	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	PRILOSEC (omeprazole) Delayed-Release Capsule
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
488	Case Category	Routine (Sara Mehreen)
	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	(4TN-AV1-1QLT, 2024-10-23)
	Detail of Fee Submitted	75000.0, 2024-09-16,
	The proposed proprietary name / brand name	**NIMS 100mg Granules for Oral Suspension**
	Label Claim	Each sachet of granules for oral suspension contain: Nimesulide.....100mg Innovator's Specs.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 YearDo not store over 30°C
	For generic drugs (me-too Status)	NA
	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	EFRIDOL 100mg Granules for Oral Suspension, AIFA approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm conducted CDP at pH 6.4, 7.4 & 7.8. They were asked about not submitting CDP data at pH 1.2 & 4.5. In reply, they submitted that: "According to World Health Organization guideline, dissolution testing should be conducted under conditions that ensure adequate solubility and discriminatory capability. Similarly, United States Food and Drug Administration (FDA) and European Medicines Agency recommend avoiding conditions where sink conditions cannot be maintained, as results may be misleading and not suitable for comparison. Therefore, CDP was performed in pH 6.8, 7.4, and 7.8 buffers with addition of tween 80 to enhance the dissolution profile, where adequate solubility and sink conditions were achieved, providing reliable and discriminatory dissolution profiles. These media are also biorelevant to intestinal conditions, the primary site of absorption for Nimesulide". Dissolution data of innovator is not available publicly. However, there are research papers those have reported dissolution behavior of Aulin granules and used them as comparator products and this data aligns with applied product's data. firm has not provided data at pH 1.2 & 4.5.	
	Decision	
	Approved	
489	Case Category	Routine (Sara Mehreen)
	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	(VGJ-ULU-8MJP, 2024-12-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-28, 2024-11-05
	The proposed proprietary name / brand name	**Nimesil 100mg Tablets**
	Label Claim	Each tablet contains: Nimesulide BP.....100mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Mesulid100mgTablets
	Pharmacotherapeutic Group of (API)	Cyclooxygenase Inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm provided 6 months stability studies data of three trial batches manufactured.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm provided document for borrowing of API from M/s Global Pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm provided pharmaceutical equivalence and comparative dissolution profile data.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	ALGIMESIL tablet 100 mg (Italy Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has Tablet Section (General) vide letter dated 17.01.2024.
	Evaluation Remarks	

	Firm was asked that "Nimesulide is BCS class II drug with low solubility & high permeability. It's a weak acid drug. Drug shows dissolution in basic media. Applied product along with reference product showing 93% and 91% dissolution at pH1.2 respectively. Firm has added Dioctyl sodium sulfosuccinate as surfactant to enhance dissolution. Dissolution of applied product decreases with increase in pH that is contrary to properties of drug.You are requested to provide reference for method and acceptable criteria. Firm replied as "Nimesulide tablets are not described in any official pharmacopeia, and no compendial dissolution method or specification is available. The innovator product is approved by the EMA; however, no publicly available information on dissolution specifications for the reference product has been identified from the EMA, MHRA, or FDA. The dissolution method was developed in accordance with the FDA guidance Dissolution Testing of Immediate Release Solid Oral Dosage Forms." In the absence of official or published specifications, dissolution limits and acceptance criteria were established based on comparative dissolution profiling against the reference(innovator) product. The proposed dissolution specification is derived from Comparative dissolution profiles (test vs. reference product). The analytical method used for dissolution sample quantification is provided in the enclosed documentation". Nimesulide is a poorly soluble acidic BCS Class II drug substance. Dissolution of weak acidic drugs increases with increasing pH due to enhanced ionization and solubility in intestinal media. However, the applied product demonstrates the unusually highest dissolution in strongly acidic medium (pH 1.2) and reduced dissolution at higher pH values (pH 4.5 and 6.8), which is contrary to the expected dissolution behavior of the drug substance. Published scientific literature on Nimesulide formulations reports poor dissolution in acidic media and improved dissolution only in higher pH surfactant-containing systems. Submitted for consideration of the Board, please.	
	Decision	
	Deferred The Registration Board in its 358th meeting held on 12.05.2026, decided that samples of the applied product be sent to the CDL for testing and analysis at the firm's expense.	
490	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Max Pharmaceuticals** Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 **(000671)**
	Application Form Dy. No / Tracking ID & date of submission	(8Z3-3NV-D6LX, 2024-10-18)
	Detail of Fee Submitted	37000.0, 9400 2024-10-03, 2026-04-17
	The proposed proprietary name / brand name	**Dexzole**
	Label Claim	Each Capsule contains: Dexlansoprazole (dual delayed release pellets) eq. to Dexlansoprazole.....30mg The Product Complies Manufacturer's Specs.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	3 x 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Delanzo DDR Capsule 30mg, Sami Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Winbrains Research Laboratories.
	Detail of stability batches of drug product	Three production batches having 18000 cap batch size
	Documents for the procurement of API with approval from DRAP	Locally purchased M/s Winbrains

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 30 mg capsules by Sami”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant, Takeda Pharmaceuticals, PMDA
	GMP status of the firm	3-106/2023-Add.dir (Qa-Lt-1-44) 16.06.23 Firm has applied for cGMP certificate dated 12.02.25
	Evidence of approval of manufacturing facility	No F.1-103/2005-Lic dated 07-07-2021 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
491	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)**
	Application Form Dy. No / Tracking ID & date of submission	(9Q3-B5D-64U3, 2024-07-16)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	**Dexlen 30mg DDR Capsules**
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Dextol 30mg DDR Capsule by M/s Seraph Pharmaceutical,
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals, Islamabad, Pakistan
	Detail of stability batches of drug product	Three production batches having 1500 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	DEXILANT 30 mg capsules by Acino”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant 30mg Capsule by Takeda Pharmaceuticals America, Inc.
	GMP status of the firm	3.4.23
	Evidence of approval of manufacturing facility	No F.1-16/2013-Lic dated 05-03-2019 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	

	Approved	
492	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(A2P-BU9-DADU, 2024-08-16)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Gufxime 400mg Capsules**
	Label Claim	Each hard gelatin capsule contains: Cefixime trihydrate equivalent to Cefixime .....400 mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-De-Controlled
	Shelf Life (Unit)	2 Year(s)15°C to 25°C
	For generic drugs (me-too Status)	Cefspan 400mg Capsule
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	Linta Pharmaceuticals-Plot No.3,Street S-5, RCCI, Rawat-
	Name & address of API manufacturer	Citi Pharma Pvt Limited Address: 3-Km, Head Baloki road, Bhai Phero, Distric Kasur
	Detail of stability batches of drug product	1000 cap each 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	local purchase
	Pharmaceutical Equivalence and Comparative Dissolution Profile	"Cefspan 400 mg capsuleof Glaxosmithkline Pharmaceuticals Ltd."
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Suprax capsule, of Lupin Pharmaceuticals Inc Manufactured by: Lupin Pharmaceuticals, Inc. Harborplace Tower 111 S. Calvert Street, 21st Floor Baltimore, MD 21202 Phone: 866-587-4617 Fax: 866-587-4627 Email: customerservice@lupinusa.com (for US marketed products only)
	GMP status of the firm	Certificate no 3-42/2019-Addl Dir(Qa-lt-1) dated 13-03-24 M/S Linta Pharmaceuticals Pvt. Ltd contract acceptor
	Evidence of approval of manufacturing facility	No F.1-4/2011-Lic dated 07-07-21 mentioning capsule cephalosporin section
	Evaluation Remarks	
	3.2.p.8.3: The analytical specification's adopted for flow rate by the firm were: Flow rate: 1ml/minute, however pharmacopoeia guides to Adjust flow rate so that the retention time of cefexime is about 10 min however it seems that the said flow rate is not adjusted as per pharmacopoeia as the chromatogram shows the retention time between 7.9-8.6 minutes' justification required. The analytical specifications for Injection volume 10µL,	As per pharmacopoeia which says that adjust the flow rate so that the retention time is about 10 minutes. As the retention time on flow rate 1ml per minute is 8.6 which is near to 10 minutes which complies the pharmacopoeia. More over we will adjust flow rate exact up to 10 minutes when we manufacture commercial batch It was over looked . In commercial batches we will keep injection volume 10uL instead of 20uL. We have already performed system suitability but at the

	however chromatogram shows Injection volume 20µL pharmacopoeia. System suitability solution for cefixime (E)-isomer and cefixime are not performed justification required	time of submission of application this was not required. Now we submit system suitability record.
	Decision	
	Approved	
493	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)**
	Application Form Dy. No / Tracking ID & date of submission	(EX3-EA4-19U2, 2024-07-09)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	**Dexlen 60mg DDR Capsules**
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Dextol 60mg DDR Capsule by M/s Seraph Pharmaceuticals, Islamabad
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals, Islamabad, Pakistan
	Detail of stability batches of drug product	Three production batches having 1500 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	DEXILANT 60mg capsules by Acino”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant 60mg Capsule by Takeda Pharmaceuticals America, Inc.
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	No F.1-16/2013-Lic dated 05-03-2019 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
494	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**GILLMAN PHARMACEUTICALS** 41/2-A, PHASE I & II, INDUSTRIAL ESTATE, HATTAR **(000683)**
	Application Form Dy. No / Tracking ID & date of submission	(JNQ-MNH-E8X6, 2024-08-28)

	Detail of Fee Submitted	75000.0, 2024-08-06,
	The proposed proprietary name / brand name	**GILSPAN 100mg/5ml Dry Suspension**
	Label Claim	Each 5ml of suspension contains: Cefixime trihydrate equivalent to Cefixime .....100 mg (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)Below 30C
	For generic drugs (me-too Status)	Cefspan Dry suspension Manufacturer: Barrett Hodgson Pakistan
	Pharmacotherapeutic Group of (API)	Cephalosporin ANTIINFECTIVES
	Name, address of Manufacturing site:	LINTA PHARMACEUTICALS PVT. LTD.-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad, Pakistan-
	Name & address of API manufacturer	Citi Pharma Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab,
	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)	City pharmaceutical Locally purchased
	Pharmaceutical Equivalence and Comparative Dissolution Profile	"Cefspan 100 mg/5ml Dry suspension of Glaxosmithkline Pharmaceuticals Ltd."
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	www.medicines.org.uk
	GMP status of the firm	Certificate no 3-42/2019-Addl Dir(Qa-lt-1) dated 13-03-24 M/S Linta Pharmaceuticals Pvt. Ltd contract acceptor
	Evidence of approval of manufacturing facility	No F.1-4/2011-Lic dated 07-07-21 mentioning dry suspension cephalosporin section
	Evaluation Remarks	
	3.2.p.8.3: The analytical specification's adopted for flow rate by the firm were: Flow rate: 1ml/minute, however pharmacopoeia guides to Adjust flow rate so that the retention time of cefexime is about 10 min however it seems that the said flow rate is not adjusted as per pharmacopoeia as the chromatogram shows the retention time between 7.9-8.6 minutes' justification required. The analytical specifications for Injection volume 10µL, however chromatogram shows Injection volume 20µL pharmacopoeia. System suitability solution for cefixime (E)-isomer and cefixime are not performed justification required	As per pharmacopoeia which says that adjust the flow rate so that the retention time is about 10 minutes. As the retention time on flow rate 1ml per minute is 8.6 which is near to 10 minutes which complies the pharmacopoeia. More over we will adjust flow rate exact up to 10 minutes when we manufacture commercial batch It was over looked . In commercial batches we will keep injection volume 10uL instead of 20uL. We have already performed system suitability but at the time of submission of application this was not required. Now we submit system suitability record.
	Decision	
	Approved	
495	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**

Application Form Dy. No / Tracking ID & date of submission	(LMT-9Z6-QMWU, 2024-07-10)
Detail of Fee Submitted	75000.0, 2024-06-26,
The proposed proprietary name / brand name	**Gufxime 200mg/5ml Dry suspension**
Label Claim	Each 5ml of suspension contains: Cefixime trihydrate equivalent to Cefixime .....200 mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	30ml suspension afte-De-Controlled
Shelf Life (Unit)	2 Year(s)15°C to 25°C
For generic drugs (me-too Status)	Zixpro 200mg/5ml Dry suspension
Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
Name, address of Manufacturing site:	Linta Pharmaceuticals-Plot No.3,Street S-5, RCCI, Rawat-
Name & address of API manufacturer	Citi Pharma Pvt Limited Address: 3-Km, Head Baloki road, Bhai Phero, Distric Kasur
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)	Citi pharma
Pharmaceutical Equivalence and Comparative Dissolution Profile	“Cefspan 200 mg/5ml Dry suspension of Glaxosmithkline Pharmaceuticals Ltd.”
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Suprax Oral Suspension USP, of Lupin Pharmaceuticals Inc Manufactured by: Lupin Pharmaceuticals, Inc. Harborplace Tower 111 S. Calvert Street, 21st Floor Baltimore, MD 21202 Phone: 866-587-4617 Fax: 866-587-4627 Email: customerservice@lupinusa.com (for US marketed products only)
GMP status of the firm	Certificate no 3-42/2019-Addl Dir(Qa-lt-1) dated 13-03-24 M/S Linta Pharmaceuticals Pvt. Ltd contract acceptor
Evidence of approval of manufacturing facility	No F.1-4/2011-Lic dated 07-07-21 mentioning dry suspension cephalosporin section

Evaluation Remarks

3.2.p.8.3: The analytical specification’s adopted for flow rate by the firm were: Flow rate: 1ml/minute, however pharmacopoeia guides to Adjust flow rate so that the retention time of cefexime is about 10 min however it seems that the said flow rate is not adjusted as per pharmacopoeia as the chromatogram shows the retention time between 7.9-8.6 minutes’ justification required. The analytical specifications for Injection volume 10µL, however chromatogram shows Injection volume 20µL pharmacopoeia. System suitability solution for cefixime (E)-isomer and cefixime are not performed justification required	As per pharmacopoeia which says that adjust the flow rate so that the retention time is about 10 minutes. As the retention time on flow rate 1ml per minute is 8.6 which is near to 10 minutes which complies the pharmacopoeia. More over we will adjust flow rate exact up to 10 minutes when we manufacture commercial batch It was over looked . In commercial batches we will keep injection volume 10uL instead of 20uL. We have already performed system suitability but at the time of submission of application this was not required. Now we submit system suitability record.

Decision

	Approved	
496	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**GILLMAN PHARMACEUTICALS** 41/2-A, PHASE I & II, INDUSTRIAL ESTATE, HATTAR **(000683)**
	Application Form Dy. No / Tracking ID & date of submission	(X6G-A1R-MBRS, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-06,
	The proposed proprietary name / brand name	**GILSPAN 200mg/5ml Dry Suspension**
	Label Claim	Each 5ml of suspension contains: Cefixime trihydrate equivalent to Cefixime .....200 mg (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)Below 30C
	For generic drugs (me-too Status)	Cefspan Dry suspension Manufacturer: Barrett Hodgson Pakistan
	Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
	Name, address of Manufacturing site:	LINTA PHARMACEUTICALS PVT. LTD.-Plot No. 03, Street No. S-5 National Industrial Zone, Rawat, Islamabad, Pakistan.-
	Name & address of API manufacturer	CITI PHARMA LIMITED 3 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR
	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)	Citi pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	“Cefspan 200 mg/5ml Dry suspension of Glaxosmithkline Pharmaceuticals Ltd.”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	www.medicines.org.uk
	GMP status of the firm	Certificate no 3-42/2019-Addl Dir(Qa-lt-1) dated 13-03-24 M/S Linta Pharmaceuticals Pvt. Ltd contract acceptor
	Evidence of approval of manufacturing facility	No F.1-4/2011-Lic dated 07-07-21 mentioning dry suspension cephalosporin section
	Evaluation Remarks	
	3.2.p.8.3: The analytical specification’s adopted for flow rate by the firm were: Flow rate: 1ml/minute, however pharmacopoeia guides to Adjust flow rate so that the retention time of cefexime is about 10 min however it seems that the said flow rate is not adjusted as per pharmacopoeia as the chromatogram shows the retention time between 7.9-8.6 minutes’ justification required. The analytical specifications for Injection volume 10µL, however chromatogram shows Injection volume 20µL pharmacopoeia. System suitability solution for cefixime (E)-isomer and cefixime are not performed justification required	As per pharmacopoeia which says that adjust the flow rate so that the retention time is about 10 minutes. As the retention time on flow rate 1ml per minute is 8.6 which is near to 10 minutes which complies the pharmacopoeia. More over we will adjust flow rate exact up to 10 minutes when we manufacture commercial batch It was over looked . In commercial batches we will keep injection volume 10uL instead of 20uL. We have already performed system suitability but at the time of submission of application this was not required. Now we submit system suitability record.

	Decision	
	Approved	
497	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Max Pharmaceuticals** Plot #12, Street # N-7, National Industrial Zone, Rawat, Islamabad. 44000 **(000671)**
	Application Form Dy. No / Tracking ID & date of submission	(XP2-9QM-LGHY, 2024-10-18)
	Detail of Fee Submitted	37000.0, 9400 2024-10-03, 2026-04-17
	The proposed proprietary name / brand name	**Dexzole**
	Label Claim	Each Capsule Contains: Dexlansoprazole (dual delayed release pellets) Eq. to Dexlansoprazole.....60mg The Product Complies Manufacturer's Specifications.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Delanzo DDR Capsule 60mg, Sami Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Winbrains Research Laboratories.
	Detail of stability batches of drug product	Three production batches having 18000 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Winbrains
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 30 mg capsules by Sami”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant, Takeda Pharmaceuticals, PMDA
	GMP status of the firm	3-106/2023-Add.dir (Qa-Lt-1-44) 16.06.23 Firm has applied for cGMP certificate dated 12.02.25
	Evidence of approval of manufacturing facility	No F.1-103/2005-Lic dated 07-07-2021 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
498	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)**
	Application Form Dy. No / Tracking ID & date of submission	(Z78-ASQ-21ZE, 2024-10-09)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-02, 2024-09-10
	The proposed proprietary name / brand name	**Fusicon Cream 2%**

	Label Claim	Each gram contains: Fusidic Acid B.P.....20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10gram-As per SRO,15gram-As per SRO,20gram-As per SRO,5gram-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a dry place
	For generic drugs (me-too Status)	Brand name: Fudic Cream 2% Manufacturer: M/s Shaigan Pharmaceutical (PVT) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	3 batches Batch Size 1000g
	Documents for the procurement of API with approval from DRAP (in case of Import)	form-6-949766821437 Fusidic acid andd commercial invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fucider H cream Leo pharmaceutical
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	Brand Name: FUCIDIN® CREAM 2% Manufacturer: LEO Pharma Inc. - Health Canada
	GMP status of the firm	Certificate no F.11-6/2023-dRAP-198 dated 10-08-23
	Evidence of approval of manufacturing facility	No F.3-14/2004-Lic dated 26-10-20 mentioning cream section
	Evaluation Remarks	
	3.2.P.8.3 As per B.P pharmacopeia when the chromatograms are recorded using the prescribed conditions, the retention time of fusidic acid is about 18 minutes. Chromatograms attached shows retention time at 13.5 minutes. justify	As per B.P. monograph recommended column is Waters Symmetry C18 whereas we utilize Waters XBridge Shield RP18. Both columns are equivalent in term of dimensions and packing material i.e. stationary phase but are of different brands. The difference in retention time may be due to utilization of different brand column. However, We have performed analytical method verification studies (report attached) which shows system suitability, theoretical plates and tailing factory. Furthermore, revised method of analysis considering B.P. recommended column is attached for your review and the same will be utilized for analysis of commercial batches.
	Decision	
	Approved	
499	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Meditech Pharmaceuticals** Plot No. 83-A,83-B, Industrial Estate, Hayatabad, Peshawar **(000544)**
	Application Form Dy. No / Tracking ID & date of submission	(1ZG-GD9-RLGB, 2024-11-05)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-04, 2024-10-24
	The proposed proprietary name / brand name	**Dexilon**
	Label Claim	Each Capsule contains: Dual delayed release dexlansoprazole Pellets eq to Dexlansoprazole .....30mg (Innovator’s Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30 Capsules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Delanzo DDR Capsules by Sami Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	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 production batches having 28 packs batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Delanzo 30 mg capsules by Sami"
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	FDA
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	No F.3-4/2021-Lic dated 24-08-2022 mentioning capsule section
	Evaluation Remarks	
	Firm has submitted manual log for hplc audit trail	
	Decision	
	Rejected Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.	
500	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(7XW-WDL-YBMM, 2024-04-30)
	Detail of Fee Submitted	30000.0, 2024-02-27,
	The proposed proprietary name / brand name	**Acogut 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains Acotiamide HCl Hydrate.....100mg
	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 cool &dry place below 30
	For generic drugs (me-too Status)	Dyspenal Tablet 100mg M/s Kaizen Pharma Pvt Ltd Approved in minutes of Meeting 333
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited Address: Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).

	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	Acofide Tablets 100 mg (Acotiamide Hydrochloride Hydrate) M/sZeria Pharmaceutical Co., Ltd (PMDA App
	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	
501	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	(WYQ-MLB-PYNA, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-06-27,
	The proposed proprietary name / brand name	**Macedol 1g IV INFUSION**
	Label Claim	Macedol 1g IV INFUSION Each 100ml contains: Paracetamol.....1g (BP Specifications).
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)	Provas infusion by M/s Sami pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Analgesic
	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)	local M/s Pharmagen.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Provas infusion by M/s 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	237/2025-Drap 22-1-25. last inspection report
	Evidence of approval of manufacturing facility	1-24/2015-Lic 3.02.25.
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	

	Decision	
	Approved	
502	Case Category	Contract Manufacturing (Shahrukh Ali)
	Name, address of Applicant.	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore **(000577)**
	Application Form Dy. No / Tracking ID & date of submission	(SP9-4LB-U4EP, 2024-07-09)
	Detail of Fee Submitted	75000.0, 2024-05-23,
	The proposed proprietary name / brand name	**Ceftam Injection 1gm**
	Label Claim	Each vial contains Cefoperazone sodium 500mg and Sulbactam sodium 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C
	For generic drugs (me-too Status)	Healthtek private limited
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhuhai united laboratories Co., ltd
	Detail of stability batches of drug product	Batch size Three trial batches/497 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	2SUM Injection 1 gm B. No AOK015 Healthtek Pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	PMDA
	GMP status of the firm	Certificate no 210/2023 dated 15-12-23
	Evidence of approval of manufacturing facility	No F.1-29/2001-Lic(vol-I) dated 25-08-2010 mentioning dry powder injection section cephalosporin
	Evaluation Remarks	
	Dear Sir We would like to request your kind consideration regarding the Ceftam 1gm injection & 2GM injection, which was applied through our portal. We want to upload both of these products on the Skimes Pharma portal because these products were mistakenly uploaded on Shrooq Pharmaceuticals portal. In this regard, we humbly request that the fee submitted for this application may kindly be allowed to be adjusted or utilized against another dossier. Following details are mentioned below: Ceftam Injection 2gm challan No. 89498421 Rs-/ 75000 Ceftam Injection 1gm challan No. 7018405016 Rs-/ 75000 We shall be grateful for your cooperation and assistance in this matter.	
	Decision	
	Rejected The request for firm to withdraw application is acceded. Application will be submitted by contract giver	
503	Case Category	New Section (Shahrukh Ali)
	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	(S1A-2M4-MJJT, 2026-02-13)

	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Resoair 10mg Tablet**
	Label Claim	Each film coated tablet contains: Rosuvastatin as rosuvastatin calcium.....10mg
	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)	Rosomed 10mg Tablet
	Pharmacotherapeutic Group of (API)	Statin class of drugs: HMG-CoA reductase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories 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)	Loan M/s Novamed pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rosomed 5mg Tablet B.NO. 19456
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life attached
	The status in reference regulatory authorities	Crestor 10mg tablet (USFDA Approved)
	GMP status of the firm	Certificate No: GMP-C-56DFD1 Date of Issue: 01/12/2025 GMP certificate valid till 01.12.2028 is submitted.
	Evidence of approval of manufacturing facility	1.26.2019 Tablet section[General] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Loan from M/s Novamed Pharmaceuticals	
	Decision	
	Deferred Deferred for verification of authenticity of submitted data.	
504	Case Category	New Section (Shahrukh Ali)
	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	(PHP-9PY-XUSD, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Resoair 20mg Tablet**
	Label Claim	Each film coated tablet contains: Rosuvastatin as rosuvastatin calcium.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)store items below 30 C
	For generic drugs (me-too Status)	Rosomed 20mg Tablet
	Pharmacotherapeutic Group of (API)	Statin class of drugs: HMG-CoA reductase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories 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)	Loan M/s Novamed pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rosomed 20mg Tablet B.NO. 19455
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life attached
	The status in reference regulatory authorities	Crestor 20mg (USFDA Approved)
	GMP status of the firm	Valid GMP and attached
	Evidence of approval of manufacturing facility	1.26.2019 Tablet section[General] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Loan from M/s Novamed Pharmaceuticals	
	Decision	
	Deferred Deferred for verification of authenticity of submitted data.	
505	Case Category	New Section (Shahrukh Ali)
	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	(JLP-64U-HB51, 2026-02-13)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**Resoair 5mg Tablet**
	Label Claim	Each film coated tablet contains: Rosuvastatin as rosuvastatin calcium.....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)	Rosomed 5mg Tablet
	Pharmacotherapeutic Group of (API)	Statin class of drugs: HMG-CoA reductase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories 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)	Loan M/s Novamed pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Rosomed 5mg Tablet B.NO. 19456
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data till shelf life attached
	The status in reference regulatory authorities	Crestor 5mg tablet (USFDA Approved)
	GMP status of the firm	Certificate No: GMP-C-56DFD1 Date of Issue: 01/12/2025
	Evidence of approval of manufacturing facility	1.26.2019 Tablet section[General] granted vide letter dated 4.02.2025
	Evaluation Remarks	
	Loan from M/s Novamed Pharmaceuticals	

	Decision	
	Deferred Deferred for verification of authenticity of submitted data.	
506	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Danas Pharmaceuticals (Pvt) Ltd.** 312-Industrial Triangle, Kahuta road,Islamabad. **(000569)**
	Application Form Dy. No / Tracking ID & date of submission	(EVM-7T7-U7DL, 2024-10-21)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-09-26
	The proposed proprietary name / brand name	**LANZOP-D**
	Label Claim	Each capsule contains: Dexlansoprazole Dual Delayed release pellets eq. to Dexlansoprazole 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30 degree centigrade
	For generic drugs (me-too Status)	Dextol 30mg DDR Capsule (Seraph Pharma)
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor WHO ATC code: A02BC06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals Pvt Ltd Islamabad
	Detail of stability batches of drug product	Three production batches having 1500 cap batch size
	Documents for the procurement of API with approval from DRAP (in case of Import)	Locally purchased M/s Vision
	Pharmaceutical Equivalence and Comparative Dissolution Profile	DEXILANT 30 mg capsules by Acino”
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Dexilant 30mg Capsule (Takeda Pharmaceuticals America, Inc. USA)
	GMP status of the firm	3-103/2023-Add.dir (Qa-Lt-1-44) 10.01.23
	Evidence of approval of manufacturing facility	No F.1-44/2003-Lic dated 21-02-2023 mentioning capsule section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Deferred The board decided to defer the instant application for verification of audit trail report/system log	
507	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(GVT-2EU-1EBA, 2025-05-05)

	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	**Cip-Rx Dry Powder Oral Suspension 250mg**
	Label Claim	Cip-Rx Dry Powder Oral Suspension 250mg Each 5ml contains: Ciprofloxacin 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30ºC
	For generic drugs (me-too Status)	Manufacturer Name: Sami Pharmaceuticals Pvt Ltd Brand Name: Novidat Suspension 125mg/5ml
	Pharmacotherapeutic Group of (API)	fluoroquinolones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE LABORATORIES (PVT) LTD.
	Detail of stability batches of drug product	3 batches 100 bottle each
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Surge pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Novidat Suspension 250mg/5ml
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Bayer plc 400 South Oak Way Reading RG2 6AD, UK
	GMP status of the firm	117/2024-Drap(AD-994015369) 01.07.24
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
508	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(RM6-M2A-LRRJ, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2025-02-10,
	The proposed proprietary name / brand name	**THERACID-250mg SUSPENSION**
	Label Claim	Each 5ml contains: 27.5 % of Clarithromycin taste mask granules.... 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30ºC
	For generic drugs (me-too Status)	Klaricid Suspension 250mg/5ml
	Pharmacotherapeutic Group of (API)	Antibiotics (Macrolide)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE LABS
	Detail of stability batches of drug product	3 batches 100 bottles each

	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased from M/s surge
	Pharmaceutical Equivalence and Comparative Dissolution Profile	“klaricid suspension of Abbot laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Mylan Products Ltd. 20 Station Close Potters Bar Herts EN6 1TL United Kingdom
	GMP status of the firm	117/2024-Drap(AD-994015369) 01.07.24
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning Tablet general section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
509	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(Y18-M27-GJ7V, 2025-05-05)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	**Cip-Rx Dry Powder Oral Suspension 125mg**
	Label Claim	Cip-Rx Dry Powder Oral Suspension 125mg Each 5ml contains: Ciprofloxacin 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30ºC
	For generic drugs (me-too Status)	Manufacturer Name: Sami Pharmaceuticals Pvt Ltd Brand Name: Novidat Suspension 125mg/5ml
	Pharmacotherapeutic Group of (API)	fluoroquinolones
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE LABORATORIES (PVT) LTD.
	Detail of stability batches of drug product	3 batches 100 bottle each
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Surge pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Novidat Suspension 125mg/5ml M/s Sammi pharmaceuticals
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Bayer plc 400 South Oak Way Reading RG2 6AD, UK
	GMP status of the firm	117/2024-Drap(AD-994015369) 01.07.24
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	

	Decision	
	Approved	
510	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(ZEY-GP6-G1D1, 2025-08-19)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	**Famtac Suspension 40mg/5mL**
	Label Claim	Each 5ml contains: Famotidine.....40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30ºC
	For generic drugs (me-too Status)	Manufacturer Name: Wilson's Pharmaceuticals Brand Name: Polypep Suspension
	Pharmacotherapeutic Group of (API)	Antiulcerative
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: RO-464F23 Date of Issue: 17-01-2025
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Polypep Suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	USFDA APPROVED REFERENCE: Merck & Co., Inc., Whitehouse Station , NJ 08889, USA
	GMP status of the firm	117/2024-Drap(AD-994015369) 01.07.24
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning dry powder suspension section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
511	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**Axis Pharmaceuticals (Pvt) Ltd** 3-B, vale Addition City, 1.5Km Khurrianwala- Sahianwala Road Faisalabad **(000667)**
	Application Form Dy. No / Tracking ID & date of submission	(ZUT-AQX-V7TZ, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	**Cefotax Injection 500mg IV/IM**
	Label Claim	Each vial contains cefotaxime (as sodium) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO

	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Claforan 0.5g Injection
	Pharmacotherapeutic Group of (API)	Antiinfective for systemic use (3rd generation cephalosporins)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Henan Kangda Pharmaceuticals co.,Ltd
	Detail of stability batches of drug product	3 Batch manufactured each having 2000 vials batch sizes
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan taken from Medisave pharma dated 17-6-2024 is provided.Intimation of loan in DRAP is provided dated 13-05-2025
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies are conducted against Claforan 0.5g Injection of Sanofi-aventis Pakistan Ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 Batches of API As per Zone IV-A
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 3-7-2024
	Evidence of approval of manufacturing facility	letter for issurance of Ceph section approval dated 23-08-2024
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
512	Case Category	Routine (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	(2AR-4EH-9ZTG, 2024-10-23)
	Detail of Fee Submitted	93000.0, 2024-10-07,
	The proposed proprietary name / brand name	**Cexon**
	Label Claim	Each Vial contains:Ceftriaxone Sodium Eq. to Ceftriaxone.....250mg(USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature below 30oC. void exposure to light, heat, and humidity.
	For generic drugs (me-too Status)	Oxidil Injection IV 250mg by Sami Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	3rd Generation Cephalosporin Antibiotic
	Name, address of Manufacturing site:	SHROOQ Pharmaceuticals (Pvt.) Ltd.-21-Km Ferozpur Road, Lahore.-
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd No. 2428, Anji Road, Sanzao Town, Jinwan District,Zhuhai, Guangdong-519040, P.R. China.
	Detail of stability batches of drug product	Batch Size: 500 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	7783959273614 dated 22.12.23

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection IV 250mg LYM002
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Rocephin Injection 250mg USFDA
	GMP status of the firm	Certificate no 210/2023 dated 15-12-23 contract acceptor
	Evidence of approval of manufacturing facility	No F.1-29/2001-Lic(vol-I) dated 25-08-2010 mentioning dry powder injection section cephalosporin

Evaluation Remarks

3.2.P.2.2.1 Pharmaceutical Equivalence Reason required for not performing following tests Particulate Matter In Injections, Crystallinity, BACTERIAL ENDOTOXINS TEST, STERILITY TESTS	Just sheets attached
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Firm has claimed that their API doesn't contain e-isomer hence no testing required
3.2.P.8 Stability: · Ph value is out of specs in 6 month accelerated study justification required · Tailing factor: NMT 2, as per USP however in STD initial month standard its out of specs System suitability is not performed as per USP monograph. lacks system suitability as provided in assay by USP monograph.	Firm has changed stability summary sheets and Ph value for 6th month

Decision

Rejected

The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited pharmaceutical equivalence data on expired batches and submission of revised stability summary sheets with visible correction of Ph from 9.89 to 6,89 by the applicant, the Board decided to reject the case

513	Case Category	Routine (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	(9D8-RA5-J16U, 2024-10-23)
	Detail of Fee Submitted	93000.0, 2024-10-07,
	The proposed proprietary name / brand name	**Cexon**
	Label Claim	Each Vial contains:Ceftriaxone Sodium Eq. to Ceftriaxone.....1gm(USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature below 30oC. void exposure to light, heat, and humidity.
	For generic drugs (me-too Status)	Oxidil Injection IV 1gm by Sami Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	3rd Generation Cephalosporin Antibiotic

	Name, address of Manufacturing site:	SHROOQ Pharmaceuticals (Pvt.) Ltd.-21-Km Ferozpur Road, Lahore.-
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd No. 2428, Anji Road, Sanzao Town, Jinwan District,Zhuhai, Guangdong-519040, P.R. China.
	Detail of stability batches of drug product	Batch Size: 500 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	7783959273614 dated 22.12.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection IV 1000mg LYM002
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Rocephin Injection 1gm USFDA
	GMP status of the firm	Certificate no 210/2023 dated 15-12-23 contract acceptor
	Evidence of approval of manufacturing facility	No F.1-29/2001-Lic(vol-I) dated 25-08-2010 mentioning dry powder injection section cephalosporin

Evaluation Remarks

3.2.P.2.2.1 Pharmaceutical Equivalence Reason required for not performing following tests Particulate Matter In Injections, Crystallinity, BACTERIAL ENDOTOXINS TEST, STERILITY TESTS	Just sheets attached
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Firm has claimed that their api doesn't contain e-isomer hence no testing required
3.2.P.8 Stability: System suitability is not performed as per USP monograph. lacks system suitability as provided in assay by USP monograph.	Firm has claimed that their api doesn't contain e-isomer hence no testing required

Decision

Rejected

The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of edited pharmaceutical equivalence data on expired batches and submission of revised stability summary sheets with visible correction of Ph from 9.89 to 6,89 by the applicant, the Board decided to reject the case

514	Case Category	Routine (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	(QJV-R91-2LJM, 2024-10-23)
	Detail of Fee Submitted	93000.0, 2024-10-07,
	The proposed proprietary name / brand name	**Cexon**
	Label Claim	Each Vial contains:Ceftriaxone Sodium Eq. to Ceftriaxone.....250mg(USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO

	Shelf Life (Unit)	2 Year(s)Store at temperature below 30oC. void exposure to light, heat, and humidity.
	For generic drugs (me-too Status)	Oxidil Injection IM 250mg by Sami Pharmaceutical (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	3rd Generation Cephalosporin Antibiotic
	Name, address of Manufacturing site:	SHROOQ Pharmaceuticals (Pvt.) Ltd.-21-Km Ferozpur Road, Lahore.-
	Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd No. 2428, Anji Road, Sanzao Town, Jinwan District,Zhuhai, Guangdong-519040, P.R. China.
	Detail of stability batches of drug product	Batch Size: 500 vials
	Documents for the procurement of API with approval from DRAP (in case of Import)	7783959273614 dated 22.12.23
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection IV 250mg LYM002
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Rocephin Injection 250mg USFDA
	GMP status of the firm	Certificate no 210/2023 dated 15-12-23 contract acceptor
	Evidence of approval of manufacturing facility	No F.1-29/2001-Lic(vol-I) dated 25-08-2010 mentioning dry powder injection section cephalosporin

Evaluation Remarks

3.2.P.2.2.1 Pharmaceutical Equivalence Reason required for not performing following tests Particulate Matter In Injections, Crystallinity, BACTERIAL ENDOTOXINS TEST, STERILITY TESTS	Revised summary sheets attached however no explanation on omission of tests submitted or performance evidence
3.2. P.5.2. ANALYTICAL PROCEDURES: Assay procedure are not in line to USP monograph, lacks system suitability as provided in assay by USP monograph. Justification required. System suitability for ceftriaxone and ceftriaxone E-isomer has not been performed	Firm has claimed that their API doesn't contain e-isomer hence no testing required
3.2.P.8 Stability: System suitability is not performed as per USP monograph. lacks system suitability as provided in assay by USP monograph.	Firm has changed stability summary sheets and Ph value for 6th month

Decision

Rejected

The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified and edited pharmaceutical equivalence data on expired batches and submission of revised stability summary sheets with visible correction of Ph from 9.89 to 6,89 by the applicant, the Board decided to reject the case

515	Case Category	Contract Manufacturing (Shahrukh Ali)
	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	(59G-TE8-B1UT, 2024-09-02)
	Detail of Fee Submitted	75000.0, 2024-08-09,

	The proposed proprietary name / brand name	**Namic 50mg/5ml Suspension (Mefenamic acid)**
	Label Claim	Each 5ml contains: Mefenamic Acid..... 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 30 °C.
	For generic drugs (me-too Status)	Mefalgic 50mg/5ml Suspension, M/s Semos Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch Size=1800 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
	Pharmaceutical Equivalence and Comparative Dissolution Profile	mefenamic acid suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Mefenamic Acid 50 mg/5 ml Suspension, United Kingdom
	GMP status of the firm	188 /2023-DRAP the, 14.11.2023 CONTRACT ACCEPTOR
	Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning Tablet (General).
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
516	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(V31-Z4D-JV2W, 2024-08-20)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Mefexa 50mg/5ml Suspension**
	Label Claim	Each 5ml contains: Mefenamic Acid..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 90ml, 120ml, 2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shaanxi Baoxin Pharmaceutical Co.,Ltd. Add: Caijiapo Economic & Technical Development Zone, Qishan County, Baoji City, Shaanxi Province, China
	Detail of stability batches of drug product	10litre

	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
	Pharmaceutical Equivalence and Comparative Dissolution Profile	(Mefenamic Acid 50 mg/5 ml Suspension)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Mefenamic Acid 50 mg/5 ml Suspension of M/s Chemidex Pharma Ltd, Chemidex House, Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK. (MHRA & HPRA Approved)
	GMP status of the firm	188 /2023-DRAP the, 14.11.2023
	Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning Syrup (General).
	Evaluation Remarks	
	"Firm has applied as new drug product however fees is paid for routine case justification required. Submit Me-too fees for new molecule." Response:We respectfully submit that the applied product is a Me-too product and not a new drug product. During dossier submission, the Me-too reference section was inadvertently marked as "N/A" due to clerical oversight. We regret the unintentional error. In this regard, we request you to kindly consider the application under the Me-too category. The relevant Me-too reference details and supporting information are being submitted accordingly. We also undertake to comply with any applicable fee difference/requirements, if deemed necessary by the authority.	
	Decision	
	Approved Registration board decided that the letter will be issued after the firm will submit fee for pre-registration variation i.e 9400/-	
517	Case Category	New Section (Shahrukh Ali)
	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	(BXE-SAR-3TG8, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-02-11,
	The proposed proprietary name / brand name	**RaceAir 10mg Sachet**
	Label Claim	Each sachet contains: Racecadotril.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15-30°C
	For generic drugs (me-too Status)	Recada Infants Sachet 10mg of M/s SAMI Pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Other Antidiarrhoeals; ATC code: A07XA04
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	BENOVA LABS PVT LTD
	Detail of stability batches of drug product	2000 sachet 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan M/s Novamed pharmaceuticals(Computerized No: RO-B3C3B9)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	receda 10mg sachet m/s sami

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	HIDRASEC 10mg sachet [MHRA Approved]
	GMP status of the firm	Certificate No: GMP-C-56DFD1 Date of Issue: 01/12/2025
	Evidence of approval of manufacturing facility	Sachet section[General] 1.26.2019 granted vide letter dated 4.02.2025
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Deferred Deferred for verification of authenticity of submitted data.	
518	Case Category	New Section (Shahrukh Ali)
	Name, address of Applicant.	**RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)**
	Application Form Dy. No / Tracking ID & date of submission	(7YL-1JA-AZ6Z, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2025-02-10,
	The proposed proprietary name / brand name	**THERACID-125mg SUSPENSION**
	Label Claim	Each 5ml contains: 27.5 % of Clarithromycin taste mask granules.... 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ML-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30ºC
	For generic drugs (me-too Status)	Klaricid Suspension 125mg/5ml
	Pharmacotherapeutic Group of (API)	Antibiotics (Macrolide)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SURGE PHARMA
	Detail of stability batches of drug product	3 batches 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	locally purchased from M/s surge
	Pharmaceutical Equivalence and Comparative Dissolution Profile	“klaricid suspension of Abbot laboratories
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Mylan Products Ltd. 20 Station Close Potters Bar Herts EN6 1TL United Kingdom
	GMP status of the firm	
	Evidence of approval of manufacturing facility	No F.1-8/2001-Lic dated 29-02-24 mentioning Tablet general section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
519	Case Category	Routine (Shahrukh Ali)

	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	(7TE-5VU-UT9G, 2024-08-29)
	Detail of Fee Submitted	30000.0, 2024-03-25,
	The proposed proprietary name / brand name	**Futiskin**
	Label Claim	Each gram contains Fusidic acid ..... 20mg (2%w/w) Hydrocortisone acetate ...10mg (1%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15g-As per SRO,30g-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)	Fusidin H cream (LEO Laboratories Limited)
	Pharmacotherapeutic Group of (API)	Antibiotic for Topical use (ATC code: D06AX01)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Joyang Laboratories Address: Joyang Laboratories Haidu North Road,Sheyang Eco-nomic Development Zone 224300 Jiangsu China ,Tianjin Jinjin Pharmaceutical Co., Ltd. Address: Industrial Zone of Zhangjiawo town,Xiqing District Eco- nomic & Developing Area
	Detail of stability batches of drug product	3 batches Batch Size 3000 tubes
	Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: K-2500846088965 Fusidic acid Computerized No: K-2377146087621 HYDROCORTISONE ACETATE
	Pharmaceutical Equivalence and Comparative Dissolution Profile	fusiderm h cream M/s Martin dow
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Medicines and Healthcare Regulatory Agency (MHRA)
	GMP status of the firm	Certificate no 41/2023-dRAP-k dated 23-06-23
	Evidence of approval of manufacturing facility	No F.3-7/2007-Lic dated 11-04-17 mentioning cream section
	Evaluation Remarks	
	"The application is complete as per codal formalities for consideration by the Registration Board"	
	Decision	
	Approved	
520	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(1MZ-SJM-WM5H, 2024-11-13)
	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Tryocon**
	Label Claim	Each Capsule Contains: Itraconazole as immediate release pellets.....100mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	1X4's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Rolac 100mg Capsule (SAMI Pharma Pakistan)
	Pharmacotherapeutic Group of (API)	Anti-fungal
	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	1500 cap 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Vision Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tryocon 100mg capsule Batch No: T001 Mfg Date: 10/23 Exp Date: 09/25
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
	The status in reference regulatory authorities	Sporanox 100mg Capsules (MHRA Approved)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has submitted replicate dossier of another company by changing title only	
	Decision	
	Rejected Registration decided to reject the instant application keeping in view that firm has submitted the same Module-III (assay verification data of drug substance by drug product manufacturer, pharmaceutical development data and stability data) as submitted by another firm i.e. M/s. Pine Pharmaceuticals	
521	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	**Danas Pharmaceuticals (Pvt) Ltd.** 312-Industrial Triangle, Kahuta road,Islamabad. **(000569)**
	Application Form Dy. No / Tracking ID & date of submission	(5NY-A8S-LNBW, 2024-09-27)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-03, 2024-09-26
	The proposed proprietary name / brand name	**Ditrazole**
	Label Claim	Each capsule contains: Itraconazole Immediate release pellets eq. to Itraconazole.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30 degree centigrade
	For generic drugs (me-too Status)	Rolac 100mg Capsule (M/s Sami Pharmaceuticals Pvt Ltd)
	Pharmacotherapeutic Group of (API)	Anti-fungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Vision Pharmaceuticals Pvt Ltd Islamabad
	Detail of stability batches of drug product	1500 cap 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	M/s Vision Pharmaceuticals

Pharmaceutical Equivalence and Comparative Dissolution Profile	SPORANOX 100mg CAPSULE
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Itraconazole 100mg Capsule TEVA UK Limited, Eastbourne, BN22 9AG. EMA
GMP status of the firm	
Evidence of approval of manufacturing facility	
Evaluation Remarks	
The firm has Waters HPLC with Empower 2 software for stability studies. The system is currently not 21CFR compliance.Data Submitted Is For Year 2021 And Record Of Digital Data Logger For Temperature And Humidity Monitoring Of Stability Chambers Is Submitted For Year 2024	
Decision	
Rejected Rejected, as the firm has submitted that compliance record of HPLC software with 21 CFR and audit trail reports for product testing are not available.	

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	CASE TITLE
1.	**SUBSTANDARD DICLOTOL TABLETS, REG. NO. 067477 BATCH NO # CQ-095 MANUFACTURED BY M/S SANTE (PRIVATE) LTD, KARACHI DML NO.000702**

CASE NO.1: <u>SUBSTANDARD DICLOTOL TABLETS, REG. NO. 067477 BATCH NO # CQ-095 MANUFACTURED BY M/S SANTE (PRIVATE) LTD, KARACHI DML NO.000702</u>

The Federal Inspector of Drugs-II, DRAP, Islamabad during inspection of M/s MM Pharmacy, Shop No.2, plot No.14-D, West Feroz center, Block-1, Fazal-e-Haq Road, Blue Area, Islamabad, dated 01-01-2026 took samples of the Diclotol Tablets on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide Test Report No IP-1-26-000006 dated 24th Feb, 2026, declared the batch# CQ-095 of product Diclotol Tablets manufactured by M/s Sante (Private) Ltd., Karachi as of "Substandard Quality''. Details of CDL test report are as under.

Drug Sample	Mfg. Date	Exp. Date	Tests	CDL Report No.	Manufacturer
Diclotol Tablets (067477) Batch No. CQ-095	05-2024	05-2026	Uniformity of Dosage Units by Content Uniformity (Diclofenac Sodium) (Stage 1). Meet the requirements of USP general chapter <905>. AV ≤ L1 where L1 = 15. **21.6 – Does not comply.** USP-NF 2026 Uniformity of Dosage Unit by Content Uniformity (Diclofenac Sodium) (Stage 2). Meet the requirements of USP general chapter <905>. AV ≤ L1 where L1 = 15. **36.0 – Does not comply.** USP-NF 2026	IP-1-26-000006 dated 24th Feb, 2026 Diclotol tablet is a layered tablet; the outer layer is of Misoprostol, and the inner core is of Diclofenac Sodium. During analysis, it is revealed that several Diclotol tablets contain two core tablets of Diclofenac Sodium, while in some only one core tablet is present. The shape of the core tablets also varies. Some core tablets are oblong, while others are spherical. The sample is of sub-standard quality under the Drugs Act 1976.	M/s Sante (Private) Ltd., Karachi.

3. Federal Inspector of Drugs-II, Islamabad issued an explanation letter to the firm vide letter No.F.4-1/2026-FID-II, dated 03-03-2026.

4. FID-II, Islamabad, forwarded the company's request for Appellate testing, which was submitted to the office of FID-II, Islamabad vide letter No. L047-26 dated 12-03-2026.

5. 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."

6. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F.No.03-23/2026-DD(QALT-VI) dated 05-05-2026 requested the Federal Government Analyst CDL Karachi and M/s. Sante (Private) Ltd., Karachi for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

7. The firm has submitted recall log of Diclotol Tablets Batch# CQ-095, wherein total packs distributed were **8130** whereas total recalled units were **328**, therefore, the percentage of recall was **4.028%.**

8. OOS Investigation was submitted by the firm vide letter No. L136-26 dated 08-05-2026. Summary of evaluation of 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 along with complete testing record as well as relevant chromatograms wherein it is informed that the sample is tested in accordance with the test/analysis method provided in the USPNF 2026 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 Sante (Private) Ltd, Karachi
M/s. Sante (Private) Ltd., Karachi in their reply has not provided the manufacturing & testing record of Diclotol Tablet Batch# CQ-095 or testing record of retention sample and warrantor portion. Instead, the firm has claimed to rule out any chance of error in the manufacturing or testing of the product in question. Details regarding technical evaluation of OOS Investigation are given below.

Technical Evaluation of OOS Investigation:

i. The product was declared as sub-standard by CDL with respect to content uniformity
ii. Content uniformity is mentioned in the product monograph and refers to chapter <905> of USP.
iii. CDL and manufacturer both performed the test as per USP.
iv. The firm has not provided the complete manufacturing & testing record of Diclotol Tablet Batch# CQ-095 or the testing records of the warrantor portion and retention sample.
v. Instead, they have just provided a statement of fact that OOS Investigation was performed and content uniformity was found within specified limits along with certificate of analyses of warrantor portion and retention samples. No details regarding phase-wise OOS investigation, raw calculations or chromatograms to support the claim have been provided by the firm. Since the documents submitted by the firm do not have supporting evidences therefore, technical evaluation was not possible.
vi. CDL, Karachi has provided complete OOS investigation along with relevant chromatograms.
vii. It would be pertinent to mention that the firm has provided Certificate of Analyses from third parties such as Pakistan Drugs Testing & Research Centre (PDTRC) and Pakistan Council of Scientific and Industrial Research (PCSIR) Laboratories Complex, Karachi wherein, content uniformity of Diclotol Tablet Batch# CQ-095 was tested by above-mentioned laboratories on firm's request and found to be complying with the USP Specifications.

Proceedings and Decision of 358th meeting of Registration Board

The Board after considering facts of the case, after thorough deliberations, and considering that the product i.e., Diclotol Tablet Batch# CQ-095 is expiring in May 2026 decided as follows:

i. ***"Not to accede to the firm's request for retesting of sample from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.***
ii. ***Direct area FID, to conduct fresh sampling of newly manufactured batch of Diclotol Tablets Registration No. (067477) for the purpose of test/analysis from CDL, Karachi.***

Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)

******

Item No. IV Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**3A Diagnostics** 12-F1, Johar Town, Lahore, Pakistan. **(05-352-0066-034496D)**
	Application Form Dy. No / Tracking ID & date of submission	(71S-EHW-PGQ6, 2026-03-30)
	Detail of Fee Submitted	313500, 2026-01-20,
	The proposed proprietary name / brand name	**Human Insulin**
	Label Claim	Human Insulin (3ml:300IU (Cartridge))
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 cartridge contains 3 ml equivalent to 300 international units-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8°c
	For generic drugs (me-too Status)	NOVOLIN® R
	Pharmacotherapeutic Group of (API)	Antidiabetic WHO ATC code: A10AB01
	Name, address of Manufacturing site:	Yichang HEC Changjiang Pharmaceutical Co., Ltd-No,3 Industrial Park of HEC, Yidu City, Hubei Province (China)-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical similarity and comparative clinical trial report attached.
	Name, address of Marketing Authorization Holder:	3A Diagnostics, 14-Airline Society, Lahore Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.HuBci20250085 dated 04-07-2025 issued by Hubei Medical Products Administration No.19 Gongzheng Road, Wuchang District, Wuhan City,Hubei Province, P.R.China. Validity: 03-07-2027
	Details of Authorization Letter :	Authorization Letter dated 03-04-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	INS201308005, INS20130806, NS201309007 Long Term Stability Study at -20 ± 5°C for 48 months Accelerated Stability Study at 5 ± 3°C for 6 months
	The status in reference regulatory authorities	NOVOLIN® R, marketed by Novo Nordisk Inc.
	Evaluation Remarks	
	Firm has submitted the required documents. Case may be approved.	
	Decision	
	Approved Registration Board approved the product subject to compliance of current import policy for Finished products.	
2	Case Category	Routine (Anam Saeed)

	Name, address of Applicant.	**3A Diagnostics** 12-F1, Johar Town, Lahore, Pakistan. **(05-352-0066-034496D)**
	Application Form Dy. No / Tracking ID & date of submission	(H9R-35H-YNGQ, 2026-02-17)
	Detail of Fee Submitted	313500, 2026-01-20,
	The proposed proprietary name / brand name	**Mixed Protamine Human Insulin Injection (30R) Injection**
	Label Claim	Human Insulin (3ml:300U (Cartridge)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 cartridge contains 3 ml equivalent to 300 international units-As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8°c
	For generic drugs (me-too Status)	NOVOLIN® R
	Pharmacotherapeutic Group of (API)	insulin and analogues ATC code: A10AE04
	Name, address of Manufacturing site:	Yichang HEC Changjiang Pharmaceutical Co., Ltd-No,3 Industrial Park of HEC, Yidu City, Hubei Province (China)-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analytical similarity and comparative clinical trial report attached.
	Name, address of Marketing Authorization Holder:	3A Diagnostics, 14-Airline Society, Lahore Pakistan, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.HuBei20250088 dated 04-07-2025 issued by ubei Medical Products Administration No. 19 Gongzheng Road, Wuchang District, Wuhan City,Hubei Province, P.R.China. Validity: 03-07-2027
	Details of Authorization Letter :	Authorization Letter dated 03-04-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long term (Real time) stability at -20°C ±5°C. Accelerated stability at 5°C ±3°C.
	The status in reference regulatory authorities	NOVOLIN® R, marketed by Novo Nordisk Inc.
	Evaluation Remarks	
	Firm has submitted the required documents. Case may be approved.	
	Decision	
	Approved Registration Board approved the product subject to compliance of current import policy for Finished products.	
3	Case Category	Routine (Anam 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	(11Y-BYP-SVY7, 2026-02-20)
	Detail of Fee Submitted	313500, 2026-02-16,
	The proposed proprietary name / brand name	**Glarin**
	Label Claim	Each prefilled pen contains; Insulin Glargine 300units/3ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	36 Month(s)2-8oC
	For generic drugs (me-too Status)	Generic
	Pharmacotherapeutic Group of (API)	Insulins and Analogues for injection, long-acting ATC Code: A10AE04
	Name, address of Manufacturing site:	Liaoning Boao Bio-Pharmaceutical Co., LTD-55 Shennong Street, Benxi Economic and Technological Development Zone, Benxi-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES (PVT) LTD., 130 D, Commercial Broadway, Phase 8 DHA, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No.Liaoning20250129 dated 03-12 2025 and valid till 02-12-2027.
	Details of Authorization Letter :	LOA dated 17-11-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Batch 20200609 , 20200610, 20200611 are kept at stability for 6 months at accelerated and 36 months at real time conditions.
	The status in reference regulatory authorities	Lantus Solostar Injection 300units/3mL (Sanofi Aventis US)
	Evaluation Remarks	
	Firm has submitted the required data. Case may be approved.	
	Decision	
	Approved Registration Board approved the product subject to compliance of current import policy for Finished products.	
4	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**3A Diagnostics** 12-F1, Johar Town, Lahore, Pakistan. **(05-352-0066-034496D)**
	Application Form Dy. No / Tracking ID & date of submission	(7UA-533-A5BA, 2026-03-02)
	Detail of Fee Submitted	313500, 2026-01-20,
	The proposed proprietary name / brand name	**Insulin Glargine Injection**
	Label Claim	Insulin Glargine (3ml:300IU (Cartridge))
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Insulin Glargine Injection HEC 100 units/ml solution for injection in -As per SRO
	Shelf Life (Unit)	36 Month(s)Store at 2-8°c
	For generic drugs (me-too Status)	-
	Pharmacotherapeutic Group of (API)	Antidiabetic WHO ATC code: A10AE04
	Name, address of Manufacturing site:	Yichang HEC Changjiang Pharmaceutical Co., Ltd-No,3 Industrial Park of HEC, Yidu City, Hubei Province (China)-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Yichang HEC Changjiang Pharmaceutical Co., Ltd, No,3 Industrial Park of HEC, Yidu City, Hubei Province (China), China
	Details of Certificates (CoPP/FSC/cGMP):	Apostile COPP No. HuBei20250075 dated 18-06-2025 issued by Hubei Medical Products

		Administration No.19 Gongzheng Road, Wuchang District, Wuhan City,Hubei Province, P.R.China. Validity: 17-06-2027
	Details of Authorization Letter :	Authorization Letter dated 03-04-2025
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at real time and accelerated conditions.
	The status in reference regulatory authorities	Lantus®, marketed by Sanofi-Aventis U.S. LLC
	Evaluation Remarks	
	Firm has submitted required data. Case may be approved.	
	Decision	
	Approved Registration Board approved the product subject to compliance of current import policy for Finished products.	
5	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore **(000655)**
	Application Form Dy. No / Tracking ID & date of submission	(E4V-EV8-RTQ8, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-04-13,
	The proposed proprietary name / brand name	**Ferulin 70/30 (Suspension for Injection in Cartridge)**
	Label Claim	Ferulin 70/30 Each Cartridge contains Human Insulin .... 300 IU/3mL or 100IU/mL (70% Human Insulin Isophane Suspension& 30% Regular Human Insulin Injection) Product Specs: BP Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5 X 3mL (Cartridges) & 1's of Pen with prefilled Cartridge -As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2°C and 8°C
	For generic drugs (me-too Status)	Humulin 70/30
	Pharmacotherapeutic Group of (API)	Insulins and analogues for injection WHO ATC Code: A10AD01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tonghua Dongbao Pharmaceutical Co., Ltd. Dongbao New Village, Tonghua County, Jilin Province.
	Detail of stability batches of drug product	Stability data of 3 batches at real time and accelerated conditions till 6 months is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP clearance attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches at real time for 36 months and at accelerated for 6 months is provided.
	The status in reference regulatory authorities	Humulin 70/30 Cartridge (Eli Lilly)
	GMP status of the firm	GMP certificate issued by DRAP on 05-09-2024.
	Evidence of approval of manufacturing facility	DML No.000655 renewed on 30-01-2024.

	Evaluation Remarks	
	Firm has submitted the required data. Case may be approved.	
	Decision	
	Approved Registration Board approved the product.	
6	Case Category	New Section (Anam 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	(HBL-2VX-UYXY, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 2.5mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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:	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 data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
7	Case Category	New Section (Anam 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	(L6Q-MA9-PDEV, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 5mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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)	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 data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
8	Case Category	New Section (Anam 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	(RY3-AGH-YSNW, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 15mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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:	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 data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
9	Case Category	New Section (Anam 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	(T7X-NX2-74DW, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 10mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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:	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 data of 3 batches attached.

	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
10	Case Category	New Section (Anam 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	(VLY-WU1-7VJV, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 12.5mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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:	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 data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.

	Evaluation Remarks	
	Decision of 358th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
11	Case Category	New Section (Anam 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	(YRD-ZU9-T5YG, 2025-12-02)
	Detail of Fee Submitted	75000, 2025-11-12,
	The proposed proprietary name / brand name	**Terza 7.5mg/0.5ml Single Dose Prefilled Syringe**
	Label Claim	Each PRE-FILLED SYRINGE (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:	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 data of 3 batches attached.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice of 300gm API attached which is not DRAP attested.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches attached.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	New section granted on 25th June 2025.
	Evidence of approval of manufacturing facility	New section granted on 25th June 2025.
	Evaluation Remarks	
	Decision of 357th meeting:DeferredThe Registration Board decided to grant the firm an opportunity for a personal hearing to clarify the observations raised by the BE&R Division. In the light of above decision, a personnel hearing letter was issued to M/s Weather Folds Pharmaceuticals, Hattar.	
	Decision	
	Deferred Registration Board deferred the case due to paucity of time.	
12	Case Category	Routine (Anam Saeed)

Name, address of Applicant.	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)**
Application Form Dy. No / Tracking ID & date of submission	(UT6-N2D-ZVN1, 2026-05-07)
Detail of Fee Submitted	97200, 2026-03-11,
The proposed proprietary name / brand name	**TERZA 7.5mg/0.5ML Injection in Pre-Filled 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-As per SRO
Shelf Life (Unit)	2 Year20-25°C
For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Area, Hattar.-
The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
Detail of previous approval	Terza 7.5mg/0.5ml Single Dose Prefilled Pen | Minutes of 352nd Meeting of Registration Board

Evaluation Remarks

The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board and Registration Letter was issued on 12th December, 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:

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	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(NLV-MLH-URP7, 2025-11-27)
	Detail of Fee Submitted	313500, 2025-10-28,
	The proposed proprietary name / brand name	**Tizaro 7.5mg/0.5ml PFS Injection**
	Label Claim	Each pre-filled syringe contains: Tirzepatide 7.5 mg in 0.5 mL solution for injection
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8°C
	For generic drugs (me-too Status)	TIRZEE Injection 7.5mg Mfg. By "Getz Pharma (Pvt.) Ltd."
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd.-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd., Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	COPP No. DA6-71/03/5917 dated 08-05-2025
	Details of Authorization Letter :	Letter of Authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches have data available only up to 9 months.
	The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection Mfg by 'ELI LILLY AND CO' (USFDA Approved)

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Cell-based Bioassay, GIP · Cell-based Bioassay, GLP-1 · Individual impurities · High molecular weight species. · Largest unspecified impurity	ICH Q6B Guidelines suggest that bioassays are crucial, it is allowed for replacement by physicochemical tests, and finished product manufacturer performed physicochemical tests by HPLC method.	The finished product specifications do not include the following tests:• Cell-based bioassay• Individual impurities• High molecular weight species• Largest

			unspecified impurity• Osmolality
2	Specify and identify L-isoAsp9, L-isoAsp15, D-Ser32/C-term Deamidation, Gln24 Deamidation, Gln19 deamidation in your drug substance and drug product as identified by innovator. Innovators have made above related substances/impurities as part of the product specifications also.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, It is under purchase order right now and they will start to perform these tests as soon as LC-MS/MS system arrives.	The firm has not performed individual impurity testing on the finished product, as conducted by the innovator.
3	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications is also required.	Comparative testing of the applied product against the innovator across all parameters outlined in the finished product specifications could not be fully performed due to limited availability of innovator samples.	The firm has performed only identification, assay, pH, and average fill volume testing in comparison with the innovator product.
4	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will be evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	18 months' real time stability data of 3 batches of finished product is provided and the parameters covered in the stability studies are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.
5	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches have data available only up to 9 months.	-	Complete stability data of drug substance is required.
6	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.
7	A risk assessment concerning the potential presence of nitrosamine impurities in the finished product has not been performed.	-	A risk assessment concerning the potential presence of nitrosamine impurities in the

			finished product has not been performed.

Decision
Rejected The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data: • The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and osmolality. • Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters. • The submitted stability study data of the applied product did not include all tests as required under finished product specifications.

14	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(TJ7-6YN-MTWM, 2025-12-09)
	Detail of Fee Submitted	313500, 2025-10-28,
	The proposed proprietary name / brand name	**Tizaro 5mg/0.5ml PFS Injection**
	Label Claim	Each pre-filled syringe contains: Tirzepatide 5 mg in 0.5 mL solution for injection
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8°C
	For generic drugs (me-too Status)	TIRZEE Injection 5mg Mfg. By "Getz Pharma (Pvt.) Ltd."
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd.-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd., Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	COPP No. DA6-71/03/5916 dated 08-05-2025
	Details of Authorization Letter :	Letter of Authorization is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches have data available only up to 9 months.

The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection Mfg by 'ELI LILLY AND CO' (USFDA Approved)

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Cell-based Bioassay, GIP · Cell-based Bioassay, GLP-1 · Individual impurities · High molecular weight species. · Largest unspecified impurity	ICH Q6B Guidelines suggest that bioassays are crucial, it is allowed for replacement by physicochemical tests, and finished product manufacturer performed physicochemical tests by HPLC method.	The finished product specifications do not include the following tests:• Cell-based bioassay• Individual impurities• High molecular weight species• Largest unspecified impurity• Osmolality
2	Specify and identify L-isoAsp9, L-isoAsp15, D-Ser32/C-term Deamidation, Gln24 Deamidation, Gln19 deamidation in your drug substance and drug product as identified by innovator. Innovators have made above related substances/impurities as part of the product specifications also.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, It is under purchase order right now and they will start to perform these tests as soon as LC-MS/MS system arrives.	The firm has not performed individual impurity testing on the finished product, as conducted by the innovator.
3	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications is also required.	Comparative testing of the applied product against the innovator across all parameters outlined in the finished product specifications could not be fully performed due to limited availability of innovator samples.	The firm has performed only identification, assay, pH, and average fill volume testing in comparison with the innovator product.
4	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will be evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	18 months' real time stability data of 3 batches of finished product is provided and the parameters covered in the stability studies are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.
5	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches	-	Complete stability data of drug substance is required.

	have data available only up to 9 months.		
6	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.
7	A risk assessment concerning the potential presence of nitrosamine impurities in the finished product has not been performed.	-	A risk assessment concerning the potential presence of nitrosamine impurities in the finished product has not been performed.

Decision

Rejected

The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data:

• The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and osmolality.

• Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters.

• The submitted stability study data of the applied product did not include all tests as required under finished product specifications.

15	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(U92-DZM-R9GN, 2025-12-09)
	Detail of Fee Submitted	313500, 2025-10-28,
	The proposed proprietary name / brand name	**Tizaro 2.5mg/0.5ml PFS Injection**
	Label Claim	Each pre-filled syringe contains: Tirzepatide 2.5 mg in 0.5 mL solution for injection
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2-8°C
	For generic drugs (me-too Status)	TIRZEE Injection 2.5mg Mfg. By "Getz Pharma (Pvt.) Ltd."
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd.-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh

Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd., Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	COPP No. DA6-71/03/5915 dated 08-05-2025
Details of Authorization Letter :	Letter of Authorization is submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches have data available only up to 9 months.
The status in reference regulatory authorities	MOUNJARO® (Tirzepatide) Injection Mfg by 'ELI LILLY AND CO' (USFDA Approved)

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Cell-based Bioassay, GIP · Cell-based Bioassay, GLP-1 · Individual impurities · High molecular weight species. · Largest unspecified impurity	ICH Q6B Guidelines suggest that bioassays are crucial, it is allowed for replacement by physicochemical tests, and finished product manufacturer performed physicochemical tests by HPLC method.	The finished product specifications do not include the following tests:• Cell-based bioassay• Individual impurities• High molecular weight species• Largest unspecified impurity• Osmolality
2	Specify and identify L-isoAsp9, L-isoAsp15, D-Ser32/C-term Deamidation, Gln24 Deamidation, Gln19 deamidation in your drug substance and drug product as identified by innovator. Innovators have made above related substances/impurities as part of the product specifications also.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, It is under purchase order right now and they will start to perform these tests as soon as LC-MS/MS system arrives.	The firm has not performed individual impurity testing on the finished product, as conducted by the innovator.
3	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications is also required.	Comparative testing of the applied product against the innovator across all parameters outlined in the finished product specifications could not be fully performed due to limited availability of innovator samples.	The firm has performed only identification, assay, pH, and average fill volume testing in comparison with the innovator product.
4	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will	18 months' real time stability data of 3 batches of finished product is provided and the parameters covered in the stability studies

		be evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.
5	Stability data for three batches of the drug substance has been provided up to 6 months under accelerated conditions. However, under real-time conditions, stability data for only one batch is available up to 12 months, while the remaining two batches have data available only up to 9 months.	-	Complete stability data of drug substance is required.
6	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.
7	A risk assessment concerning the potential presence of nitrosamine impurities in the finished product has not been performed.	-	A risk assessment concerning the potential presence of nitrosamine impurities in the finished product has not been performed.

Decision

Rejected

The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data:

• The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and osmolality.

• Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters.

• The submitted stability study data of the applied product did not include all tests as required under finished product specifications.

16	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(U5X-V18-YUUD, 2025-12-02)
	Detail of Fee Submitted	313500, 2025-10-28,

The proposed proprietary name / brand name	**Semaglo OB PFS Injection 1mg/0.5ml**
Label Claim	Each pre-filled syringe contains: Semaglutide..... 1mg in 0.5mL solution for Injection
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Month(s)Store at 2-8°C
For generic drugs (me-too Status)	Semagen by Ferozsons Laboratories Ltd.
Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd, Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. DGDA/6-71/03/13303 dated 18-07-2024
Details of Authorization Letter :	Letter of Authorization attached.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches of drug substance is submitted at accelerated conditions till 6 months and at real time conditions till 36 months.
The status in reference regulatory authorities	WEGOVY 1mg/0.5ml by US-FDA

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Identification by peptide mapping using LC-MS · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform peptide mapping and impurities testing as soon as LC-MS/MS system arrives.	The finished product specifications do not include the following tests: · Identification by peptide mapping using LC-MS · Cell-based bioassay · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins
2	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications.	Comparative testing of applied product against innovator on all parameters mentioned in FP specifications is attached as Annexure-V	The firm has not conducted impurity testing, high molecular weight protein analysis, and identification by peptide mapping as part of the comparative testing with the innovator.
3	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will be	The parameters covered in the stability studies are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.

		evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	
4	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is required.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.

Decision

Rejected

The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data:

• The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and identification by peptide mapping.

• Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters.

• The submitted stability study data of the applied product did not include all tests as required under finished product specifications.

17	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(MD6-29T-XQ41, 2025-12-02)
	Detail of Fee Submitted	313500, 2025-10-28,
	The proposed proprietary name / brand name	**Semaglo PFS Injection 0.25mg/0.188ml**
	Label Claim	Each pre-filled syringe contains: Semaglutide INN 0.25mg in 0.188mL solution for injection
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C
	For generic drugs (me-too Status)	Semagen by Ferozsons Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh

Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd, Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh, Bangladesh
Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. DGDA/6-71/03/13303 dated 18-07-2024
Details of Authorization Letter :	Letter of Authorization attached.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches of drug substance is submitted at accelerated conditions till 6 months and at real time conditions till 36 months.
The status in reference regulatory authorities	Ozempic 0.25mg Solution for Injection by MHRA

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Identification by peptide mapping using LC-MS · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform peptide mapping and impurities testing as soon as LC-MS/MS system arrives.	The finished product specifications do not include the following tests: · Identification by peptide mapping using LC-MS · Cell-based bioassay · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins
2	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications.	Comparative testing of applied product against innovator on all parameters mentioned in FP specifications is attached as Annexure-V	The firm has not conducted impurity testing, high molecular weight protein analysis, and identification by peptide mapping as part of the comparative testing with the innovator.
3	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will be evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	The parameters covered in the stability studies are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.
4	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is required.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.

		MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	

Decision

Rejected

The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data:

• The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and identification by peptide mapping.

• Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters.

• The submitted stability study data of the applied product did not include all tests as required under finished product specifications.

18	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	**Martin Dow Limited** Plot No. 37, Sector 19, Korangi Industrial Area Karachi-74900, Pakistan **(0639)**
	Application Form Dy. No / Tracking ID & date of submission	(GBE-V82-3RE2, 2025-12-02)
	Detail of Fee Submitted	313500, 2025-10-28,
	The proposed proprietary name / brand name	**Semaglo PFS Injection 0.5mg/0.375ml**
	Label Claim	Each pre-filled syringe contains: Semaglutide.... 0.5mg in 0.375mL solution for injection
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C
	For generic drugs (me-too Status)	Semagen by Ferozsons Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Name, address of Manufacturing site:	Ziska Pharmaceuticals Ltd-Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh-Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Ziska Pharmaceuticals Ltd, Karolsurichala, Shafipur, Kaliakoir, Gazipur, Bangladesh, Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate No. DGDA/6-71/03/13303 dated 18-07-2024
	Details of Authorization Letter :	Letter of Authorization attached.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 3 batches of drug substance is submitted at accelerated conditions till 6 months and at real time conditions till 36 months.

The status in reference regulatory authorities	Ozempic 0.5mg Solution for Injection by MHRA

Evaluation Remarks

Certain queries were raised to the firm, and reply has been submitted thereto. However, certain matters remain unclear or have not yet been complied with by the manufacturer, as detailed in the table below;

Sr.No.	Queries	Reply	Remarks
1	Following tests are not part of finished product specifications; · Identification by peptide mapping using LC-MS · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform peptide mapping and impurities testing as soon as LC-MS/MS system arrives.	The finished product specifications do not include the following tests: · Identification by peptide mapping using LC-MS · Cell-based bioassay · Individual impurities i.e hydrophilic and hydrophobic impurities. · High molecular weight proteins
2	Comparative testing of applied product with innovator is required on all parameters as mentioned in FP specifications.	Comparative testing of applied product against innovator on all parameters mentioned in FP specifications is attached as Annexure-V	The firm has not conducted impurity testing, high molecular weight protein analysis, and identification by peptide mapping as part of the comparative testing with the innovator.
3	Stability data of 3 commercial batches of finished product is required till claimed shelf life on all parameters as mentioned in finished product specifications.	The tests that are currently not included in the stability studies but are part of the finished product specifications will be incorporated in future stability studies. These parameters will be evaluated concurrently upon revision of the specifications, which will be implemented following the procurement of LC–MS/MS system.	The parameters covered in the stability studies are limited to fill volume, assay, particulate matter, pH, sterility, and bacterial endotoxin only.
4	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is required.	It has been communicated by Finished Product Manufacturer i.e., Ziska Pharmaceuticals Ltd., that they do not have LC-MS/MS system, it is under purchase order right now and they will start to perform PK/PD testing as soon as LC-MS/MS system arrives.	Pharmacokinetic/ pharmacodynamic (PK/PD) equivalence studies using the reference product is not performed.

Decision

Rejected

The Registration Board decided to reject the application on the grounds that the manufacturer failed to provide the following required data:

	• The finished product specifications were deficient with respect to inclusion of cell-based bioassay, individual impurities, high molecular weight species, largest unspecified impurity, and identification by peptide mapping. • Comparative testing between the applied product and the reference/innovator product was not performed on all required parameters. • The submitted stability study data of the applied product did not include all tests as required under finished product specifications.	
19	Case Category	Routine (Anam Saeed)
	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	(DQT-GWV-PHZU, 2026-04-13)
	Detail of Fee Submitted	313500, 2026-03-18,
	The proposed proprietary name / brand name	**23-valent Pneumococcal Polysaccharide Vaccine**
	Label Claim	One dose (0.5 mL) contains 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's (Pre-Filled Syringe)-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)	Brand Name: Pneumo 23 Registration Number: 025265 Composition: Purified Capsular Polysaccharides of strepto coccus pneumoniae 1,2,3,4,5,6B,7F,8,9N,9V,10A,11A,12F, Manufactured by: Sanofi Pasteur SA,
	Pharmacotherapeutic Group of (API)	Pneumococcal vaccines
	Name, address of Manufacturing site:	Sinovac Biotech Co., Ltd. -No.39, Shangdi Xi Rd., Haidian District, Beijing, 100085, P.R. China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Sinovac Biotech Co., Ltd. , No.39, Shangdi Xi Rd., Haidian District, Beijing, 100085, P.R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted Apostile COPP No.Beijing20260106 dated 25-02-206 issued by Beijing Municipal Medical Products Administration China. Validity: 24-02-2029
	Details of Authorization Letter :	Letter of Authorization dated 20th March, 2026.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies for the drug substance (final bulk polysaccharides) have been conducted under long-term (2–8°C) and accelerated conditions, using multiple batches manufactured across different years (2019, 2020, 2021, and 2023), demonstrating consistency of the manufacturing process over time.

	The status in reference regulatory authorities	Brand Name: PNEUMOVAX 23 Composition: For active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F) Manufactured by: Merck Sharp & Dohme Corp.
	Evaluation Remarks	
	Firm has submitted the required data. Case may be approved.	
	Decision	
	Approved Registration Board approved the product subject to compliance of current import policy for Finished products.	
20	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**Vetline International** 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore **(05-352-0066-040712D)**
	Application Form Dy. No / Tracking ID & date of submission	(5SZ-M13-5E36, 2025-06-23)
	Detail of Fee Submitted	300000.0, 2025-06-16,
	The proposed proprietary name / brand name	**Fowl Adenovirus (Group I) Trivalent Vaccine Inactivated (Serotype 4, Serotype 8 & Serotype 11)**
	Label Claim	Each Dose (0.3ml) contains: Fowl Adenovirus (Group I, Serotype 4).....≥10^6.5$TCID_{50}$ Fowl Adenovirus (Group I, Serotype 8b).....≥10^7.0$TCID_{50}$ Fowl Adenovirus (Group I, Serotype 11).....≥10^7.0$TCID_{50}$
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	18 Month(s)2-8 °C
	For generic drugs (me-too Status)	GPVAC Hydro-TC Plus Injection, GPVAC Hydro-TC Plus Injection, Nobilis FAV 0.25, Emulmax IBH, OLEOVAC HCI PLUS+®
	Pharmacotherapeutic Group of (API)	Inactivated Veterinary Vaccine
	Name, address of Manufacturing site:	Sinopharm Yangzhou VAC Biological Engineering Co.,-Number 15, Muyang Road, Hanjiang Industrial Estates, Yangzhou, Jiangsu-China
	Name, address of Marketing Authorization Holder:	Sinopharm Yangzhou VAC Biological Engineering Co.,, Number 15, Muyang Road, Hanjiang Industrial Estates, Yangzhou, Jiangsu, China
	Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille FSC dated 15-02-2025 valid for 03 years. Copy of Apostille GMP No. (2020) GMP 10030 dated 15-06-2022 valid 14-12-2025.
	Details of Authorization Letter :	Copy of Apostille LOA dated 10-04-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches 20210708, 20210714 and 20210721 stored at 2-8 for 18 months
	Evaluation Remarks	

	Registration Board in its 353rd meeting deferred the application for clarification of submitting same stability data for 500ml as was submitted initially for 100ml with only difference of batch size and batch numbers. The firm in response submitted the following: "The quality standards for this product are completely consistent for both the 100ml and 500ml sizes. The dosage description states that it complies with the current regulations of the Chinese Veterinary Pharmacopoeia, Part III. The regulations stipulate that the dosage of each test sample should not be less than the amount indicated on the label. That is, during the final product testing process, the dosage check should be no less than 100ml/bottle or 500ml/bottle."	
	Decision	
	Rejected Keeping in view the stability data integrity issue and non-availability of stability data of applied pack presentation; Registration Board rejected the application.	
21	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**u.m.enterprises** plot no.12 sector 15 korangi industrial area-74900 **(313)**
	Application Form Dy. No / Tracking ID & date of submission	(11V-QM5-GET7, 2026-01-27)
	Detail of Fee Submitted	313500, 2026-01-21,
	The proposed proprietary name / brand name	**PULIVAC ND-La Sota+IB**
	Label Claim	Newcastle disease virus strain La Sota (CVCC AV1615) and infectious bronchitis virus strain H120 (CVCC AV1514). The virus titer per dose is not less than 106.0 EID_{50} for Newcastle disease virus and not less than $10^{3.5}$ EID_{50} for infectious bronchitis virus
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	300 ml / bottle-De-Controlled
	Shelf Life (Unit)	18 Month2-8 degree centigrade
	For generic drugs (me-too Status)	IZOVAC H120 LA SOTA (by Ghazi brothers)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Pulike Biological Engineering, Inc.-No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. Tel:(+86)0379-69902166-China
	Name, address of Marketing Authorization Holder:	Pulike Biological Engineering, Inc., No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. Tel:(+86)0379-69902166, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Following are the observations: 1. In clinical justification, following is mentioned: "It is not developed by Pulike Biological Engineering, INC., we didn't do field trial, it's impossible for us to submit clinical justification." The firm submitted the following in response: "Since the vaccine was registered in China based on the national unified regulations (not independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly". 2. Address of MAH on LOA is different from FSC.	
	Decision	

	Rejected Registration Board rejected the application due to non availability of safety and efficacy data of the product.	
22	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**u.m.enterprises** plot no.12 sector 15 korangi industrial area-74900 **(313)**
	Application Form Dy. No / Tracking ID & date of submission	(X3Y-DBE-Z3SU, 2026-01-27)
	Detail of Fee Submitted	313500, 2026-01-21,
	The proposed proprietary name / brand name	**PULIVAC MG**
	Label Claim	This product contains inactivated Mycoplasma gallisepticum strain CR, before inactivation, the content is not less than 3.5 × 10.8.5ccu/ml.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	18 Month2-8 degree centigrade
	For generic drugs (me-too Status)	F VAX-MG® by ICI pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Pulike Biological Engineering, Inc.-Intersection of South Tianzhong Road and Binhe Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone Tel:(+86)0379-69902166-China
	Name, address of Marketing Authorization Holder:	Pulike Biological Engineering, Inc., Intersection of South Tianzhong Road and Binhe Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone Tel:(+86)0379-69902166, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Following are the observations: 1. In Stability data, Filling amount check is around 100 while applied pack size is 500ml. Pease explain. Also submit COAs of stability batches. 2. In clinical justification, following is mentioned: "It is not developed by Pulike Biological Engineering, INC., we didn't do field trial, it's impossible for us to submit clinical justification." 3. Address of MAH on LOA is different from FSC. The firm submitted the following response: 1. Based on the identical formulation, equivalent packaging materials, and existing regulatory approval, we respectfully submit that the provided 100ml stability data is sufficient to support the registration and approval of the 500ml pack size. 2. "Since the vaccine was registered in China based on the national unified regulations (not independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly".	
	Decision	
	Rejected Registration Board rejected the application due to non availability of safety & efficacy data and stability data of applied pack presentation of the product.	
23	Case Category	Routine (M. Zubair Masood)

	Name, address of Applicant.	**u.m.enterprises** plot no.12 sector 15 korangi industrial area-74900 **(313)**
	Application Form Dy. No / Tracking ID & date of submission	(JJZ-AGZ-PZAT, 2026-01-27)
	Detail of Fee Submitted	313500, 2026-01-21,
	The proposed proprietary name / brand name	**PULIVAC ND-La Sota+IB+EDS**
	Label Claim	The vaccine contains inactivated avian Newcastle disease virus strain La Sota， virus titer:≥3×10^{8}.0 EID_{50}/0.1 mL before inactivation, avian infectious bronchitis virus strain M41， virus titer before inactivation: ≥3×10^{6}.0 EID_{50}/0.1 mL before inactivation, and avian egg drop syndrome virus strain AV127,HA titer:≥1:30720 before inactivation.
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	500mL/bottle-De-Controlled
	Shelf Life (Unit)	18 Month2-8 degree centigrade
	For generic drugs (me-too Status)	Nobilis® IB+ND+EDS by MSD (USA) distributed by Vety-Care (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Pulike Biological Engineering, Inc.-Intersection of South Tianzhong Road and Binhe Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone Tel:(+86)0379-69902166-China
	Name, address of Marketing Authorization Holder:	Pulike Biological Engineering, Inc., Intersection of South Tianzhong Road and Binhe Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone Tel:(+86)0379-69902166, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Following are the observations: 1. In Stability data, Filling amount check is around 250 while applied pack size is 500ml. Pease explain. 2. In clinical justification, following is mentioned: "It is not developed by Pulike Biological Engineering, INC., we didn't do field trial, it's impossible for us to submit clinical justification." 3. In dossier pack specifications are mentioned as 300ml/bottle while applied pack size is 500ml. 4. Address of MAH on LOA is different from FSC. The firm submitted the following response: 1. Based on the identical formulation, equivalent packaging materials, and existing regulatory approval, we respectfully submit that the provided 250ml stability data is sufficient to support the registration and approval of the 500ml pack size. 2. "Since the vaccine was registered in China based on the national unified regulations (not independent clinical trial data of the company), and its long-term use record has verified its safety and efficacy, Chinese companies usually do not need to submit clinical data repeatedly".	
	Decision	
	Rejected Registration Board rejected the application due to non availability of safety & efficacy data and stability data of applied pack presentation of the product.	
24	Case Category	Routine (M. Zubair Masood)

	Name, address of Applicant.	**Snam Pharma** 61-G, Phase 1, Commercial Area, DHA, Lahore **(05-352-0058-036985D)**
	Application Form Dy. No / Tracking ID & date of submission	(MHW-QAZ-WRE6, 2025-12-12)
	Detail of Fee Submitted	313500, 2025-12-11,
	The proposed proprietary name / brand name	**RINVAC IC ABC**
	Label Claim	Each ml of vaccine contains: Inactivated Avibacterium paragallinarum serotype A strain C-Apg-8.....$6.0\times10^{8.0}$CFU Inactivated Avibacterium paragallinarum serotype B strain Apg-BJ05.....$10.0x10^{8.0}$ Inactivated Avibacterium paragallinarum serotype C strain Apg-668.....$8.0\times10^{8.0}$CFU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	500ml/Bottle-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	Same Strains already registered in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	Tianjin Ringpu Bio-technology Co., Ltd., Airport E-No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China
	Name, address of Marketing Authorization Holder:	Tianjin Ringpu Bio-Technology Co., Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China
	Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille GMP Certificate No. (2022) GMP 02002 dated 25-07-2025 valid till 13-01-2027. Scanned Apostille FSC No. 2025041 dated 18-11-2025.
	Details of Authorization Letter :	Scanned Apostille Product Specific LOA valid till 03-11-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	The application was considered in 10th meeting of EWG wherein the experts deliberated that the cross protection of single serotype of Avibacterium paragallinarum is limited and for proper cross protection multiple strains are required, hence the product is recommended for grant of registration.	
	Decision	
	Approved Keeping in view the recommendations of EWG and FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
25	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**u.m.enterprises** plot no.12 sector 15 korangi industrial area-74900 **(313)**
	Application Form Dy. No / Tracking ID & date of submission	(V6Q-BWW-3NT5, 2025-09-27)
	Detail of Fee Submitted	313500, 2025-09-04,
	The proposed proprietary name / brand name	**VAvi NI-LH5**

	Label Claim	Each dose contains: Compound Virus content (EID50/dose) Newcastle Disease Virus (La Sota Strain) ≥106.0EID50 Infectious Bronchitis Virus (H52 Strain) ≥103.5EID50
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	2000 dose 10 vial / box-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store below -15°C
	For generic drugs (me-too Status)	Newcastle Disease and Infectious Bronchitis Combination Vaccine(Strain La Sota + Strain H52)
	Pharmacotherapeutic Group of (API)	.
	Name, address of Manufacturing site:	Qingdao Vland Animal Health Group Co., Ltd.-No.85 Keyun Road, High-Tech Zone, Qingdao City, Shandong Province, China-China
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, Plot 12 sector 14 Korangi industrial Karachi, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	.
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	Evaluation Remarks	
	1. The firm initially submitted stability data of 03 batches 202201, 202202, 202203 indicating them of 1000 doses batch but the applied pack size was of 2000 doses. The firm was asked for stability data of 2000 doses batches. The firm submitted the same data and indicated these batches as of 2000 doses. When the firm was asked for clarification, the firm submit stability study data of 03 more batches 202204, 202205, 202206 indicating them as of 2000 doses batches. When the stability data was compared with already submitted data, following was observed: i. In efficacy testing of ND component, results of batch 202201 were similar to that of batch 202204, results of batch 202202 were similar to that of batch 202205 & results of batch 202203 were similar to that of batch 202206 at 12, 18 & 24 months time point. ii. In efficacy testing of Infectious Bronchitis component, results of batch 202201 were similar to that of batch 202204 at all time points, results of batch 202202 were similar to that of batch 202205 at 12, 18 & 24 months time points & results of batch 202203 were similar to that of batch 202206 at all months time points. iii. In residual moisture testing, results of batch 202201 were similar to that of batch 202204, results of batch 202202 were similar to that of batch 202205 & results of batch 202203 were similar to that of batch 202206 at 18 & 24 months time point.	
	Decision	
	Rejected Keeping in view the stability data integrity issue; Registration Board rejected the application.	
26	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**M & M Pharma** Javaid Plaza, Gurumangat Road, Gulberg II, Lahore **(05-352-0065-035822D)**
	Application Form Dy. No / Tracking ID & date of submission	(SSB-P5X-NZH6, 2026-05-08)
	Detail of Fee Submitted	313500, 2026-01-13,
	The proposed proprietary name / brand name	**Pneubevax 14 Vaccine**
	Label Claim	Each dose of 0.5 mL contains: Pneumococcal polysaccharide serotype 1....3.0 µg Pneumococcal polysaccharide serotypes 3, 4, 5,

		7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F (each).....2.2 µg Pneumococcal polysaccharide serotype 6B.....4.4 µg (Polysaccharides conjugated to 20-50 µg of CRM197) Adsorbed onto Aluminum Phosphate, as Al+++ ...≤ 0.75 mg 2- Phenoxyethanol (Multidose only)....4 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10's 48's-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	not available
	Pharmacotherapeutic Group of (API)	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)
	Name, address of Manufacturing site:	Biological E. Limited-Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal–Malkajgiri (District), Telangana, INDIA – 500078-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	M&M Pharma, 1st floor, Javed Plaza, Opposite Gate # 2 Gurumangat Road, Gulberg II, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ Vaccine
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Data of Conjugated Bulk is submitted
	The status in reference regulatory authorities	WHO PQ Vaccine
	Evaluation Remarks	
	Decision	
	Approved Keeping in view the WHO Pre-Qualifiction status of product; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and clarification of difference in address of manufacturer on CoPP and official website of WHO.	
27	Case Category	Routine (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	
	The Registration Board in its 357th meeting decided to grant the firm an opportunity for a personal hearing to justify their response submitted on 14-04-2026 in respect of queries raised by the Board in its 354th meeting: The applicant vide TID: BDV-A8P-Y7BE dated 05.05.2026 submitted as under: We M/s CCL Pharmaceuticals Pvt. Ltd. (“CCL Pharma”) submitted applications for registration of SEJARO Inj. 2.5mg, 5mg and 7.5mg (Tirzepatide) vide tracking ID’s no. UB8-EW5-6GP4, VW9-TGH-MJTM and JT6-AHL-L99A as the authorized representative of its foreign principal, M/s GEROPHARM, Russia. The complete technical dossier, including subsequent responses to queries, were prepared and provided by the said foreign principal. It is hereby clarified that CCL Pharma had no role in the preparation or compilation of the technical data and documentation, as its intended role was limited to import and marketing of the product. It has been communicated to CCL Pharma that the learned Drug Registration Board observed certain discrepancies between the initially submitted dossiers and the subsequently provided documents. In the meantime, CCL Pharma has taken a commercial decision not to proceed further with the subject applications and intends to withdraw the same. With reference to the decision of Personal hearing before the Drug Registration Board, it is submitted that the principal manufacturer, M/s GEROPHARM, Russia, is unable to attend due to unavoidable circumstances, as communicated by them. Given the technical nature of the queries raised, and in the absence of relevant technical personnel from the manufacturer, it would not be feasible to adequately respond to the Board’s queries at this stage. In view of the above, and in order to avoid any undue consumption of the Board’s time, it is respectfully requested that the subject applications for registration may kindly be treated as withdrawn at this stage. We remain grateful for the Board’s time and consideration and may consider/allow re-submission of the registration application in the future, as appropriate.	
	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
28	Case Category	Routine (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	
	The Registration Board in its 357th meeting decided to grant the firm an opportunity for a personal hearing to justify their response submitted on 14-04-2026 in respect of queries raised by the Board in its 354th meeting: The applicant vide TID: BDV-A8P-Y7BE dated 05.05.2026 submitted as under: We M/s CCL Pharmaceuticals Pvt. Ltd. (“CCL Pharma”) submitted applications for registration of SEJARO Inj. 2.5mg, 5mg and 7.5mg (Tirzepatide) vide tracking ID’s no. UB8-EW5-6GP4, VW9-TGH-MJTM and JT6-AHL-L99A as the authorized representative of its foreign principal, M/s GEROPHARM, Russia. The complete technical dossier, including subsequent responses to queries, were prepared and provided by the said foreign principal. It is hereby clarified that CCL Pharma had no role in the preparation or compilation of the technical data and documentation, as its intended role was limited to import and marketing of the product. It has been communicated to CCL Pharma that the learned Drug Registration Board observed certain discrepancies between the initially submitted dossiers and the subsequently provided documents. In the meantime, CCL Pharma has taken a commercial decision not to proceed further with the subject applications and intends to withdraw the same. With reference to the decision of Personal hearing before the Drug Registration Board, it is submitted that the principal manufacturer, M/s GEROPHARM, Russia, is unable to attend due to unavoidable circumstances, as communicated by them. Given the technical nature of the queries raised, and in the absence of relevant technical personnel from the manufacturer, it would not be feasible to adequately respond to the Board’s queries at this stage. In view of the above, and in order to avoid any undue consumption of the Board’s time, it is respectfully requested that the subject applications for registration may kindly be treated as withdrawn at this stage. We remain grateful for the Board’s time and consideration and may consider/allow re-submission of the registration application in the future, as appropriate.	
	Decision	
	Rejected Registration Board rejected the application as withdrawn by the firm.	
29	Case Category	Routine (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

The Registration Board in its 357th meeting decided to grant the firm an opportunity for a personal hearing to justify their response submitted on 14-04-2026 in respect of queries raised by the Board in its 354th meeting: The applicant vide TID: BDV-A8P-Y7BE dated 05.05.2026 submitted as under: We M/s CCL Pharmaceuticals Pvt. Ltd. (“CCL Pharma”) submitted applications for registration of SEJARO Inj. 2.5mg, 5mg and 7.5mg (Tirzepatide) vide tracking ID’s no. UB8-EW5-6GP4, VW9-TGH-MJTM and JT6-AHL-L99A as the authorized representative of its foreign principal, M/s GEROPHARM, Russia. The complete technical dossier, including subsequent responses to queries, were prepared and provided by the said foreign principal. It is hereby clarified that CCL Pharma had no role in the preparation or compilation of the technical data and documentation, as its intended role was limited to import and marketing of the product. It has been communicated to CCL Pharma that the learned Drug Registration Board observed certain discrepancies between the initially submitted dossiers and the subsequently provided documents. In the meantime, CCL Pharma has taken a commercial decision not to proceed further with the subject applications and intends to withdraw the same. With reference to the decision of Personal hearing before the Drug Registration Board, it is submitted that the principal manufacturer, M/s GEROPHARM, Russia, is unable to attend due to unavoidable circumstances, as communicated by them. Given the technical nature of the queries raised, and in the absence of relevant technical personnel from the manufacturer, it would not be feasible to adequately respond to the Board’s queries at this stage. In view of the above, and in order to avoid any undue consumption of the Board’s time, it is respectfully requested that the subject applications for registration may kindly be treated as withdrawn at this stage. We remain grateful for the Board’s time and consideration and may consider/allow re-submission of the registration application in the future, as appropriate.

Decision

Rejected

	Registration Board rejected the application as withdrawn by the firm.	
30	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** Plot # 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(X1S-A5W-ZMGW, 2026-05-09)
	Detail of Fee Submitted	313500, 2026-02-17,
	The proposed proprietary name / brand name	**Adsorbed Td Vaccine**
	Label Claim	Each dose (0.5ml) contains: Purified Diphtheria toxoid.....2 Lf Purified Tetanus toxoid.....7.5 Lf Aluminum phosphate .....1.5mg Thimerosal.....0.05 mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 Vials @ 5ml (10 doses)-As per SRO
	Shelf Life (Unit)	36 Month(s)2-8°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Vaccine for immunization against diphtheria and tetanus
	Name, address of Manufacturing site:	PT Bio Farma (Persero)-Jl. Pasteur No. 28, Pasteur Subdistrict, Sukajadi District, Bandung City, West Jawa Province, 40161-Indonesia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	PT Bio Farma (Persero), Jl. Pasteur No. 28, Pasteur Subdistrict, Sukajadi District, Bandung City, West Jawa Province, 40161, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	All 3 batches of Td vaccine 10 ds have completed 6 months of stability study period at temperature of 25±2°C. and 37±1°C. The result shows that adsorbed Td vaccine 10 ds is stable until 6 months at temperature of 25±2 °C. and 37±1 °C.
	The status in reference regulatory authorities	WHO Prequalified (Link: https://extranet.who.int/prequal/vaccines/p/none)
	Evaluation Remarks	
	Decision	
	Approved Keeping in view the WHO Prequalification; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
31	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**Amson Vaccines & Pharma (Pvt.) Ltd** Plot # 115, Industrial Triangle Kahuta Road **(017/DSL(D)/PS&DC-ICT/2025)**
	Application Form Dy. No / Tracking ID & date of submission	(HV6-SER-PNA4, 2026-05-10)

	Detail of Fee Submitted	313500, 2026-02-18,
	The proposed proprietary name / brand name	**Adsorbed DT Vaccine 5ml (10 Doses)**
	Label Claim	Each dose (0.5ml) contains: Purified Diphtheria Toxoid.....20 Lf Purified Tetanus Toxoid.....7.5 Lf Aluminum Phosphate as Al+++....0.33mg Thimerosal.....0.05mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 Vials @ 5ml (10 Doses)-As per SRO
	Shelf Life (Unit)	36 Month(s)2-8°C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Diphtheria-Tetanus Vaccine
	Name, address of Manufacturing site:	PT Bio Farma (Persero)-Jl. Pasteur No. 28, Pasteur Subdistrict, Sukajadi District, Bandung City, West Jawa Province, 40161-Indonesia
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	PT Bio Farma (Persero), Jl. Pasteur No. 28, Pasteur Subdistrict, Sukajadi District, Bandung City, West Jawa Province, 40161, Indonesia
	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)	Submitted
	The status in reference regulatory authorities	WHO Prequalified (Link: https://extranet.who.int/prequal/vaccines/p/adsorbe dt-vaccine)
	Evaluation Remarks	
	Decision	
	Approved Keeping in view the WHO Prequalification; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
32	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**HOSPITAL SERVICES & SALES** 13-C Annexe, Block 6, PECHS, Shahrah e Faisal **(0398)**
	Application Form Dy. No / Tracking ID & date of submission	(EQ8-7LT-SQXE, 2026-05-10)
	Detail of Fee Submitted	313500, 2026-02-17,
	The proposed proprietary name / brand name	**Poliomyelitis vaccine (Inactivated) multidose, suspension for injection 10 Dose x 5 ml Vial**
	Label Claim	Active immunisation against poliomyelitis. One dose consists of 0.5 mL contains: Inactivated poliomyelitis virus type 1 (Mahoney)* 40 D-antigen units Inactivated poliomyelitis virus type 2 (MEF 1)* 8 D-antigen units Inactivated poliomyelitis virus type 3 (Saukett)*

		32 D-antigen units *Cultivated on Vero cells
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	10 Dose x 5ml Vial-Controlled
	Shelf Life (Unit)	36 Month(s)2 - 8 ºC
	For generic drugs (me-too Status)	Imovax Polio Vaccine by Hoechst Pak. Ltd., (Reg. No. 045700)
	Pharmacotherapeutic Group of (API)	Viral Vaccines, Active Immunization against poliomyelitis
	Name, address of Manufacturing site:	Bilthoven Biologicals B.V.-Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven The Netherlands.-Netherlands
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Bilthoven Biologicals B.V., Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven, Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	WHO PQ product and origin is The Netherland.
	Evaluation Remarks	
	Decision	
	Approved Keeping in view the WHO Prequalification; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
33	Case Category	Priority As Per 257-M of RB (Muneeb Ahmed Cheema)
	Name, address of Applicant.	**HOSPITAL SERVICES & SALES** 13-C Annexe, Block 6, PECHS, Shahrah e Faisal **(0398)**
	Application Form Dy. No / Tracking ID & date of submission	(N2X-4LH-79DZ, 2026-05-10)
	Detail of Fee Submitted	313500, 2026-02-17,
	The proposed proprietary name / brand name	**Poliomyelitis vaccine (Inactivated) multidose, suspension for injection 5 Dose x 2.5 ml Vial**
	Label Claim	One dose consists of 0.5 mL contains: Inactivated poliomyelitis virus type 1 (Mahoney)* 40 D-antigen units Inactivated poliomyelitis virus type 2 (MEF 1)* 8 D-antigen units Inactivated poliomyelitis virus type 3 (Saukett)* 32 D-antigen units * Cultivated on Vero-cells.
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	5 Dose x 2.5ml Vial-Controlled
	Shelf Life (Unit)	36 Month(s)2 - 8 ºC
	For generic drugs (me-too Status)	Imovax Polio Vaccine by Hoechst Pak Ltd., (Reg. No.045700)

	Pharmacotherapeutic Group of (API)	Viral Vaccine
	Name, address of Manufacturing site:	Bilthoven Biologicals B.V.-Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven.-Netherlands
	Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
	Name, address of Marketing Authorization Holder:	Bilthoven Biologicals B.V., Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven., Netherlands
	Details of Certificates (CoPP/FSC/cGMP):	WHO PQ Vaccine
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	WHO PQ and also approved NRA of Netherlands
	Evaluation Remarks	
	Decision	
	Approved Keeping in view the WHO Prequalification; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
34	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(6XZ-WX5-NAPG, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 15mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe (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)	2 Year(s)2˚C - 8˚C
	For generic drugs (me-too Status)	Zeptide 15mg/0.5ml by BF Biosciences Ltd.
	Pharmacotherapeutic Group of (API)	GLP/GIP Agonist
	Name, address of Manufacturing site:	M/s Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of three batches 400 PFS each is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP certificate of clearance for import API/Reference standard/Impurities reference standards
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence with reference product provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance submitted
	The status in reference regulatory authorities	Mounjaro 15 mg solution for injection by M/s Eli Lilly and Co, Inc. (USFDA approved)

GMP status of the firm	Firm is GMP compliant as per submitted GMP Certificate
Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility

Evaluation Remarks

The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. “Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request”.

Decision

Approved

The Registration Board approved application 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.

	Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.	
35	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(A3G-RHT-8RV5, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 10mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe contains: Tirzepatide 7.5mg per 0.5 ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per S.R.O-As per SRO
	Shelf Life (Unit)	2 Year(s)Store ZAVI PFS in a refrigerator at 2°C to 8°C (36°F to 46°F).
	For generic drugs (me-too Status)	Tirzee 10mg/0.5ml (1 Pre-filled Pen), manufactured by Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GLP/GIP Agonist
	Name, address of Manufacturing site:	M/s Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan. Tel: +92 42 35403361-4-
	Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm has submitted stability data of three batches of 400 PFS each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP certificate of clearance for import API/Reference standard/Impurities reference standards
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence with reference product provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Reference Regulatory Authority (RRA) is attached in module-1
	GMP status of the firm	GMP compliant facility
	Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility
	Evaluation Remarks	
	The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. “Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months	

	of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request".	
	Decision	
	Approved The Registration Board approved application 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. Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.	
36	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(GE5-7ED-YV1D, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 2.5mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe (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)2 °C-8 °C
	For generic drugs (me-too Status)	Tirzi Injection 2.5mg/0.5ml (Approved in 350th DRB Meeting) by Getz Pharma
	Pharmacotherapeutic Group of (API)	GIP/GLP Agonist
	Name, address of Manufacturing site:	M/s Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan..-

Name & address of API manufacturer	
Detail of stability batches of drug product	Firm has submitted stability data of three batches of 400 PFS each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP certificate of clearance for import API/Reference standard/Impurities reference standards
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Mounjaro 2.5 mg solution for injection by M/s Eli Lilly and Co, Inc. (USFDA approved)
GMP status of the firm	GMP compliant facility
Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility

Evaluation Remarks

The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. “Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request”.

Decision

Approved

The Registration Board approved application 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. Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.	
37	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(MNV-6HV-NZGZ, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 7.5mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe contains: Tirzepatide 7.5mg per 0.5 ml solution
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per S.R.O-As per SRO
	Shelf Life (Unit)	2 Year(s)Store ZAVI PFS in a refrigerator at 2°C to 8°C (36°F to 46°F).
	For generic drugs (me-too Status)	Tirzee 7.5mg/0.5ml (1 Pre-filled Pen), manufactured by Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GLP/GIP Agonist
	Name, address of Manufacturing site:	Nextar Pharma-E-58, North Western Industrial Zone Port Qasim Karachi-
	Name & address of API manufacturer	Sinopep-Allsino Biopharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Firm has submitted stability data of three batches of 400 PFS each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted stability data of three batches of 400 PFS each.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence with reference product provided.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	Reference Regulatory Authority (RRA) is attached in module-1
	GMP status of the firm	GMP compliant
	Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility
	Evaluation Remarks	
	The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. “Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were	

	developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request".	
	Decision	
	Approved The Registration Board approved application 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. Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.	
38	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(XZY-PEN-MG9W, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 5mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe (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)2 °C-8 °C
	For generic drugs (me-too Status)	Tirzi Injection in PFS with Disposable Auto-injector (Approved in 350 DRB Meeting),Getz

	Pharma
Pharmacotherapeutic Group of (API)	GLP/GIP Agonist
Name, address of Manufacturing site:	M/s Nextar Pharma (Pvt.) Limited-Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.-
Name & address of API manufacturer	
Detail of stability batches of drug product	Firm has submitted stability data for three batches of 400 PFS each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP certificate of clearance for import API/Reference standard/Impurities reference standards
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE Provided-Dissolution is not applicable
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Mounjaro 5 mg solution for injection by M/s Eli Lilly and Co, Inc. (USFDA approved)
GMP status of the firm	Firm is GMP compliant
Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility

Evaluation Remarks

The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. “Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request”.

Decision

Approved

The Registration Board approved application 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. Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.	
39	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(ZS3-PA6-E43M, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-04-22,
	The proposed proprietary name / brand name	**Zavi 12.5mg/0.5ml PFS with Disposable Auto-injector**
	Label Claim	Each Pre Filled Syringe (0.5ml) contains: Tirzepatide.....12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO.-De-Controlled
	Shelf Life (Unit)	2 Year(s)2˚C - 8˚C
	For generic drugs (me-too Status)	Tirzee 12.5mg/0.5ml by Getz Pharma, Korangi, Karachi.
	Pharmacotherapeutic Group of (API)	GLP/GIP Agonist
	Name, address of Manufacturing site:	M/s Nextar Pharma (Pvt.) Ltd-Plot No. E-58 North Western Industrial Zone, Port Qasim Karachi - Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Firm has submitted stability data for three batches of 400 PFS each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted DRAP certificate of clearance for import API/Reference standard/Impurities reference standards
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE Submitted, Dissolution NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Mounjaro 12.5 mg solution for injection by M/s Eli Lilly and Co, Inc. (USFDA approved)
	GMP status of the firm	GMP Compliant
	Evidence of approval of manufacturing facility	Firm has approved biotech/ biological manufacturing facility
	Evaluation Remarks	
	The firm was advised to submit data as per requirements defined in DRAP Guidance Document vide No. BE&R/GL/AF (2nd Edition) effective since 16th March 2026. In response the firm submitted through TID: G59-AA5-8R2Z dated 7th May 2026. "Please refer to the applications submitted for the Registration of Zavi (Tirzepatide) PFS with Disposable Auto-injector Range and the subsequent	

query raised by the Division of Biological Evaluation and Research regarding the submission of stability data in accordance with the recently approved guideline BE&R/GL/AF (2nd Edition) effective since 16th March 2026 which requires submission of 12 months of real time stability data. In this regard, we would like to submit that the activities related to development of Zavi (Tirzepatide) were started in June 2025. Accordingly, API was sourced and protocols were developed and subsequently development studies including stability studies were started as per the previous version of guideline which was effective at that time with the requirement for stability data of 6 months for real time studies. Therefore, the dossiers were submitted upon completion of six month's studies in the month of April. Keeping in view the above-mentioned facts, we sincerely request your good office to grant a one-time relaxation in terms of stability data and accept 6 months of real-time stability data, as was the case in the old guideline. Your good office is assured that continued research into stability is being carried out and other data, as they become available, will be submitted. We shall be grateful for your kind consideration of this request".

Decision

Approved

The Registration Board approved application 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.

Registration Board further decided to consider all such applications in light of CTD Guidance Document for Biological Drugs Edition 1, wherein, the development of product was started before 16-03-2026.

Drug Regulatory Authority of Pakistan

(Pharmaceutical Evaluation & Registration Division)

******

Item No. V **Additional / Supplementary Minutes**

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad **(000927)**
	Application Form Dy. No / Tracking ID & date of submission	(ZJB-AMP-4GYE, 2026-04-22)
	Detail of Fee Submitted	38700, 2026-04-14,
	The proposed proprietary name / brand name	**Nagodine Solution**
	Label Claim	Each ml of cutaneous solution contains: Iodinated Povidone.....100mg (10% w/w)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml, 60 ml, 70 ml, 100 ml, 200 ml, 300 ml, 400 ml, 450 ml, 500 ml, 1000 ml, 4.5 L, 5 L-As per SRO
	Shelf Life (Unit)	2 Year(s)Room temperature
	For generic drugs (me-too Status)	Pyodine by Brooks Pharma
	Pharmacotherapeutic Group of (API)	Antiseptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches : 50 bottles each 50mL 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)	Loan letter for 1kg of material along with memorandum of understanding for loan dated 04-08-2025 is submitted. Clearance certificate dated 24-07-2024 issued to M/s Kohinoor Industries is submitted. Stability batches were manufactured in September, 2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Pyodine 10% by M/s brookes.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Health Products Regulatory Authority (HPRA)
	GMP status of the firm	External preparation (Liquid) General Section is approved on 18-03-2026.
	Evidence of approval of manufacturing facility	External preparation (Liquid) General Section is approved.
	Evaluation Remarks	
	The stability batches were manufactured in September, 2025. The firm has taken the Loan from M/s Kohinoor Industries on 04-08-2025 whereas DRAP's notification No.14-1/2022-PEC dated	

	01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug ManufacturingLicenses (DMLs).	
	Decision	
	Deferred for clarification borrowing of loan after DRAP's notification No.14-1/2022-PEC dated 01.08.2025	
2	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	**QASIM TRADERS** Shop No.7 Medicine Centre Kutchi Gali No.1, Denso Hall, Marriot Road **(645.)**
	Application Form Dy. No / Tracking ID & date of submission	(Q3V-MSG-X1XH, 2025-08-05)
	Detail of Fee Submitted	300000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Paracetamol Infusion**
	Label Claim	Each 100 ml contains: Paracetamol.....1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Month(s)30 °C
	For generic drugs (me-too Status)	Bofalgan Infusion 1g/100ml Reg No. 070607 BOSCH PHARMACEUTICALS (PVT) LTD
	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
	Name, address of Manufacturing site:	Shandong Qidu Pharmaceutical Co., Ltd.-No.17, Hongda Road, Linzi District, Zibo City, Shandong province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performd agaisnt Perfalgan by M/s Bristol Mayers Squibb, France.
	Name, address of Marketing Authorization Holder:	Shandong Qidu Pharmaceutical Co., Ltd., No.17, Hongda Road, Linzi District, Zibo City, Shandong Province, China, China
	Details of Certificates (CoPP/FSC/cGMP):	GMP compliance inspection result report No. GMP2022054 is submitted dated 30-09-2022 issued by Shandong Medical Products Administration.
	Details of Authorization Letter :	FSC: FSC No. 20250256 issued on 10-02-2025 is submitted. The applied product is available in free sale in exporting country as per submitted FSC. Agency agreement: Apostille Agency agreement dated 27-03-2025 is submitted. DSL: DSL valid till 23-03-2029 is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone II.
	The status in reference regulatory authorities	MHRA Approved
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding imported drugs.	
	Decision	
	Approved Subject to submission of valid legalized/apostille CoPP and Notarized letter of authorization.	
3	Case Category	New Section (Haleema Sharif)

	Name, address of Applicant.	**Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)**
	Application Form Dy. No / Tracking ID & date of submission	(PAE-TQ2-XQR3, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-05-20,
	The proposed proprietary name / brand name	**Mexifer Injection 100mg / 5ml**
	Label Claim	Each 5ml Contains: Iron Sucrose Complex eq. to Elemental Iron..... l00mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5 x 5ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 degree celcius
	For generic drugs (me-too Status)	VENOROCK INJECTION 100MG/5ML (ADAMJEE PHARMACEUTICALS)
	Pharmacotherapeutic Group of (API)	Anti-anemic agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SNJ Lab Pvt Ltd
	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	VENOFER INJECTION (VIFOR (INTERNATIONAL) INC., SWITZERLAND)
	GMP status of the firm	GMP certificate attached (Valid till 22-09-2027)
	Evidence of approval of manufacturing facility	Attached. DML number 000884
	Evaluation Remarks	
	The firm was advised in 352nd meeting to clarify the actual manufacturer of the drug substance, i.e., whether it was M/s. Symed Labs (mentioned on clearance certificate and batch analysis) or M/s. SNJ Labs (rest of dossier is by SNJ). In response, the firm clarified that the drug substance manufacturer is M/s. Symed Labs. However, the DML/GMP certificate for M/s. Symed Labs has still not been provided.	
	Decision	
	Rejected The Board decided to reject the case primarily due to concerns regarding the integrity and authenticity of the chromatograms, as they appeared manipulated or edited, with identical retention times, along with the non-availability of spectra for Atomic Absorption Spectrophotometer.	
4	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Werrick Pharmaceuticals** Plot No. 216 - 217, I-10/3, Industrial Area Islambad **(000340)**
	Application Form Dy. No / Tracking ID & date of submission	(M3X-7BQ-MDR9, 2024-10-10)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-27, 2024-09-12
	The proposed proprietary name / brand name	**Flueze Night Time Severe Cold & Cough Sachets**
	Label Claim	Each sachet contains: Paracetamol.....650mg

		Diphenhydramine HCl .....25mg Phenylephrine HCl.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Colynol Night Time Severe Cold & Cough Sachets
	Pharmacotherapeutic Group of (API)	Analgesic/Antiallergic/Alpha-1 adrenergic receptor agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attested Invoice Submitted for two APIs but not for Diphenhydramine HCl
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Theraflu Night Time Severe Cold & Cough Sachets
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-
	Evaluation Remarks	
	1. For Diphenhydramine Hydrochloride. Submit Documents confirming Import of drug substance like clearance certificate or DRAP attested Invoice. Evidence of guideline indicating that there is no need to quantify Class II & III solvents and to be mentioned in COA	
	Decision	
	Approved During commercial manufacturing, the manufacturer shall ensure the use of API batches/lots for which residual solvent testing has been performed and reported in compliance with ICH guidelines.	
5	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	(WMN-6P4-569X, 2026-01-30)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**LOTINOL-T Ophthalmic Suspension**
	Label Claim	Each ml of Suspension Contains: Loteprednol Etabonate ....5.0mg Tobramycin .....3.0mg (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)	Lotinol-T BY Winthrox (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Loteprednol Etabonate: Corticosteroid Tobramycin: Aminoglycoside Antibiotic

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Livzon group Fuzhou Fuxing Pharmaceutical CO.LTD. NO.8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing Fuzhou City Fujian Province P.R China 350309 China,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)	Loan without timely intimation to DRAP
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data submitted against Lotinol-T Ophthalmic Suspension of M/s Winthrox Laboratories 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	Justify broader/relaxed acceptance limit for pH (5.0-6.0); pH of innovator product ranges from 5.7 to 5.9	Firm has submitted the following justification without giving reference to specific guidelines.· Ophthalmic preparations are generally well tolerated within a pH range of approximately 4.0–8.0 due to the buffering capacity of tear fluid, which rapidly adjusts the pH of instilled formulations toward physiological tear pH (~7.4). Therefore, the proposed pH range falls well within the acceptable physiological limits for ophthalmic administration and is not expected to cause ocular discomfort. · In addition, maintaining the formulation in a slightly acidic pH environment supports the chemical stability of both active ingredients by minimizing potential degradation pathways such as hydrolysis and maintaining optimal physicochemical conditions for the formulation components. This helps preserve the potency of the active substances, maintains the integrity of the suspension system, and ensures consistent product quality during manufacturing as well as

			throughout the product's shelf life.· Furthermore, the proposed specification encompasses the observed pH range of the innovator product (5.7–5.9) while allowing reasonable manufacturing and analytical variability without affecting the safety, efficacy, or overall performance of the ophthalmic preparation.· pH Stability of APIs Loteprednol Etabonate is an ester-based corticosteroid whose stability is influenced by pH. Studies on steroid esters indicate that maximum chemical stability is generally observed in slightly acidic conditions (approximately pH 4 5), while higher alkaline pH may accelerate hydrolytic degradation of the ester linkage. Therefore, maintaining the formulation in a slightly acidic environment helps minimize degradation pathways such as hydrolysis and supports long term stability of the active ingredient in ophthalmic suspensions. · Tobramycin, an aminoglycoside antibiotic widely used in ophthalmic products, exhibits good stability in slightly acidic to near-neutral pH conditions, which are commonly used for ophthalmic formulations. In combination ophthalmic suspensions containing both loteprednol etabonate and tobramycin, studies have shown that the presence of tobramycin can also contribute to improved pH stability of the formulation during storage, resulting in minimal pH drift over time.
	Decision		
	Deferred for submission of guidelines allowing broader/relaxed acceptance limit for pH range contrary to that of the innovator product.		
6	Case Category	New License (Saima Hussain)	
	Name, address of Applicant.	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. **(000985)**	

Application Form Dy. No / Tracking ID & date of submission	(88V-9A8-PS4W, 2024-10-09)
Detail of Fee Submitted	37000.0, 2024-09-27,
The proposed proprietary name / brand name	**Micam**
Label Claim	Each Tablet Contains: Piroxicam as Beta-Cyclodextrin...20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2x10's-As per SRO
Shelf Life (Unit)	2 Year(s)15-30 degree Celsius
For generic drugs (me-too Status)	Brexin 20mg Tablet by Chiesi Pharmaceuticals Pvt. Ltd., Lahore-Pakistan
Pharmacotherapeutic Group of (API)	NSAID
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nantong Jinghua Pharmaceutical co Ltd China
Detail of stability batches of drug product	3 batches: 2000 Tablet
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from Quaper and claerance certificate dated 19-06-2022
Pharmaceutical Equivalence and Comparative Dissolution Profile	Brexin Tablet of Chiesi: PE and CDP 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	AIFA Approved
GMP status of the firm	26-10-2023: New DML issued
Evidence of approval of manufacturing facility	26-10-2023: New DML issuance letter specifies Tablet General Section

Evaluation Remarks

Deferred case

Decision of M-344	Response by the firm
Deferred for for clarification for adopting UV method for the analysis of drug product since the innovator's product recommend HPLC testing.	We have used a derivative ultraviolet (UV) spectrophotometric method for the determination of piroxicam in piroxicam--beta-cyclodextrin tablets was developed. In the bulk/finished & stability studies stage, determination of piroxicam was conducted by using first order derivative amplitudes at 242.0 nm (n=4). Standards for the calibration graph ranging from 0.096mg/ml +/- 20% were prepared from working standard. The proposed method is accurate with 99.99%+/-0.25 recovery value and precise with coefficient of variation (CV) of 1.29. The results were compared with those obtained using a high-performance liquid chromatography (HPLC) procedure (for comparison purpose only). A reversed-phase C(18) column with aqueous phosphate buffer:methanol, 60:40, v/v, mobile phase was used. UV detector was set at 242 nm (for comparison purpose only). Calibration solutions used in HPLC were ranging from 5 to 20 microg/ml (for comparison purpose only). Results obtained in HPLC were comparable to those obtained by derivative UV spectrophotometric method.So the analytical

		method used for the finished product and stabilities studies is a validated analytical testing method.
	Registration Board in its 347th meeting deferred the case for adaptation of HPLC method for analysis of drug product along with submission of results of stability studies as per the revised HPLC method. Firm in their reply submitted the revised assay method on HPLC along with performance report, chromatograms and audit trail.	
	Decision	
	Approved Firm shall submit requisite fee for pre-registration variation as per the latest SRO.	
7	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	(4ZL-JZ5-2RR9, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-15,
	The proposed proprietary name / brand name	**Xantro 125mg/30mg Capsules**
	Label Claim	Xanomeline and Trospium Chloride 125mg and 30mg/Capsule
	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 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
	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 (in case of Import)	Attached in Module 3 in section 3.2.P.8
	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	COBENFY (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
	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

COBENFY (xanomeline and trospium chloride) is for oral administration and is available in capsules in the following strengths: x 50 mg/20 mg (equivalent to 76.7 mg xanomeline tartrate and 18.3 mg trospium). x 100 mg/20 mg (equivalent to 153.3 mg xanomeline tartrate and 18.3 mg trospium). x 125 mg/30 mg (equivalent to 191.7 mg xanomeline tartrate and 27.5 mg trospium). COBENFY capsules contain a combination of pellets of xanomeline and pellets of trospium chloride. COBENFY is indicated for the treatment of schizophrenia in adults 2.1 Recommended Testing and Monitoring Prior to Initiation and During Treatment with COBENFYx Assess liver enzymes and bilirubin prior to initiating COBENFY and as clinically indicated during treatment [see Contraindications (4) and Warnings and Precautions (5.2, 5.3)]. x Assess heart rate at baseline and as clinically indicated during treatment [see Warnings and Precautions (5.7)].2.2 Recommended Dosage and Administration The recommended dosage of COBENFY is as follows: x The recommended starting dosage is one 50 mg/20 mg capsule (contains 50 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least two days. x Increase the dosage to one 100 mg/20 mg capsule (contains 100 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least five days. x The dosage may be increased to one 125 mg/30 mg capsule (contains 125 mg of xanomeline and 30 mg of trospium chloride) orally twice daily based on patient tolerability and response [see Clinical Studies (14)].x Maximum recommended dosage is 125 mg/30 mg orally twice daily. Administer COBENFY orally at least one hour before a meal or at least two hours after a meal

Sr.no.	Observations	Response of the firm
1.	Submit evidence of availability of manufacturing facility/equipment for immediate release pellets.	Firm informed that they have JW-mini Extrude Spheroidizing Pellets System for manufacturing of immediate release pellets.

Decision

Deferred

The Board decided that the firm shall submit:

1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.

2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07

3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.

8	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	(EGN-H9U-GEB8, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-12,
	The proposed proprietary name / brand name	**Xantro 100mg/20mg Capsules**
	Label Claim	Xanomeline and Trospium Chloride 100mg and 20mg/Capsule
	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 YearBelow 30°C

For generic drugs (me-too Status)	NA
Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
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 (in case of Import)	Attached in Module 3 in section 3.2.P.8
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	COBENFY (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
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

COBENFY (xanomeline and trospium chloride) is for oral administration and is available in capsules in the following strengths: x 50 mg/20 mg (equivalent to 76.7 mg xanomeline tartrate and 18.3 mg trospium). x 100 mg/20 mg (equivalent to 153.3 mg xanomeline tartrate and 18.3 mg trospium). x 125 mg/30 mg (equivalent to 191.7 mg xanomeline tartrate and 27.5 mg trospium). COBENFY capsules contain a combination of pellets of xanomeline and pellets of trospium chloride. COBENFY is indicated for the treatment of schizophrenia in adults 2.1 Recommended Testing and Monitoring Prior to Initiation and During Treatment with COBENFYx Assess liver enzymes and bilirubin prior to initiating COBENFY and as clinically indicated during treatment [see Contraindications (4) and Warnings and Precautions (5.2, 5.3)]. x Assess heart rate at baseline and as clinically indicated during treatment [see Warnings and Precautions (5.7)].2.2 Recommended Dosage and Administration The recommended dosage of COBENFY is as follows: x The recommended starting dosage is one 50 mg/20 mg capsule (contains 50 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least two days. x Increase the dosage to one 100 mg/20 mg capsule (contains 100 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least five days. x The dosage may be increased to one 125 mg/30 mg capsule (contains 125 mg of xanomeline and 30 mg of trospium chloride) orally twice daily based on patient tolerability and response [see Clinical Studies (14)].x Maximum recommended dosage is 125 mg/30 mg orally twice daily. Administer COBENFY orally at least one hour before a meal or at least two hours after a meal

Sr.no.	Observations	Response of the firm
1.	Submit evidence of availability of manufacturing facility/equipment for immediate release pellets.	Firm informed that they have JW-mini Extrude Spheroidizing Pellets System for manufacturing of immediate release pellets.

Decision

Deferred

The Board decided that the firm shall submit:

1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.

2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07

3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.

9	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	(UY4-74H-VX4L, 2026-02-10)
	Detail of Fee Submitted	75000, 2025-12-12,
	The proposed proprietary name / brand name	**Xantro 50mg/20mg Capsules**
	Label Claim	Xanomeline and Trospium Chloride 50mg and 20mg/Capsule
	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 YearBelow 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Xanomeline Tartrate & Trospium Chloride: This is a novel combination: centrally acting muscarinic agonist (Xanomeline) plus a peripherally selective muscarinic antagonist (Trospium chloride) formulated to treat schizophrenia
	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 (in case of Import)	Attached in Module 3 in section 3.2.P.8
	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	COBENFYTM (Xanomeline and Trospium chloride) capsules, for oral use, Capsules: (Xanomeline/Trospium chloride): 50mg/20mg, 100mg/20mg, 125mg/30mg, Initial U.S. Approval: 2024, Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
	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

COBENFY (xanomeline and trospium chloride) is for oral administration and is available in capsules in the following strengths: x 50 mg/20 mg (equivalent to 76.7 mg xanomeline tartrate and 18.3 mg trospium). x 100 mg/20 mg (equivalent to 153.3 mg xanomeline tartrate and 18.3 mg trospium). x 125 mg/30 mg (equivalent to 191.7 mg xanomeline tartrate and 27.5 mg trospium). COBENFY capsules contain a combination of pellets of xanomeline and pellets of trospium chloride. COBENFY is indicated for the treatment of schizophrenia in adults 2.1 Recommended Testing and Monitoring Prior to Initiation and During Treatment with COBENFYx Assess liver enzymes and bilirubin prior to initiating COBENFY and as clinically indicated during treatment [see Contraindications (4) and Warnings and Precautions (5.2, 5.3)]. x Assess heart rate at baseline and as clinically indicated during treatment [see Warnings and Precautions (5.7)].2.2 Recommended Dosage and Administration The recommended dosage of COBENFY is as follows: x The recommended starting dosage is one 50 mg/20 mg capsule (contains 50 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least two days. x Increase the dosage to one 100 mg/20 mg capsule (contains 100 mg of xanomeline and 20 mg of trospium chloride) orally twice daily for at least five days. x The dosage may be increased to one 125 mg/30 mg capsule (contains 125 mg of xanomeline and 30 mg of trospium chloride) orally twice daily based on patient tolerability and response [see Clinical Studies (14)].x Maximum recommended dosage is 125 mg/30 mg orally twice daily. Administer COBENFY orally at least one hour before a meal or at least two hours after a meal

Sr.no.	Observations	Response of the firm
1.	Submit evidence of availability of manufacturing facility/equipment for immediate release pellets.	Firm informed that they have JW-mini Extrude Spheroidizing Pellets System for manufacturing of immediate release pellets.

Decision

Deferred

The Board decided that the firm shall submit:

1. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.

2. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07

3. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division.

10	Case Category	Routine (Shahrukh Ali)
	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	(1QG-ZNT-XMXZ, 2024-08-19)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**Mefasian 50mg/5ml Suspension**
	Label Claim	Each 5ml contains: Mefenamic Acid..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml, 90ml,120ml, 20-Free of Cost
	Shelf Life (Unit)	2 Year(s)Store below 30 °C

For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Analgesic
Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
Name & address of API manufacturer	Shaanxi Baoxin Pharmaceutical Co.,Ltd
Detail of stability batches of drug product	10litre
Documents for the procurement of API with approval from DRAP (in case of Import)	Computerized No: E-4678282807468 Date of issue: 17-Mar-2023 Loan from M/s Jawa
Pharmaceutical Equivalence and Comparative Dissolution Profile	Mefenamic acid suspension
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Mefenamic Acid 50 mg/5 ml Suspension (Chemidex Pharma Ltd, Chemidex House, Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK)
GMP status of the firm	188 /2023-DRAP the, 14.11.2023 CONTRACT ACCEPTOR
Evidence of approval of manufacturing facility	No. F.1-51/2024-Lic dated 7 .02. 2014 mentioning syrup (General).
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)

******

Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**CLOUD AGRI PAKISTAN** 45-A2 JOHAR TOWN LAHORE **(2029-02)**
	Application Form Dy. No / Tracking ID & date of submission	(68N-V54-LE8X, 2024-07-21)
	Detail of Fee Submitted	300000.0, 2024-07-04,
	The proposed proprietary name / brand name	**Bioaftogen Inactivated FMD vaccine**
	Label Claim	Bioaftogen Inactivated FMD vaccine
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	50mL-De-Controlled
	Shelf Life (Unit)	24 Month2 to 8 C
	For generic drugs (me-too Status)	UVAS-FMD+HS-VAC
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	BIOGENESIS BAGO-Ruta Panamericana 38.5 KM,(B1619IEA), GARIN, Province Benos Aires, -Argentina
	Name, address of Marketing Authorization Holder:	CLOUD AGRI Pakistan, Lahore, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting referred the case to M/o National Food Security for their comments regarding need of strain in Pakistan as FMD viruses circulating in Argentina belongs to Pool 7 while viruses circulating in Pakistan belongs to Pool 3, which are genetically different. Accordingly, letter was issued to M/o NFS&R and their response is as follows: "The undersigned is directed to refer to DRAP letter No. 3-1/2026-DD(BIO) dated 9th January 2026 on the subject cited above and to furnish the following in the subject matter: Bioaftogen inactivated FMD vaccine is the multivalent formulation designed to target major circulating serotypes O, A, and Asia-1, with the O and A strains relevant to Pool-7 and the Asia-1 component intended for markets where that serotype circulates (e.g., Pool-3).It incorporates reference strains (O1 Campos, A24 Cruzeiro, A2001 Argentina, Asia-1) which are widely used internationally for cross-protection within heterologous lineages. Antigenic matching data generated at the WOAH reference laboratory (Pirbright Institute) for this vaccine provides r_1-based evidence suggesting likely cross-neutralization against circulating field viruses, forming an acceptable scientific basis for consideration for the circulating viruses in Pakistan of Pool 3. The declared antigen payload (≥10–15 µg per strain per dose) indicates the formulation potentially capable of inducing protective neutralizing antibody titers, subject to consistent manufacturing quality. However, being an inactivated vaccine, its safety profile depends critically on validated virus inactivation and absence of residual infectivity, which must be demonstrated through batch testing. Expected immunogenicity is dependent not only on formulation but also on adjuvant quality, cold-	

	chain maintenance, and administration compliance in field conditions. The inclusion of multiple serotypes enhances its suitability for endemic settings where co-circulation of strains is common, improving population-level coverage potential; however, cross-protection remains partial and strain-dependent, and antigenic drift within Pool-3 lineages may reduce field effectiveness over time. Batch-to-batch consistency, potency testing (PD_{50}), and standardized antigen quantification methods are essential to ensure reproducible field performance.While the above considerations support this vaccine as acceptable candidate for approval, it should be recognized that vaccines based on heterologous or geographically distant strains may be more susceptible to reduced field performance in the presence of ongoing antigenic drift within locally circulating lineages. Consequently, their protective efficacy may vary over time and across epidemiological settings, necessitating continuous monitoring through field effectiveness studies and updated antigenic matching. Importantly, approval of such a vaccine should be interpreted strictly within the framework of evidence-based cross-protection and should not be construed as the precedent for blanket acceptance of all vaccines across different FMD pools, as regulatory decisions remain fundamentally dependent on strain relevance, validated immunogenicity, and demonstrated field performance rather than pool classification alone."	
	Decision	
	Deferred Registration Board referred the case to "Sub-Committee for consultative discussion on Foot and Mouth Disease Vaccines Imported from different Pools than Pakistan'.	
2	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**QAS INTERNATIONAL** PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE **(09-341-0134-103105D)**
	Application Form Dy. No / Tracking ID & date of submission	(1NN-RD7-YZJP, 2025-07-25)
	Detail of Fee Submitted	300000.0, 9400 2025-07-22, 2026-02-17
	The proposed proprietary name / brand name	**ANIVAC Mg, Ms**
	Label Claim	Active substances Quantity per dose (0.5 ml) Mycoplasma gallisepticum > 1x107 CFU Mycoplasma synoviae > 1x107 CFU
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500ml/1000 doses-De-Controlled
	Shelf Life (Unit)	12 MonthStore at 2 ~ 8°C
	For generic drugs (me-too Status)	ANIVAC Mg, Ms
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SAN Group Biotech Germany GmbH-Muehlenstr. 13 49685 Hoeltinghausen GERMANY-Germany
	Name, address of Marketing Authorization Holder:	Ahmed Saleem Goriya, Plot # 153/155, Mustafa Abad, Tehsil Kamoki, District Gujranwala, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Decision	
	Deferred	

	Registration Board deferred the case for further deliberation in next meeting regarding non-performance of assay testing during stability studies and non-availability of product in country of origin.	
3	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	**QAS INTERNATIONAL** PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE **(09-341-0134-103105D)**
	Application Form Dy. No / Tracking ID & date of submission	(A8L-JPS-97NT, 2025-07-04)
	Detail of Fee Submitted	300000.0, 9400.0 2025-07-02, 2025-08-27
	The proposed proprietary name / brand name	**ANIVAC FAdV 5**
	Label Claim	Fowl Adenovirus (FAdV) Serotype 2, 4, 8a, 8b and 11 Fowl Adenovirus Serotype 2 > 1x106.5 TCID50 Fowl Adenovirus Serotype 4 > 1x106.5 TCID50 Fowl Adenovirus Serotype 8a > 1x106.5 TCID50 Fowl Adenovirus Serotype 8b > 1x106.5 TCID50 Fowl Adenovirus Serotype 11 > 1x106.5 TCID50
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	500ml/1000 doses-De-Controlled
	Shelf Life (Unit)	12 MonthStore at 2 ~ 8°C
	For generic drugs (me-too Status)	ANIVAC FAdV 5
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	SAN Group Biotech Germany GmbH-Muehlenstraße 13 49685 Hoeltinghausen Germany-Germany
	Name, address of Marketing Authorization Holder:	SAN Group Biotech Germany GmbH, Muehlenster 13, 49685 Hoeltinghuasen,, Germany
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	Registration Board referred the case to Expert Working Group on Veterinary Drugs for their opinion regarding safety, efficacy data submitted by the firm and antigenic similarity of applied product with Pakistani field isolate as recommended by M/s NFS&R. EWG in its 10th meeting recommended the product for grant of Registration.	
	Decision	
	Deferred Registration Board deferred the case for further deliberation in next meeting regarding non-performance of assay testing during stability studies and non-availability of product in country of origin.	
4	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(1VL-4Y6-LUUV, 2026-04-06)
	Detail of Fee Submitted	313500, 2026-01-06,

The proposed proprietary name / brand name	**Ovinox Solution for Injection 4000 anti-Xa IU/0.4ml**
Label Claim	Each pre-filled syringe Ovinox 4000 anti-Xa IU contains: Enoxaparin Sodium.....40mg Water for Injections..... up to 0.4ml
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
Shelf Life (Unit)	36 MonthDo not store and transport above 25 degree centigrade.
For generic drugs (me-too Status)	Clexane Injection Imported by Hoechst Pakistan Limited, Plot 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, China, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France

Evaluation Remarks

Sr. No.	Query	Response
1.	Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.	Pharmacokinetic (PK) and pharmacodynamic (PD) profile of the applied product (ovine-derived Enoxaparin Sodium) has been evaluated and found to be comparable to that of the innovator product.
2.	Whether the product approved in Indonesia under the name PT Biofarma is approved as a finished imported product or for local manufacturing.	The API of Ovine Enoxaparin Sodium is sourced from Suzhou Ronnsi Pharma Co., Ltd., China, while the finished pharmaceutical product approved in Indonesia under PT Biofarma is locally manufactured. In Indonesia, there are currently two locally registered manufacturers utilizing the API sourced from Suzhou Ronnsi Pharma Co., Ltd., China, including PT Etana Biotechnologies Indonesia. Copies of the registration certificates of PT Etana Biotechnologies Indonesia for Enoxaparin Sodium 40 mg and 60 mg are attached for reference.

3.	Whether the facility/production line used for manufacturing ovine enoxaparin API and finished product is also used for porcine-origin enoxaparin products..	The facility/production line used for manufacturing Ovine Enoxaparin API and finished product is dedicated exclusively to ovine-origin enoxaparin products and is not used for porcine-origin enoxaparin products.
4.	The submitted PSUR/PBRER for Ovine Enoxaparin Sodium covers the reporting interval from 05 October 2022 to 04 April 2023. Clarify whether subsequent PSUR/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority. You are also required to provide the latest cumulative PSUR/PBRER, including current post-marketing safety data up to the most recent Data Lock Point (DLP), along with justification for submission of an outdated reporting interval as supportive pharmacovigilance evidence.	Subsequent PSURs/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority in accordance with applicable pharmacovigilance requirements.

Decision

Deferred

Registration Board noted that the product is not licensed and available for sale in country of origin, hence, the applicant is required to conduct indigenous clinical trials to establish safety and efficacy of the product.

5	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(7L6-V1B-ZM4G, 2026-04-06)
	Detail of Fee Submitted	313500, 2026-01-06,
	The proposed proprietary name / brand name	**Ovinox Solution for Injection 10000 anti- Xa IU/1ml**
	Label Claim	Each pre-filled syringe Ovinox 10000 anti-Xa IU contains: Enoxaparin Sodium.....100mg Water for Injections..... up to 1ml
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
	Shelf Life (Unit)	36 MonthDo not store and transport above 25 degree centigrade.
	For generic drugs (me-too Status)	Not Available.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, China, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France

Evaluation Remarks

Sr. No.	Query	Response
1.	Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.	Pharmacokinetic (PK) and pharmacodynamic (PD) profile of the applied product (ovine-derived Enoxaparin Sodium) has been evaluated and found to be comparable to that of the innovator product.
2.	Whether the product approved in Indonesia under the name PT Biofarma is approved as a finished imported product or for local manufacturing.	The API of Ovine Enoxaparin Sodium is sourced from Suzhou Ronnsi Pharma Co., Ltd., China, while the finished pharmaceutical product approved in Indonesia under PT Biofarma is locally manufactured. In Indonesia, there are currently two locally registered manufacturers utilizing the API sourced from Suzhou Ronnsi Pharma Co., Ltd., China, including PT Etana Biotechnologies Indonesia. Copies of the registration certificates of PT Etana Biotechnologies Indonesia for Enoxaparin Sodium 40 mg and 60 mg are attached for reference.
3.	Whether the facility/production line used for manufacturing ovine enoxaparin API and finished product is also used for porcine-origin enoxaparin products..	The facility/production line used for manufacturing Ovine Enoxaparin API and finished product is dedicated exclusively to ovine-origin enoxaparin products and is not used for porcine-origin enoxaparin products.
4.	The submitted PSUR/PBRER for Ovine Enoxaparin Sodium covers the reporting interval from 05 October 2022 to 04 April 2023. Clarify whether subsequent PSUR/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority. You are also required to provide the latest cumulative PSUR/PBRER, including current post-marketing safety data up to the most recent Data Lock Point (DLP), along with justification for submission of an outdated reporting interval as supportive pharmacovigilance evidence.	Subsequent PSURs/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority in accordance with applicable pharmacovigilance requirements.

Decision

Deferred

Registration Board noted that the product is not licensed and available for sale in country of origin, hence, the applicant is required to conduct indigenous clinical trials to establish safety and efficacy of the product.

6	Case Category	Routine (Muneeb Ahmed Cheema)
	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	(8NB-TT2-NHJE, 2026-04-06)
Detail of Fee Submitted	313500, 2026-01-06,
The proposed proprietary name / brand name	**Ovinox Solution for Injection 6000 anti-Xa IU/0.6ml**
Label Claim	Each pre-filled syringe Ovinox 6000 anti-Xa IU contains: Enoxaparin Sodium.....60mg Water for Injections..... up to 0.6ml
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2 pre-filled syringes packed in a box, (1 ml of Each Syringe).-Controlled
Shelf Life (Unit)	36 MonthDo not store and transport above 25 degree centigrade.
For generic drugs (me-too Status)	Clexane Injection Imported by Hoechst Pakistan Limited, Plot 23, Sector 22, Korangi Industrial Area, Karachi, Pakistan.
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Suzhou Erye Pharmaceutical Co., Ltd.-Factory: No. 2, Anmin Road, Dongqiao, Huangdai Town, Xiangcheng District. Suzhou, Jiangsu 215152, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	
Name, address of Marketing Authorization Holder:	Suzhou Ronnsi Pharma Co., Ltd. , 108 Yuxin Road, Suite 1001, building A Suzhou, Jiangsu 215123, China, 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	Clexane Injection Manufactured by Sanofi: 46 Avenue de la Grande Armée, 75017 Paris, France

Evaluation Remarks

Sr. No.	Query	Response
1.	Confirmation of equivalence of results of PK/PD studies of applied product of ovine source with Innovator product.	Pharmacokinetic (PK) and pharmacodynamic (PD) profile of the applied product (ovine-derived Enoxaparin Sodium) has been evaluated and found to be comparable to that of the innovator product.
2.	Whether the product approved in Indonesia under the name PT Biofarma is approved as a finished imported product or for local manufacturing.	The API of Ovine Enoxaparin Sodium is sourced from Suzhou Ronnsi Pharma Co., Ltd., China, while the finished pharmaceutical product approved in Indonesia under PT Biofarma is locally manufactured. In Indonesia, there are currently two locally registered manufacturers utilizing the API sourced from Suzhou Ronnsi Pharma Co., Ltd., China, including PT Etana Biotechnologies Indonesia. Copies of the registration certificates of PT Etana Biotechnologies Indonesia for Enoxaparin Sodium 40 mg and 60 mg are attached for reference.

3.	Whether the facility/production line used for manufacturing ovine enoxaparin API and finished product is also used for porcine-origin enoxaparin products..	The facility/production line used for manufacturing Ovine Enoxaparin API and finished product is dedicated exclusively to ovine-origin enoxaparin products and is not used for porcine-origin enoxaparin products.
4.	The submitted PSUR/PBRER for Ovine Enoxaparin Sodium covers the reporting interval from 05 October 2022 to 04 April 2023. Clarify whether subsequent PSUR/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority. You are also required to provide the latest cumulative PSUR/PBRER, including current post-marketing safety data up to the most recent Data Lock Point (DLP), along with justification for submission of an outdated reporting interval as supportive pharmacovigilance evidence.	Subsequent PSURs/PBRERs covering the period after 04 April 2023 have been prepared and submitted to the reference regulatory authority in accordance with applicable pharmacovigilance requirements.
Decision		
Deferred Registration Board noted that the product is not licensed and available for sale in country of origin, hence, the applicant is required to conduct indigenous clinical trials to establish safety and efficacy of the product.		

Case No. 1: <u>Registration of Imported Biological Product applied by M/s Revive Healthcare deferred in 351st meeting.</u>

Teriparatide is a recombinant human parathyroid hormone analog (PTH 1-34). It has an identical sequence to the 34 N-terminal amino acids (the biological active region) of the 84-amino acid human parathyroid hormone. It is used in the treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

Name, address of Applicant / Importer	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
Details of Drug Sale License of importer	Address: Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. Validity: 21-05-2027 Status: License to sell drugs as distributor
Name and address of marketing authorization holder (abroad)	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Name, address of manufacturer(s)	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Name of exporting country	India
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original valid legalized CoPP Certificate No. 4222631/TS/2023 Valid upto 11-12-2025 issued by by Drug Control Administration, Government of Telangana State, India. The COPP confirms free sale status of the product (Osteotide Injection 750mcg/3mL, prefilled cartridge with pen device) in exporting country as well as GMP status of the manufacturing site. The submitted legalized GMP is valid upto 11-12-2025
Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from Virchow Biotech Private Limited . The letter species that the manufacturer appoints M/s Revive Healthcare Lahore to register their products in Pakistan. The authorization letter is issued on 13-03- 2023
Status of the applicant	☐ Manufacturer 0 Importer □ Is involved in none of the above (contract giver)
Status of application	0 New Drug Product (NDP) □ Generic Drug Product (GDP)
Intended use of pharmaceutical product	0 Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	0 Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No.1298 : dated 08-11-2023
Details of fee submitted	PKR 75,000/-: 26-10-2023
The proposed proprietary name / brand	OSTEOTIDE INJECTION 750 mcg/3mL

name	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL of prefilled pen device contains: Teriparatide ……. 250mcg
Pharmaceutical form of applied drug	Solution for injection
Pharmacotherapeutic Group of (API)	Antineoplastic agent ATC Code: H05AA02
Reference to Finished product specifications	USP
Proposed Pack size	1's
Proposed unit price	AS PER SRO
The status in reference regulatory authorities	FORSTEO INJECTION (250mcg/mL) by Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands MHRA Approved
For generic drugs (me-too status)	Not applicable
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD
	template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Virchow Biotech Private Limited Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted DS stability study data of 3 batches of API Batch # 4- BOST00120 5- BOST00220 6- BOST00320 at accelerated as well as real time conditions. The real time stability data provided for claimed shelf life of 18 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted results

	of pharmaceutical equivalence against the reference product which is Forteo Injection by Lilly, France.
Analytical method validation/verification of product	Firm has submitted analytical verification validation studies for the applied product.
Container closure system of the drug product	The drug product is filled into 3.0 mL sterile USP Type-I siliconized glass cartridges closed with lined seals, followed by solid plunger.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Batch No. 1- 5400119 2- 5400219 3- 5400319 The accelerated stability study data is conducted at 25oC ±2oC / 60% ± 5% RH and real time stability study data conducted at 5oC ±3oC for 36 months with the claimed shelf life of 24 months.
Non-clinical (Module-IV)	The firm has submitted non-clinical data following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity
Clinical (Module-V)	Firm has submitted clinical data of • Reports of Biopharmaceutic Studies • Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials • Reports of Human Pharmacokinetic (PK) Studies • Reports of Human Pharmacodynamic (PD) Studies • Reports of Efficacy and Safety Studies

Evaluator's remarks:
The firm has provided incomplete data of non-clinical and clinical studies.

Decision of 344th RB meeting: *After detailed discussion and deliberation, the Board decided to defer the case for provision of following:*

i. *Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogeneicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:*
ii. *Documented and published clinical studies, biosimilarity studies including In vitro-In vivo Correlation Study Reports, Reports of Bioanalytical and Analytical Methods for Human Studies, Human Pharmacokinetic and Pharmacodynamics studies, Study Reports of Controlled Clinical Studies Pertinent to the claimed indication:*

iii. *Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:*

iv. *Post-marketing surveillance (Pharmacovigilance) study reports*

Evaluation by BE&R:

Now the firm has submitted a reply as under:

In non-clinical part, firm has submitted following;

- Comparative pharmacodynamic study conducted in White Albino Rabbits.
- In Repeat-Dose toxicity, following studies are performed:
- To investigate the acute and Sub-chronic toxicity effects when administered intravenously and subcutaneously to Sprague Dawley Rats.
- To assess the safety and local effects when administrated subcutaneously to male and female New Zealand white albino rabbits

In clinical part, firm has submitted following studies;

- A phase I study was conducted to assess the safety and pharmacokinetic profile of rhPTH (1-34) drug product. The objective of the study was to assess pharmacokinetics profile of Osteotide of Virchow Biotech, containing 20 µg of rhPTH following subcutaneous injection in healthy, adult, human subjects.
- A phase II comparative study was conducted to compare the safety bioavailability and pharmacodynamic effects of rhPTH (1-34) drug product (test drug) and a reference product (Forteo®). The objective of the study was to assess and compare the pharmacodynamic profile and bioavailability of Osteotide of Virchow Biotech, with that of Forteo of Eli Lilly containing 20µg of rhPTH following subcutaneous injection.
- Phase 3 study title: Safety and Efficacy of **OSTEOFORM** (rhParathyroid Hormone (1-34)) in increasing Bone Mineral Density in Osteoporosis -A Randomised control open-label multicenter study in India VB006/09/05 Prot.3 Dated 04/09/2005
- Phase IV study: A Non-inferiority, multicenter, comparative study between **Bonista** and Forteo in the treatment of osteoporosis;
- PERIODIC SAFETY UPDATE REPORT on TERIPARATIDE (rhParathyroid Hormone) of every year from 2010 to 2017 is attached.

Decision of 350th meeting:

Deferred for submission of bio similarity data in accordance with WHO guidelines or other relevant guidelines from Stringent Regulatory Authorities (SRAs) for the applied product.

Evaluation by BE&R:

Teriparatide is a rDNA peptide of 34 amino acids sequence and evaluated as per decision of the Board for peptide drugs. Following is submitted by the applicant;

- Physico-chemical and biological characterization of Teriparatide (rhPTH (1-34)) USP drug substance and Teriparatide Injection (rhPTH (1-34)) USP drug product which is manufactured at Virchow Biotech Private limited, Hyderabad.
- Comparative study results of Osteotide with Forteo (reference product).
- Comparative pharmacodynamic study conducted in White Albino Rabbits.
- A phase II comparative study to compare the safety bioavailability and pharmacodynamic effects of rhPTH (1-34) drug product (test drug) and a reference product (Forteo®). The objective of the study was to assess and compare the pharmacodynamic profile and bioavailability of Osteotide of Virchow Biotech, with that of Forteo of Eli Lilly containing 20µg of rhPTH following subcutaneous injection.

Remarks:

- Peptide mapping is done by HPLC.
- Comparative impurity testing of applied product with innovator is required including product related and process related impurities.

- Innovator product Forteo is available as 600µg/2.4ml (the strength 750µg/3ml is discontinued) while the applied product is 750µg/3ml.

Decision of 351st meeting:

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

- *Justification of performing Peptide mapping by HPLC instead of LC-MS.*
- *Comparative impurity testing of applied product with innovator including product related and process related impurities.*
- *Reason of discontinuation of Innovator in applied strength in USFDA.*
- *Evidence of availability of formulation in applied strength in Reference Regulatory Authorities.*

Remarks by BE&R:

The Innovator product Forteo 750 mcg/3 mL was previously available in Health Canada but has been discontinued there as of February 2026. It had already been discontinued earlier by the US FDA. So, the applied strength is no longer available in any reference regulatory authority designated by Registration Board.

Same case was applied by M/s Lab Diagnostic Systems (SMC) Pvt. Ltd., Taxila Rawalpindi vide tracking ID: MUB-RTU-21WW, dated 2025-02-13 and was rejected by Registration Board in its 357th meeting due to non-availability of evidence of applied strength i.e 750mcg/3ml Pre-filled Pen/cartridge in any of the reference regulatory authorities as approved by Registration Board.

Decision of 358th meeting:

Registration Board rejected the application due to non-availability of evidence of applied strength i.e 750mcg/3ml Pre-filled Pen/cartridge in any of the reference regulatory authorities as approved by Registration Board.

Case No. 2: 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 of 354th meeting:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided 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.

In the light of above decision, a personnel hearing letter was issued to M/s CLOUD AGRI PAKISTAN, Lahore.

Decision of 358th meeting:

The Registration Board deferred the case due to paucity of time.

Case No. 3: 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	**Cleven 20 Injection** Each 0.2ml prefilled syringe contains:	The Registration Board after thorough deliberation

Ltd, 19 Dhanmondi R/A, Road No. 7, Dhaka 1205, Bangladesh.	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	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 pharmaceutical products (e.g., penicillin and others) along with biological products and no clarification submitted by the applicant.	The inclusion of pharmaceutical products such as penicillin under a license designated for biological 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**

Submitted for consideration of Registration Board please.

Decision of 354th meeting:

Keeping in view the recommendations of panel of inspectors of DRAP; Registration Board decided 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.

In the light of above decision, a personnel hearing letter was issued to M/s Highnoon Laboratories, Lahore.

Decision of 358th meeting:

The Registration Board deferred the case due to paucity of time.

Case No. 4: 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 Getz Pharma (Pvt.) Ltd., Karachi 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

Accordingly, the case was considered in 354th meeting of Registration Board wherein the Board decided as follows:

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.

Accordingly, personal hearing letter regarding Liraglid was issued to the firm on 07-05-2026. Moreover, the firm has submitted the reply of Show Cause Notice regarding Semaglutide.

Decision of 358th meeting: The Registration Board deferred the case due to paucity of time.

Case No. 5: Imported human Biologicals applied by M/s Inouku Animal Health (Pvt.) Ltd., Lahore approved in 344th meeting.

Following product of M/s Inouko Animal Health Pvt. Limited, Lahore was approved in 330th meeting of Registration Board as per following details:

Sr. No.	Name of MAH & Manufacturer	Brand Name & Composition	Decision of RB
1.	M/s Ceva Animal Health Inc. 131 Malcolm Road, Guelph, Ontario, Canada N1K1A8	Immucox ® 5 Eimeria Acervulina-Brunetti-Maxima-Necatrix –Tenella Vaccine, Live oocysts Each dose of vaccine contains: Eimeria acervulina……at least 151 oocysts Eimeria brunetti……at least 40 oocysts Eimeria maxima……at least 50 oocysts Eimeria necartrix……...at least 51 oocysts Eimeria tenella……...at least 25 oocysts Innovator's Specifications	*Keeping in view legalized FSC indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs. The firm shall submit fee of 7500/- for correction/pre-approval change in Form-5A as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.* **(Pages-117-118/corr.)**

Later on, M/s Vigilant Pharma filed a complaint that the instant product is already registered in their name. The case was discussed in different meetings of Registration Board and in 344th meeting, following was decided:

"Keeping in view the email received from Lucas Figueiredo, Campus Director & Kelly Groskopf, Regulatory Affairs Specialist, Ceva Animal Health – Canada, the Board decided to regret the complaint lodged by M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore, with the following directions;

i. *The Board directed the Division of Biological Evaluation & Research to issue registration letter of Immucox-5 Vaccine already approved in 331st meeting of the Board in the name of M/s Inouko Animal Health (Private) Limited, Lahore.*
ii. *The Board further directed the Division of Biological Evaluation & Research to issue show-cause notice and letter of personal hearing to M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore as to why the registration of their product Immucox Vaccine (Reg. No. 015484) may not be cancelled?"*

Accordingly, registration letter was processed for issuance and it was advised by Chairman Registration Board to get updated LOA from M/s Inouku Animal Health and firm was advised to submit the same vide E-App External Communication tracking ID: MS8-8RL-LJ5W. The firm has not yet submitted any response.

Moreover, a show cause letter was issued to M/s Vigilant Veterinary Services (Pvt.) Limited, Lahore in response of which the firm submitted that the emails referred in notice were never shared to them by DRAP or Ceva Animal Health.

They asserted that it is their legal right to be furnished with aforesaid email, in order to effectively defend their rights and interests.

The firm further submitted that in absence of provision of the complete evidence upon which show cause notice is founded, the issuance of such notice is in contravention of principles of natural justice, due process, and the protection guaranteed under Articles 4 and 10A of Constitution.

The firm requested to with draw show cause notice and prayed to provide them complete and original contents of the emails.

In light of above, a personal hearing letter was issued to the firm on 29th August to attend the meeting on 10th September. Later on, as the meeting was rescheduled, hence, another letter was issued on 17th September, 2025 to attend the meeting on 24th September. The copy of letter was also communicated to the firm through official E-App External Communication vide tracking ID: LM4-VJV-VU2M.

M/s Vigilant Services vide its letter dated 18-09-2025 authorized their counsel, Ms. Iram Iqbal Khan, Advocate High Court to represent them in proceeding before the Board. Ms. Iram Iqbal vide her letter dated 18-09-2025 requested to adjourn the hearing due to her professional engagement before the Honourable Lahore High Court. She further submitted that despite two prior letters for disclosure of the relevant e-mail correspondence, the same has not be furnished to date.

The case was considered in 351st meeting of Registration Board wherein the Board decided as follows:

"Registration Board decided as follows:

i. *M/s Inouku Animal Health shall be directed to provide the original valid Letter of Authorization from Product License Holder in its favor.*
ii. *The request of M/s Vigilant Services for adjournment is acceded to till next meeting of Registration Board.*

The request of M/s Vigilant Services for provision of original contents of emails discussed in 344th meeting, is not acceded to as the complete contents of the emails are already included in 344th meeting of Registration Board and minutes of the said meeting are publically available at official website of DRAP @ https://www.dra.gov.pk."

The decision of the Board was communicated to M/s Vigilant Services on 14-10-2025 and personal hearing letter was issued on 10-11-2025. Moreover, M/s Inouko Animal Health (Private) Limited has submitted scanned copy of Apostille Sole Agency Agreement in their name indicating Immucox 5 vaccine from M/s eva Animal Health Inc., 131 Malcolm Road, Guelph, Ontario, Canada N1K 1A8 ("Ceva Canada") dated 25-09-2025 w.e.f. 01-09-2025.

The firm has now filed a Writ Petition in The Islamabad High Court, Islamabad vide no. 4818 of 2025 where the Honorable High Court decided the following:

"CM No. 01/2025

Exemption, sought for is allowed subject to all just and legal exceptions.

CM No. 02/2025

Notice. In the meanwhile, proceedings on show cause notices dated 07.08.2025, 29.08.2025 and 10.11.25 shall remain suspended till the next date of hearin. It is clarified that if counsel for the petitioner fails to proceed with the matter, the interim order passed tody shall be automatically recalled."

Registration Board in its 358th meeting decided as under:

"In the light of above order; Registration Board deferred the case till decision by Honorable Islamabad High Court."

Now, DRAP has received an email from M Shafiq ur Rehman Dab, Advocate Supreme Court on 07-05-2026 stating the following:

"Dear Sir,

I am Counsel of DRAP in W.P.no. 4818/2025.The subject Petition was fixed for hearing today before Islamabad High Court, Islamabad. As per direction of Islamabad High Court, I presented the printout of the emails record of M/s Ceva Animal Canada which I procured yesterday with DRAP. The court announced the disposal of the instant petition. It would be appropriate that the annexures mentioned in emails be provided to the petitioner and present the matter before Registration Board in its meeting scheduled on 12.05.2026 and decide the matter after hearing the petitioner."

In light of above email, personal hearing notice was issued to the petitioner on 07-05-2026 and email annexures were issued on 11-05-2026. The same have also been communicated through E-App to the firm.

It is to be informed that a letter from the firm has been received on 11-05-2026 stating that their Chief Executive, Dr. Muhammad Azam Chohan, is presently out of Pakistan and is in Canada and he will return on 25-05-2026 and firm requested to adjourn the hearing to a date after 25-05-2026.

Moreover, a letter from Amir Alam Khan & Associates has been received on 11-05-2026 stating the following:

"It is respectfully submitted that, during proceedings before the Honorable Islamabad High Court, the undersigned was informed in person by the learned counsel/ representative for DRAP that the matter had been fixed for personal hearing before DRAP on 12-05-2026. This intimation was given in Court even before any fresh show cause notice had been duly issued and communicated to the company in accordance with law. Also in the High Court, it was mentioned that the remaining documents were to be provided on 11-05-2026, 1 day before this hearing, which is extremely short notice. It is pertinent to state that, till date, no such show cause notice has been served upon the undersigned counsel through post by DRAP, nor has the same been received by the legal office of the undersigned from DRAP in the ordinary course.

It is further submitted that Dr. Muhammad Azam Chohan, being the principal officer and instructing representative of the Company, is presently in Canada. A copy of his return ticket is annexed herewith. In his absence, the undersigned has been unable to obtain complete instructions and the necessary factual information required for the purpose of preparing and presenting a proper reply. It is, therefore, humbly prayed that the matter may kindly be adjourned until his return, so that the company may not suffer prejudice and may be afforded a fair opportunity of hearing."

Decision of 358th meeting:

Registration Board deliberated that during hearing before Honorable Islamabad High Court, Islamabad, the firm has already been advised to appear before Registration Board in this meeting on 12.05.2026 and yet the firm is again requesting for adjournment. Therefore, Registration Board decided as follows:

i. **Issue registration letter of Immucox-5 Vaccine already approved in 331st meeting of the Board in the name of M/s Inouko Animal Health (Private) Limited, Lahore.**
ii. **Issue cancellation letter in name of M/s Vigilant Veterinary Services, Lahore for their product Immucox Vaccine (Reg. No. 015484).**

Case No. 6: Imported Veterinary Biological applied by M/s. Jovac Global-PAK, Lahore deferred in 329th meeting of Registration Board.

Following product of M/s. Jovac Global-PAK is deferred in 329th meeting of Registration Board as per following details:

Name and address of Importer	**M/s. Jovac Global-PAK,** Plot No. 17, Block D, EME, DHA Phase 12, Lahore
Detail of DSL	M/s. Jovac Global-PAK Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore. Valid up to:15.06.2023
Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
Name of exporting country	Jordan
Brand Name +Dosage Form + Strength	Jova Zeit 6 Plus vaccine. (Injectable oil emulsion)
Diary No. Date of R& I & fee	Dy. No. 25502 R&I Dated 14-09-2022 Rs. 150,000/- (Slip No. 9269169953)
Composition	Each dose contains: Inactivated Adenovirus Serotype 2,4 &8 at least…. $10^{6.5}$ $TCID_{50}$
Pharmacological Group	Inactivated Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	2 years (20C-80C)
Document Details	a. Valid legalized free sale certificate is submitted by the firm however it does not confirm the availability of product in country of origin. b. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020.
Pack size	300ml(1000doses)
Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	GPVAC Hydro TC Plus of Grand Pharma Each 0.3ml contains: Inactivated Avian Adenovirus 4…. ≥ 7log10 EID50/dose Inactivated Avian Adenovirus-8…. ≥ 7log10 EID50/dose
Decision in 329th RB meeting	Registration Board referred the case to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the serotype 2 in Pakistan
Remarks of evaluator	The firm has now informed through E-App tracking ID: QSL-1M8-7PL5 that a product containing Serotype 2 has already been approved by the Board in its 352nd meeting with brand name GPVAC Poly-Hep in name of M/s Grand Pharma on the recommendations of EWG.

Decision **Keeping in view the GMP Certificate & FSC indicating availability of product is country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

Case No. 7: **APPLICATION FOR THE APPROVAL OF MANUFACTURER'S SPECIFICATIONS FOR SOLVENT FOR HERCEPTIN 440 MG VIAL (Reg. No. 032131).**

M/s Roche Pakistan Limited, Karachi has submitted a request for grant of manufacturer specifications for their registered drug, Solvent for Herceptin (Reg No. 032131) which is Bacteriostatic Water for Injection.

It is submitted that aforesaid solvent's monograph is included in the USP Pharmacopeia and however not available in BP and European Pharmacopeia. The firm has submitted the comparison of the their specs with USP monograph wherein all other specs defined in USP are stringent/ equivalent except pH. Comparison is as below:

Specifications	USP	Roche
pH	pH 〈791〉 USP Sample: To 100 mL of Bacteriostatic Water for Injection add 0.3 mL of saturated potassium chloride solution. Acceptance criteria: 4.5–7.0	Same method applied. Acceptance criteria set to 4.5 – 9.0 pH measurement performed in accordance to USP and Ph. Eur. 2.2.3

The applicant was asked to submit justification regarding the wide range of pH limits as compared to the USP Pharmacopeia and they responded as under:

Herceptin 440 mg is formulated in a L-Histidine buffer system. The side chain (imidazole) of histidine has a pKa of approximately 6.0–6.5, making it capable of acting as a buffer to maintain a drug product and reconstituted solution pH to ensure stability. As demonstrated by the calculations, a 5 mM Histidine buffer provides excess capacity to buffer any diluent variability within the specified range for BWFI (pH 4.5–9.0). The Bacteriostatic Water for Injection (BWFI) provided is not intended for independent sale; it is marketed exclusively as a co-packaged combination with Herceptin 440 mg for reconstitution of the drug product. The variability of the BWFI is therefore to be assessed in the context of the reconstituted dose solution. As calculated above, the buffer capacity of the Herceptin formulation is sufficient to buffer the ionic load from BWFI within its specified pH range. The L-Histidine buffer system ensures that the pH remains within a range of 5.9-6.4 upon reconstitution which was furthermore demonstrated in the study. This ensures stability of Trastuzumab in the dose solution.

Decision in 356th meeting:

Registration Board deferred the case due to relaxed pH specifications of applied Bacteriostatic Injection as compared to United States Pharmacopoeia.

The firm has now submitted reply on 21st April 2026 of which is reproduced as below:

"Roche, Pharma Technical Regulatory, hereby clarifies that the Herceptin Solvent 20 ml (bacteriostatic water for injection, BWFI) is an integral component of the Herceptin 440 mg drug product. It is intended exclusively for the reconstitution of Herceptin 440 mg lyophilized powder, and as such has been developed to ensure the appropriate degree of quality of the reconstituted Herceptin drug product.
It must be noted that no claim is made by the MAH that Herceptin Solvent represents an "off-the-shelf" USP BWFI as its sole intended use is the reconstitution of Herceptin 440 mg lyophilized powder. USP (or equivalent) test methods and acceptance criteria are used where applicable.
The proposed Herceptin Solvent specifications and limits are currently approved as part of the dossier at the following stringent authorities:
● Swissmedic (Switzerland)
● Health Canada (Canada)
The quality, safety and efficacy of Herceptin 440 mg drug product, including both of its lyophilized powder and solvent components, has been demonstrated in product development studies, presented in the dossier, and confirmed through extensive global post-approval use experience."

Decision of 358th meeting:

Keeping in view the approval of product in RRAs (Swissmedic and Health Canada etc.); Registration Board approved Manufacturer's Specifications of Solvent for Herceptin (Reg No. 032131) i.e. Bacteriostatic Water for Injection.

Case No 8: **APPLICATION FOR GRANT OF ONE REGISTRATION NUMBER FOR MENVEO POWDER AND SOLUTION FOR INJECTION (MENINGOCOCCAL ACWY CONJUGATE VACCINE**

M/s GSK Pakistan Limited Karachi vide TID: LM1-TW9-Z3G1 dated 22.4.2026 has submitted request Registration Number: 063927 may be allowed as combo pack for their registered product under below particulars:

Reg. No.	Product Details	Date of Reg	Manufacturer
063927	**MenA Powder Vial** Lyophilized Conjugate Component Each dose (0.5mL of the reconstituted vaccine) contains: Meningococcal group A oligosaccharide 10 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein: Protein 16.7 to 33.3 micrograms	16.12.2016	**Product License Holder:** GSK Vaccines S.r.l,, via Fiorentina, 1, 53100 Siena, Italy; **Manufacturer:** GSK Vaccines S.r.l.,, Bellaria-Rosia, 53018 Sovicille (SI),, Italy
083137	**MenCWY Solution Vial** Liquid Conjugate Component Each dose (0.5mL of the reconstituted vaccine) contains: Meningococcal group C oligosaccharide 5 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein: 7.1 to 12.5 micrograms; Meningococcal group W-135 oligosaccharide 5mcg conjugated to Corynebacterium diphtheriae CRM197 protein: 3.3 to 8.3 micrograms; Meningococcal group Y oligosaccharide 5 microgram conjugated to Corynebacterium diphtheriae CRM197 protein: 5.6 to 10.0mcg	16.12.2016	

It is practice in vogue that products in combo pack are being registered under one registration number. The product is also registered internationally in combo pack (Lyophilized Conjugate Component+ Liquid Conjugate Component).

Decision of 358th meeting:

Registration Board acceded to request of the firm and granted one registration number (Reg. No. 063927) for MenA Powder Vial + MenCWY Solution Vial imported in combo pack.

Meeting ended with a vote of thanks to and from the Chair,

-------End of Document------