

**MINUTES FOR 353RD MEETING OF REGISTRATION BOARD
HELD ON 14TH – 15TH JANUARY, 2026**

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

353rd meeting of Registration Board was held on 14th – 15th January, 2026 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad. Instant meeting was scheduled for 14th January, 2026 and then extended for 15th January, 2026.

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

The meeting was attended by the following:

1.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
2.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore.	Member
3.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member
4.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member
5.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member (Virtual)
6.	Mr. Ijaz Alvi, Director Drugs Testing Laboratory, Govt. of Punjab, Rawalpindi.	Member (Virtual)
7.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member (Virtual)
8.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
9.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member
10.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
11.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
12.	Hafiz M. Ali Tayyab, Additional Director, Pharmaceutical Evaluation & Registration Division, DRAP.	Member/ Secretary
13.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan.	Co-Opted Member
14.	Dr. M. Shahjahan Zafar, Representative of Animal Husbandry Commissioner Ministry of National Food Security and Research.	Co-Opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Dr. Riaz Ahmed and Mr. Nasir M. Mughal (PPMA) attended the meeting as observers.

Item No. I Confirmation of Minutes of 352nd meeting of Registration Board.

352nd meetings of Registration Board were held on 19th – 20th November, 2025. Accordingly, draft minutes of the 352nd 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 352nd meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 352nd meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 352nd meeting.

Form-5 Cases Deferred in various Registration Board Meetings

1.	Name and address of manufacturer / Applicant	M/s Frontier Dextrose Ltd., Plot # 18/3, Phase-I Hattar Industrial Estate, Haripur									
	Brand Name +Dosage Form + Strength	Sterifluid WFI									
	Composition	Each 1000ml contains: Water for injection qs									
	Diary No. Date of R& I & fee	Dy No. 309: 03-12-2015 PKR 20,000/-: 30-10-2015									
	Pharmacological Group	Water for injection									
	Type of Form	Form 5									
	Finished Product Specification	USP									
	Pack size & Demanded Price	1000ml: As per SRO									
	Approval status of product in Reference Regulatory Authorities	Sterile Water for Injection, in VIAFLEX Plastic Container 1000ml by Baxter corporation (USFDA Approved)									
	Me-too status	Could not be confirmed									
	GMP status	Last inspection report dated 02-05-2018 confirms good compliance to GMP									
	Decision of the 285 th Registration Board Meeting	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) in 1000ml pack size along with registration number, brand name and name of firm.									
	Evaluator Remarks	The firm has submitted evidence of submission of reply via R&I DRAP on 31.10.2024 in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024 through General Request TID GBX-JZT-H277 on eApp. The firm in their reply have provided Me too Status as follows: <table><tr><td>Brand Name</td><td>Aqua Steril Injection 1000 ml</td></tr><tr><td>Generic Name</td><td>Water For Injection</td></tr><tr><td>Pack Size</td><td>1000ml</td></tr><tr><td>Manufacturer</td><td>Medipak Limited</td></tr><tr><td>Registration No.</td><td>106363</td></tr></table>	Brand Name	Aqua Steril Injection 1000 ml	Generic Name	Water For Injection	Pack Size	1000ml	Manufacturer	Medipak Limited	Registration No.
Brand Name	Aqua Steril Injection 1000 ml										
Generic Name	Water For Injection										
Pack Size	1000ml										
Manufacturer	Medipak Limited										
Registration No.	106363										
Decision: Approved.											
2.	Name and address of manufacturer / Applicant	M/s Frontier Dextrose Ltd., Plot # 18/3, Phase-I Hattar Industrial Estate, Haripur									
	Brand Name +Dosage Form + Strength	Sterifluid NaCl 3%									
	Composition	Each 100ml contains: Sodium chloride.....3g									
	Diary No. Date of R& I & fee	Dy No. 307: 03-12-2015 PKR 20,000/-: 30-10-2015									
	Pharmacological Group	Electrolyte									
	Type of Form	Form 5									
	Finished Product Specification	USP									
	Pack size & Demanded Price	500ml: As per SRO									
	Approval status of product in Reference Regulatory Authorities	Sodium Chloride 3% In Plastic Container by Baxter Healthcare (USFDA Approved)									

	Me-too status	Could not be confirmed
	GMP status	Last inspection report dated 02-05-2018 confirms good compliance to GMP
	Decision of the 285 th Registration Board Meeting	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) in 1000ml pack size along with registration number, brand name and name of firm.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via R&I DRAP on 31.10.2024 in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024 through General Request RQ\$-EA&-D7LZ on eApp. - The firm in their reply have stated that: <i>"We would like to submit that there is no generic /me-too available in Pakistan for our applied product i.e. Sterifluid NaCl 3% 500ml. However, NaCl 3% 500ml is already registered and marketed in countries regulated by Stringent Regulatory Authorities. So, kindly consider it under the <u>New Product Category</u>."</i>
	Decision: Rejected being applied on Form 5 instead of Form 5-D.	
3.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Each ml contains: Dorzolamide HCl.....2% Timolol Maleate.....0.5%
	Composition	Each 100ml contains: Sodium chloride.....3g
	Diary No. Date of R& I & fee	Dy. No. 17146 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Carbonic Anhydrase Inhibitors with Beta Blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml, price As per SRO
	Approval status of product in Reference Regulatory Authorities	Cosopt ophthalmic solution by M/s OakPharms INC, USFDA approved
	Me-too status	COSOPT 2% 5ml Drops OBS Pharmaceuticals (Pvt) Ltd, Pakistan Reg # 25294
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for the following: Revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.
	Evaluator Remarks	The firm has submitted evidence of submission of reply via Case Management System TID Y9W-EYY-DHR4 on 01.06.2025.

		• However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
4.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Medesone-CL Cream 0.05% & 1%
	Composition	Each Gram of cream contains: Betamethasone Dipropionate.....0.05% Clotrimazole.....1%
	Diary No. Date of R& I & fee	Dy. No.17141 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Corticosteroids/Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5gm/tube and 1×10gm/tubeAs per SRO
	Approval status of product in Reference Regulatory Authorities	Lotriderm Cream by M/S MSD Ltd (MHRA Approved)
	Me-too status	Lotriderm-B Cream by M/s Hoover (R# 064534)
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for revision of formulation as per reference product along with submission of requisite fee.
	Evaluator Remarks	The firm has submitted evidence of submission of reply via Case Management System TID Q7Y-UN7-NXMA with R&I stamp dated 01.06.2025. • However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
5.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Oflomark drops 0.3% (Ophthalmic Solution/Eye drops)
	Composition	Each ml contains: Ofloxacin as HCl.....0.3% (w/v)
	Diary No. Date of R& I & fee	Dy. No.12248; 06/03/2019, PKR 20,000/=, 05/03/2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml, Price As per SRO
	Approval status of product in Reference Regulatory Authorities	Ofloxacin 0.3% Ophthalmic Solution by M/s Akorn, USFDA approved
	Me-too status	Flobacin 0.3% Eye Drops Reg. No. 031208

		M/s Alza Pharmaceuticals,
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for revision of formulation as per reference product along with submission of requisite fee.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID 9UL-R2T-JPWQ with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
6.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Ramphen Drops (ophthalmic solution/ Eye-Ear Drops)
	Composition	Each ml contains: Chloramphenicol.....0.5% (w/v)
	Diary No. Date of R& I & fee	Dy. No. 17167 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Dichloroacetic Acid Derivatives/antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml price As per SRO
	Approval status of product in Reference Regulatory Authorities	Chloramphenicol 0.5% Eye Drops (solution), by M/s Martindale Pharmaceuticals Limited, MHRA approved
	Me-too status	Op-chlor eye drops 0.5% by M/s E.pharm lab Karachi, Reg # 85676
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID YUP-WZG-P9NW with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
7.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Nicimarbot Drops (154ructod154154154 solution Eye/Ear drops)

	Composition	Each ml contains: Tobramycin Sulphate.....0.3% (w/v)
	Diary No. Date of R& I & fee	Dy. No.12248 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Aminoglycosides Antibiotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml Price As per SRO
	Approval status of product in Reference Regulatory Authorities	TOBREX 0.3% Eye Drops NOVARTIS PHARMACEUTICALS Ltd, USFDA Approved
	Me-too status	ORBACIN 0.3% eye drops by M/s Zafa Pharma, Reg # 20200
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID 9QV-QAY-SH5H with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
8.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Nepaf 0.1% Eye Drops (Ophthalmic solution/ Eye-Ear drops)
	Composition	Each ml contains: Nepafenac.....0.1% (w/v)
	Diary No. Date of R& I & fee	Dy. No. 17168 07/03/2019, PKR 20,000/=
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1×5ml Price As per SRO
	Approval status of product in Reference Regulatory Authorities	Nevanac 0.1% Eye Drops (suspension) by M/s NOVARTIS, USFDA Approved
	Me-too status	Cannot be confirmed
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for the following: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm.

		Revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID 9AP-BG2-TZGS with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
9.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Natam Drops 0.5% (Ophthalmic solution / Eye-Ear drops)
	Composition	Each ml contains: Natamycin..... 5%
	Diary No. Date of R& I & fee	Dy. No.12245 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Aminoglycosides Antibiotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml, 1×10ml Price As per SRO
	Approval status of product in Reference Regulatory Authorities	NATACYN 5% eye suspension by M/s NOVARTIS PHARMS COPPs, USFDA Approved
	Me-too status	NATACIN 5% 5ml Drops SCHAZOO Pharmaceuticals (Pvt) Ltd, Pakistan
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for revision of formulation as per reference product along with submission of requisite fee.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID 8NZ-H7V-S3EE with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
10.	Name and address of manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Medesone-N Cream 0.1% & 0.5%
	Composition	Each Gram of cream contains: Betamethasone as velerate.....0.1% Neomycin Sulphate.....0.5%
	Diary No. Date of R& I & fee	Dy. No.12255 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Corticosteroids/antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator's Specs
	Pack size & Demanded Price	1×5gm/tube and 1×15gm/tube price as per SRO

	Approval status of product in Reference Regulatory Authorities	Cannot be confirmed.
	Me-too status	Betaderm-N Cream By M/s Atco Laboratories. Reg # 8564
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate
	Decision of the 292 nd Registration Board Meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluator Remarks	- The firm has submitted evidence of submission of reply via Case Management System TID 96Q-6GL-WZRV with R&I stamp dated 01.06.2025. - However, 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024
	Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 30-12-2024.	
11.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Levoxol Infusion 750mg/150ml
	Composition	Each 150ml of solution for infusion contains: Levofloxacin (as hemihydrate).....750mg
	Diary No. Date of R& I & fee	Diary No: 24072, 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx150ml /As per SRO
	Approval status of product in Reference Regulatory Authorities	Cravit IV by M/s Daiichi Sankyo, Japan (Pack size of 150ml not confirmed from approved website of PMDA)
	Me-too status	Leflox 750mg/150ml Infusion By Getz Pharma (Reg.No. 058590),
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML. As per DRIS, Renewal Inspection conducted on 25/Sep/2024 with Recommendation. GMP Complaint remarks.
	Decision of the 292 nd Registration Board Meeting	<u>Previous Decision (M-278)</u> Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals". <u>Decision (M-292)</u> Deferred for evidence of approval of applied pack size for formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting
	Evaluator Remarks	30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024.

		The firm has submitted evidence of submission of reply via General Request TID 7R7-YNW-TYN4 with R&I stamp dated 28.11.2024 with following reply: <i>The applied pack size for formulation in reference regulatory authorities is mentioned below: Levaquin 750mg/150ml Janssen Pharmaceuticals (USFDA Approved)</i> 5 mg/mL (750 mg), 150 mL flexible container (NDC 0045-0066-01)
	Decision: Rejected being applied on Form 5 instead of Form 5-D.	
12.	Duplication, at Sr. No. 11	
13.	Name and address of manufacturer / Applicant	M/s. Friends Pharma, Lahore
	Brand Name +Dosage Form + Strength	Floronol Injection 40mg
	Composition	Each 3ml contains:- Phloroglucinol.....40mg
	Diary No. Date of R& I & fee	Dy No. 465 8000/- 23-05-2011 (recorded in M-265 that this challan is in photocopy) 12000/- 31-3-2015
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1's -As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluximem injection by Lifenergy Pvt Ltd China (reference provided is from China)
	Me-too status	Europas by Ophth Pharma
	GMP status	Last inspection report 6-10-2016 The panel grant the cGMP for export purpose.
	Decision of the Previous Registration Board Meetings	<u>Previous Decision (M-265)</u> Deferred for confirmation of approval of applied formulation in reference regulatory authorities

	Evaluator Remarks	• 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024. • The firm has submitted evidence of submission of reply via General Request TID RJ7-2RP-HESS with R&I stamp dated 09.12.2024 with following reply: PSUSA/00010355/201809 in EMA for phloroglucinol, phloroglucinol/trimethylphloroglucinol However, the firm has referred to a product approved by ANSM France with following composition in 4ml: Phloroglucinol hydrate..... 40.00 mg Quantity corresponding to..... 31.12 mg of anhydrous phloroglucinol Trimethylphloroglucinol..... 0.04 mg
	Decision: Rejected being applied on Form 5 instead of Form 5-D.	
14.	Name and address of manufacturer / Applicant	M/s Friends Pharma Pvt Ltd. 31-km Ferozpur Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Fendoquine Injection 200mg/5ml
	Composition	Each 5ml Contains: Chloroquine Phosphate...200mg
	Diary No. Date of R& I & fee	Dy.No. 6387 dated 08/04/2020 Rs. 20,000/- 08-04-2020
	Pharmacological Group	--
	Type of Form	Form 5
	Finished Product Specification	--
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	--
	GMP status	--
	Decision of the Previous Registration Board Meetings	<u>Previous Decision (M-295)</u> Registration Board deferred the cases from serial number 744 to 835 for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluator Remarks	• 30.12.2024 was the due date in accordance with letter No.F.15-1/2022-PEC dated 18.10.2024. • The firm has submitted evidence of submission of reply via General Request TID LPT-Z9P-44NB with R&I stamp dated 09.12.2024 in which firm has attached an un-verified Summary of Product Characteristics without name of approving authority. The status of the product in the Reference Authorities/agencies is still unverified.
	Decision: Rejected being applied on Form 5 instead of Form 5-D.	

15.	Duplication, at Sr. No. 13	
16.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories, Karachi
	Brand Name + Dosage Form + Strength	Tzime Injection IV/IM
	Composition	Each vial contains: Ceftazidime pentahydrate eq to ceftazidime.....2000mg
	Diary No. Date of R& I & fee	Dy. No.15017; 25-4-2018; Rs.20,000/- (18-4-2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, As per Drap Policy
	Approval status of product in Reference Regulatory Authorities.	Fortum 2g powder for solution for injection by M/s GlaxoSmithKline UK (MHRA Approved)
	Me-too status	Not confirmed
	GMP status	CLB granted additional section of Sterile dry powder Injection (Cephlosporin) section on 259 th meeting held on 29 th & 30 th March 2018.
	Remarks of the Evaluator.	Me-too status could not be confirmed.
	Decision of M-282: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The firm has informed via General request Form TID WP1-ESJ-6AWT dated 08th May 2025 wherein a letter of the firm dated 05-05-2025, without DRAP R&I, is attached in which following evidence is provided: Fortez Injection 2 gm by Curexa Health, Marketed by Highnoon, Reg. # 113218 Decision: Rejected as the firm fails to submit the reply within the notified time i.e. 31-12-2024.	
17.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 10mg
	Composition	Each Tablet Contains: Methotrexate.....10mg
	Dairy No. date of R & I fee	Form-5 Dy.No 10798 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants WHO ATC code: L04AX03
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 10mg tablets MHRA Approved
	Me-too-status	Methotrexate tablet 10mg of M/s Pak China International (Reg# 066009)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator ^{XI}	The firm revised the 1 st page of form 5 as per approved format

Previous Decision (M-296-DRB)	Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.
Firm's Response	• The firm submitted that according to W.H.O ATC Classification, our applied product "methotrexate tablet" lie in the category L-04 which refers to IMMUNOSUPPRESSANTS, indicated for the treatment of Rheumatoid Arthritis (ATC Index confirming the same is attached). However, in category L-01, Parenteral formulations used for Neoplastic diseases are classified. • The firm also refer to decision of 271th meeting of registration board, "There is no need for segregated / dedicated / self-contained premises / facilities for the production of drugs belonging to the categories namely immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene. Registration Board decided to grant registration of these products in general manufacturing areas.
Evaluation by PEC	Decision of 297th meeting of Registration Board: Registration Board after thorough deliberation and considering the high-risk classification i.e., "Anticancer (L01)", and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrexate etc. in the "Anti-cancer" section only (being high risk products).
Decision of M-336: Deferred for evidence of required manufacturing facility / section of "cytotoxic/oncology tablet section", from Licensing Division since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. <u>Reply of the firm received on 17th June 2025 via General Request Form TID QJ5-8P2-8GMD</u> We respectfully submit that in our case, the requirement of a separate cytotoxic/oncology area does not apply, based on the following internationally and locally recognized justifications: 1. Scope of Use – Limited to Non-Oncological Indications (L04) Our submitted formulations are strictly intended for the treatment of non-oncological autoimmune conditions such as Rheumatoid Arthritis and Psoriasis, which fall under the WHO ATC classification L04AX03 – Immunosuppressants, and not L01 (cytotoxic drugs). We are not applying for oncology indications, nor will we market or label the product for such use. 2. WHO ATC Classification Reference According to the official WHO ATC index, Methotrexate falls under different categories depending on its indication: • L01BA01 – When used as an antineoplastic (i.e., oncology use) • L04AX03 – When used as an immunosuppressant (i.e., Rheumatoid Arthritis, Psoriasis) We enclose herewith the relevant excerpt from the WHO ATC index, clearly confirming our product's intended use under L04, where cytotoxic classification and associated facility requirements do not apply. 3. International Regulatory Practices In several Stringent Regulatory Authorities (SRAs) including: • United States FDA • European Medicines Agency (EMA) • UK MHRA • Health Canada Methotrexate used for non-oncological indications is manufactured and approved under standard oral solid dosage (OSD) conditions without requiring a dedicated cytotoxic manufacturing zone. This approach is based on risk classification by intended use and dosage, not merely the chemical name. 4. Local Precedent – DRB Meeting No. 271 (June 19–20, 2017) We respectfully refer to the DRB meeting no. 271, which clearly states: "There is no need for segregated/dedicated/self-contained premises/facilities for the production of drugs belonging to the category 'Immunosuppressants' and the Registration Board decided to grant registration of such products in general manufacturing areas." This decision supports our position and aligns with international norms. 5. Commitment to Labeling Compliance To avoid any off-label or oncology-related use, we	

	confirm: • All labeling will explicitly state: “For the treatment of non-oncology indications only (e.g., Rheumatoid Arthritis, Psoriasis)” • Product literature (SmPC/PIL) will strictly limit indications to L04-related diseases. • We are also willing to include this limitation in the registration file and manufacturing documentation as a binding condition. Prayer for Reconsideration In light of the above international references, WHO classification, and DRB’s own precedent, we humbly request the honorable Registration Board to kindly reconsider our application for the registration of Methotrexate Tablets 2.5mg and 10mg, under non-oncology (L04) use, without the requirement of a cytotoxic section. We remain available for any clarification or further documentation required, and thank you for your time and kind attention. Decision: Deferred for deliberation on requirement of manufacturing facility for immunosuppressant.	
18.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 2.5mg
	Composition	Each Tablet Contains: Methotrexate.....2.5mg
	Dairy No. date of R & I fee	Form-5 Dy.No 10797 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 2.5mg Tablets MHRA Approved
	Me-too-status	Methotrexate 2.5mg by PAK CHINA INTERNATIONAL (Reg #066007)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator ^{XI}	The firm revised the 1 st page of form 5 as per approved format
	Previous Decision (M-296-DRB)	Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.
	Firm’s Response	• The firm submitted that according to W.H.O ATC Classification, our applied product “methotrexate tablet” lie in the category L-04 which refers to IMMUNOSUPPRESSANTS, indicated for the treatment of Rheumatoid Arthritis (ATC Index confirming the same is attached). However, in category L-01, Parenteral formulations used for Neoplastic diseases are classified. • The firm also refer to decision of 271th meeting of registration board, “There is no need for segregated / dedicated / self-contained premises / facilities for the production of drugs belonging to the categories namely immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene. Registration Board decided to grant registration of these products in general manufacturing areas.
	Evaluation by PEC	Decision of 297th meeting of Registration Board: Registration Board after thorough deliberation and considering the high-risk classification i.e., “Anticancer (L01)”, and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both “Antineoplastic (L01)” & “Immunosuppressants (L04)”

	class including everolimus and methotrexate etc. in the “Anti-cancer” section only (being high risk products).
Decision of M-336: Deferred for evidence of required manufacturing facility / section of “cytotoxic/oncology tablet section”, from Licensing Division since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. <u>Reply of the firm received on 17th June 2025 via General Request Form TID QJ5-8P2-8GMD</u> We respectfully submit that in our case, the requirement of a separate cytotoxic/oncology area does not apply, based on the following internationally and locally recognized justifications: 1. Scope of Use – Limited to Non-Oncological Indications (L04) Our submitted formulations are strictly intended for the treatment of non-oncological autoimmune conditions such as Rheumatoid Arthritis and Psoriasis, which fall under the WHO ATC classification L04AX03 – Immunosuppressants, and not L01 (cytotoxic drugs). We are not applying for oncology indications, nor will we market or label the product for such use. 2. WHO ATC Classification Reference According to the official WHO ATC index, Methotrexate falls under different categories depending on its indication: • L01BA01 – When used as an antineoplastic (i.e., oncology use) • L04AX03 – When used as an immunosuppressant (i.e., Rheumatoid Arthritis, Psoriasis) We enclose herewith the relevant excerpt from the WHO ATC index, clearly confirming our product's intended use under L04, where cytotoxic classification and associated facility requirements do not apply. 3. International Regulatory Practices In several Stringent Regulatory Authorities (SRAs) including: • United States FDA • European Medicines Agency (EMA) • UK MHRA • Health Canada Methotrexate used for non-oncological indications is manufactured and approved under standard oral solid dosage (OSD) conditions without requiring a dedicated cytotoxic manufacturing zone. This approach is based on risk classification by intended use and dosage, not merely the chemical name. 4. Local Precedent – DRB Meeting No. 271 (June 19–20, 2017) We respectfully refer to the DRB meeting no. 271, which clearly states: “There is no need for segregated/dedicated/self-contained premises/facilities for the production of drugs belonging to the category ‘Immunosuppressants’ and the Registration Board decided to grant registration of such products in general manufacturing areas.” This decision supports our position and aligns with international norms. 5. Commitment to Labeling Compliance To avoid any off-label or oncology-related use, we confirm: • All labeling will explicitly state: “For the treatment of non-oncology indications only (e.g., Rheumatoid Arthritis, Psoriasis)” • Product literature (SmPC/PIL) will strictly limit indications to L04-related diseases. • We are also willing to include this limitation in the registration file and manufacturing documentation as a binding condition. Prayer for Reconsideration In light of the above international references, WHO classification, and DRB’s own precedent, we humbly request the honorable Registration Board to kindly reconsider our application for the registration of Methotrexate Tablets 2.5mg and 10mg, under non-oncology (L04) use, without the requirement of a cytotoxic section. We remain available for any clarification or further documentation required and thank you for your time and kind attention. Decision: Deferred for deliberation on requirement of manufacturing facility for immunosuppressant.	

Form 5 Deferred cases of Duplicate Dossiers in accordance with decision of Authority

In its 344th meeting held on 19th -20th December, 2023, the Registration Board addressed the status of duplicate dossiers (Form-5/5D) submitted after the official deadline of April 30, 2024. The Authority previously decided in its 184th meeting not to grant further extensions, the Board noted that this specific decision regarding the timeline had not been formally notified. Consequently, the Board has deferred all such late submissions and referred the matter back to the Authority for final directions. Accordingly, Authority in its 206th meeting held on 04th June, 2025 decided that:

“The Authority, in light of the agenda presented and upon deliberation, directed the Division of Pharmaceutical Evaluation and Registration to review and process all remaining cases of duplicate dossiers submitted by the companies till 31st December 2024.”

The following applications were considered in the 344th meeting of the Registration Board and were deferred.

19.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reozine Syrup
	Composition	Each 5ml contains: Levocetirizine Dihydrochloride 2.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12857 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml As per PRC
	RRA status	
	Me-too status	Neo-Sedil Syrup Sami
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	<u>Decision of M-344:</u> The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
20.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reotolin Syrup
	Composition	Each 5ml contains: Salbutamol as sulphate 2mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12856 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Bronchodilator
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	MHRA

	Me-too status	Ventolin syrup
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
21.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reotalin Syrup
	Composition	Each ml contains: Terbutaline sulphate 0.3mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12854 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Selective B2 Stimulant
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	MHRA
	Me-too status	Britanyl Syrup Barrett Hodgson
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
22.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodine Syrup
	Composition	Each ml contains: Desloratadine 0.5mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12855 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	MHRA
	Me-too status	Neo-Antial 0.5mg/ml Syrup
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: R&I submission of Duplicate dossier dated 02-12.2024 and verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
23.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name + Dosage Form + Strength	Reoton Syrup
	Composition	Each 5ml contains: Ondansetron as HCl Dihydrate 4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12853 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Selective 5HT-3 Receptor antagonist
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Onset
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore

	Brand Name +Dosage Form + Strength	Riocoline Syrup
	Composition	Each 5ml contains: Citicoline 500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12858 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Psychostimulant
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Cercolin syrup
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: • R&I submission of Duplicate dossier dated 02-12.2024 and • verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
25.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Roecetam Syrup
	Composition	Each 5ml contains: Piracetam 1gm
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12852 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Nootropic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	Spain
	Me-too status	Ceremin Syrup Schazoo
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: • R&I submission of Duplicate dossier dated 02-12.2024 and • verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with innovator's specifications and subject to verification of fee challan as	

	per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
26.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reolid Suspension
	Composition	Each 5ml contains: Linezolid 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12851 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antibiotic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	MHRA
	Me-too status	Nazkil suspension SJ&G
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: • R&I submission of Duplicate dossier dated 02-12.2024 and • verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
27.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodon Suspension
	Composition	Each 5ml contains: Domperidone 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12850 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	MHRA
	Me-too status	Domel
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated	

	11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
28.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riocone Cream
	Composition	Each gm contains: Miconazole nitrate 2%
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12849 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Antifungal
	Finished product Specifications	In-house
	Pack size & Demanded Price	20gm As per PRC
	RRA status	MHRA
	Me-too status	Micoral Cream Elko
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
29.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riofenac Gel
	Composition	Each gm contains: Diclofenac Dimethylamine eq. to Diclofenac sodium .. 1%
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12846 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	20gm As per PRC
	RRA status	MHRA
	Me-too status	Voltral gel
	GMP status	
	Remarks of the Evaluator	Submitted after dead line

	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. <u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: R&I submission of Duplicate dossier dated 02-12.2024 and verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
30.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riocam Gel
	Composition	Each gm contains: Piroxicam 5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12847 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	25gm As per PRC
	RRA status	MHRA
	Me-too status	Xorip Gel 5mg Reliance
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. <u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019 Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
31.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals. 112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Riofuse Cream
	Composition	Each gm contains: Fusidic Acid 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 12848 dated 02-12-2024 Rs.20000/- (photocopy) dated 07-03-2019 to be verified from R&I DRAP
	Pharmacological Group	Steroidal antibiotic
	Finished product Specifications	In-house
	Pack size & Demanded Price	15gm As per PRC

	RRA status	MHRA
	Me-too status	Baxidin Cream 2% Baxter
	GMP status	
	Remarks of the Evaluator	Submitted after dead line
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> The firm has submitted following evidence of vide General Request Form TID M62-WLR-U76P dated 11 December, 2025: - R&I submission of Duplicate dossier dated 02-12.2024 and - verification of Fee Challan vide letter Serial No. 91/STO/2018-19 date 07-03-2019	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
32.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Pregaba 100 Capsules
	Composition	Each capsule contains: Pregabalin 100mg
	Type of Form, Diary No. Date of R&	Form-5 (Duplicate dossier) Dy. No. 13517 dated 19-12-2024
	I & fee	Rs.8000/- (photocopy) dated 11-01-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	In-house
	Pack size & Demanded Price	10's, As per PRC
	RRA status	FDA
	Me-too status	Gabica 100mg Capsule Getz
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	<u>Remarks:</u> Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
33.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Pregaba 300 Capsules

	Composition	Each capsule contains: Pregabalin 300mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13511 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Anticonvulsant
	Finished product Specifications	In-house
	Pack size & Demanded Price	10's, As per PRC
	RRA status	FDA
	Me-too status	Gabica 300mg Capsule Getz
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
34.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	L-Fox Suspension 125mg
	Composition	Each 5ml contains: Levofloxacin 125mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13504 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	antibiotics
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	Not found
	Me-too status	Levox Dry Suspension 125mg Reg. No. 075394
	GMP status	

	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Deferred for evidence of approval of the applied product in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting.	
35.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	L-Fox Suspension 250mg
	Composition	Each 5ml contains: Levofloxacin 250mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13508 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	antibiotics
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	Not found
	Me-too status	Levox Dry Suspension 250mg Reg. No. 075395
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section
		Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Deferred for evidence of approval of the applied product in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting.	
36.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa Suspension
	Composition	Each 5ml contains: Domperidone 5mg

	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13528 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, 120ml, As per PRC
	RRA status	FDA
	Me-too status	Motillium Syrup
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
37.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa tablet
	Composition	Each film coated tablet contains: Domperidone as maleate 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13526 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- receiving not attached
	Pharmacological Group	antiemetic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Motillium V Tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	

	Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
38.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Mikassa C tablet
	Composition	Each film coated tablet contains: Domperidone as maleate 15mg Cinnarizine 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13525 dated 19-12-2024 Rs.8000/- (photocopy) dated 09-03-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	Antiemetic, antihistamine
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 30, 50 As per PRC
	RRA status	FDA (could not be confirmed)
	Me-too status	Pelton C Tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by Registration Board in it 275th meeting.	
39.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Pacid Tablet
	Composition	Each film coated tablet contains: Flurbiprofen 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13510 dated 19-12-2024 Rs.8000/- (photocopy) dated 21-06-2011 to be verified from R&I DRAP
		Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	NSAID

	Finished product Specifications	In-house
	Pack size & Demanded Price	30 As per PRC
	RRA status	FDA
	Me-too status	Ansaid tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
40.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Ribra 10mg Tablet
	Composition	Each enteric coated tablet contains: Rabeprazole 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13524 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	PPI
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 14 As per PRC
	RRA status	FDA
	Me-too status	Promoto tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	

41.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Ribra 20mg Tablet
	Composition	Each enteric coated tablet contains: Rabeprazole 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13523 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	PPI
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 14 As per PRC
	RRA status	FDA
	Me-too status	Promoto tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
42.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther Tablet
	Composition	Each film coated tablet contains: Artemether 20mg Lumefantrine 120mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13527 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	8 As per PRC
	RRA status	FDA
	Me-too status	Aertem tablet
	GMP status	

	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with International Pharmacopoeial specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
43.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther DS ablet
	Composition	Each film coated tablet contains: Artemether 40mg Lumefantrine 240mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13512 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	8 As per PRC
	RRA status	WHO PQ
	Me-too status	Aertem tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with International Pharmacopoeial specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
44.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore

	Brand Name +Dosage Form + Strength	Fanther Forte ablet
	Composition	Each film coated tablet contains: Artemether 80mg Lumefantrine 480mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13515 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	4 As per PRC
	RRA status	WHO PQ
	Me-too status	Aertem tablet
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with International Pharmacopoeial specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
45.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Fanther suspension
	Composition	Each 5ml contains: Artemether 15mg Lumefantrine 90mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13514 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antimalarial
	Finished product Specifications	In-house
	Pack size & Demanded Price	60ml, As per PRC
	RRA status	WHO pre-qualified formulation
	Me-too status	Aertem plus suspension
	GMP status	

	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with International Pharmacopoeial specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
46.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Epril 5mg Tablet
	Composition	Each film coated tablet contains: Enalapril 5mg
	Type of Form, Diary No. Date of R&I & fee	Form-5 (Duplicate dossier) Dy. No. 13521 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	ACE inhibitor
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 20 As per PRC
	RRA status	FDA
	Me-too status	Cardace zafa
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications and revision of label claim as per innovator's product: The correct label claim is: Each tablet contains: Enalapril Maleate.....5mg	
47.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore

	Brand Name +Dosage Form + Strength	Epril 10mg Tablet
	Composition	Each film coated tablet contains: Enalapril 10mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13522 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	ACE inhibitor
	Finished product Specifications	In-house
	Pack size & Demanded Price	10, 20 As per PRC
	RRA status	FDA
	Me-too status	Cardace zafa
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications and revision of label claim as per innovator's product: The correct label claim is: Each tablet contains: Enalapril Maleate.....5mg	
48.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Fonza M Tablet
	Composition	Each film coated tablet contains: Sumatriptan as succinate 85mg Naproxen sodium 500mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13520 dated 19-12-2024 Rs.8000/- (photocopy) dated 26-12-2010 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	5HT agonist, NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Synflex M
	GMP status	

	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
49.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Afelo 100mg Tablet
	Composition	Each film coated tablet contains: Aceclofenac 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13519 dated 19-12-2024 Rs.8000/- (photocopy) dated 06-06-2012 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Acenac
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
50.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Volima Tablet

	Composition	Each film coated tablet contains: Activated Attapulgit 100mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13513 dated 19-12-2024 Rs.8000/- (photocopy) dated 21-06-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	ENTOX-P TAB
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard.	
	Decision: Deferred for policy decision of molecules falling in grey area.	
51.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Codofen Tablet
	Composition	Each film coated tablet contains: Ibuprofen 200mg Codeine Phosphate 20mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13506 dated 19-12-2024 Rs.8000/- (photocopy) dated 20-12-2010 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 03-12-2019 to be verified from R&I DRAP
	Pharmacological Group	Opioid, NSAID
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Brufen Plus Tablets Abbott
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022

	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved subject to confirmation of Narcotic/Psychotropic Section and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
52.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Moxidal Lotion
	Composition	Each ml contains: Minoxidil 0.05mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13509 dated 19-12-2024 Rs.8000/- (photocopy) dated 23-05-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Antihypertensive
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Minoxi plus solution Danas
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
53.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Scape Lotion
	Composition	Each ml contains: Permethrin 10mg
	Type of Form, Diary No. Date of R&I & fee	Form-5 (Duplicate dossier) Dy. No. 13516 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP

	Pharmacological Group	Scabicide
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Lotrix lotion GSK
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
54.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Scape Cream
	Composition	Each gm contains: Permethrin 50mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13507 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Scabicide
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Lotrix cream GSK
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide N0. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with innovator's specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of	

	specifications.	
55.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Porex Syrup
	Composition	Each 5ml contains: Codeine Phosphate 10mg Chlorpheniramine maleate 4mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13518 dated 19-12-2024 Rs.8000/- (photocopy) dated 23-05-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Cough suppressant, anti-allergic
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	
	Me-too status	Not confirmed
	GMP status	
	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Rejected as no evidence was submitted by the applicant on any available drug in local or Reference Regulatory Authority as adopted by the RB in its 275th meeting.	
56.	Name and address of manufacturer / Applicant	Xenon Pharmaceuticals Pvt Ltd., 9.5 K.M Sheikhpura Road, Lahore
	Brand Name +Dosage Form + Strength	Shapex Gel
	Composition	Each gm contains: Isotretinoin 0.5mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No. 13505 dated 19-12-2024 Rs.8000/- (photocopy) dated 11-01-2011 to be verified from R&I DRAP Rs.12000/- (photocopy) dated 30-01-2020 to be verified from R&I DRAP
	Pharmacological Group	Retinoid
	Finished product Specifications	In-house
	Pack size & Demanded Price	As per PRC
	RRA status	FDA
	Me-too status	Isotin gel Shaigan
	GMP status	

	Remarks of the Evaluator	Submitted after dead line Capsule General Section Tablet General Section
		Dry powder suspension General Section Oral liquid / syrup General Section Ointment /cream General Section confirmed vide NO. F. 1-11/84-Lic (Vol-III) dated 29-04-2022
	Decision: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: Duplicate dossier R&I dated 19.12.2024	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	

Form 5 cases of Duplicate Dossiers not considered in any meeting

57.	Name and address of manufacturer / Applicant	M/s Allmed (Pvt.) Ltd. Plot no. 590, Sundar Industrial Area, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gablika
	Composition	Each hard gelatin Capsule contains Pregabalin..... 150 mg
	Diary No. Date of R& I & fee	Duplicate Dossier submitted on 26.03.2024 (requires verification form DRAP R&I) Rs. 8,000/- dated 28-01-2009 Rs. 12,000/- dated 07-11-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pregabalin Capsule 150 mg, Toronto, Ontario Apotex, Toronto, Ontario
	Me-too status	Gabica 150 mg Capsules by Getz Pharma (Pvt) Ltd, (Reg. # 048724)
	GMP status	----
	Remarks of the Evaluator.	Firm needs to follow BP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
58.	Name and address of manufacturer / Applicant	M/s Allmed (Pvt.) Ltd. Plot no. 590, Sundar Industrial Area, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gablika
	Composition	Each hard gelatin Capsule contains Pregabalin..... 75 mg
	Diary No. Date of R& I & fee	Dy. No. 4176 Duplicate Dossier submitted on 26.03.2024 (requires verification form DRAP R&I) Rs. 8,000/- dated 28-01-2009 Rs. 12,000/- dated 11-11-2018
	Pharmacological Group	Anti-epileptics

Type of Form	Form 5
Finished Product Specification	Manufacturer Specifications
Pack size & demanded price	14's, As per SRO
Approval status of product in Reference Regulatory Authorities.	Pregabalin Capsule 150 mg, Toronto, Ontario Apotex, Toronto, Ontario
Me-too status	Gabica 75 mg Capsules by Getz Pharma (Pvt) Ltd, (Reg. # 047365)
GMP status	----
Remarks of the Evaluator.	Firm needs to follow BP specifications as monograph available now and to submit prescribed fee for change in specification.
Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	

Form 5 Deferred cases of Duplicate Dossiers

59.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhpura Road Faisalabad
	Brand Name +Dosage Form + Strength	Capsule Higab 300 mg
	Composition	Each hard gelatin Capsule contains Pregabalin 300 mg
	Diary No. Date of R& I & fee	<i>Duplicate Dossier</i> Dy. No. 27630 dated 29-09-2022 Dy. No 3177 dated 04-03-2011 Rs. 8,000/- dated 04-03-2011 Rs. 12,000/- dated 07-11-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Lamisil GSK
	GMP status	Inspection report submitted- section GMP compliant
	Remarks of the Evaluator ³ .	Firm needs to follow BP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision of M-333 (held on 19th to 20th December 2023) The Board decided to refer the case to subcommittee for pharmaceuticals.	
	The firm has submitted vide General request form TID 2ON-RB7-GOR7 on 09 th May 2025 that they want to change the specifications from Manufacturers to BP for which they have submitted fee of Rs. 9000/-.	
	Decision: Approved with B.P. specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
60.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhpura Road Faisalabad
	Brand Name +Dosage Form + Strength	Tablet Linzo 400 mg
	Composition	Each film coated tablet contains Linezolid..... 400 mg
	Diary No. Date of R& I & fee	<i>Duplicate Dossier</i> Dy. No. 27629 dated 29-09-2022 Dy. No 2247 dated 15-04-2010 Rs. 8,000/- dated 15-04-2010 Rs. 12,000/- dated 15-10-2018

	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Ecasil 400 mg Tablet by Sami Pharma
	GMP status	Inspection report submitted– section GMP compliant
	Remarks of the Evaluator ³ .	Firm needs to follow USP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision of M-333 (held on 19th to 20th December 2023)	
	The Board decided to refer the case to sub committee for pharmaceuticals.	
	The firm has submitted vide General request form TID B93-2X8-Y3OJ on 09 th Mav 2025 that they want to change the specifications from Manufacturers to USP for which they have submitted fee of Rs. 9000/-.	
	Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	
61.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) 19-Km Sheikhpura Road Faisalabad
	Brand Name +Dosage Form + Strength	Tablet Linzo 600 mg
	Composition	Each film coated tablet contains Linezolid..... 600 mg
	Diary No. Date of R& I & fee	<i>Duplicate Dossier</i> Dy. No. 27631 dated 29-09-2022 Dy. No 2248 dated 15-04-2010 Rs. 8,000/- dated 15-04-2010 Rs. 12,000/- dated 15-10-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Ecasil 600 mg Tablet by Sami Pharma
	GMP status	Inspection report submitted– section GMP compliant
	Remarks of the Evaluator ³ .	Firm needs to follow USP specifications as monograph available now and to submit prescribed fee for change in specification.
	Decision of M-333 (held on 19th to 20th December 2023)	
	The Board decided to refer the case to sub committee for pharmaceuticals.	
	The firm has submitted vide General request form TID 914-19O-WRAP on 09 th Mav 2025 that they want to change the specifications from Manufacturers to USP for which they have submitted fee of Rs. 9000/-.	
	Decision: Approved with USP specifications and subject to verification of fee challan as per decision of 285th meeting of RB. The firm shall submit applicable fee for change of specifications.	

Form 5F Deferred Cases

62.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) Dry • Powder Injection (Penicillin) Injection • (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale Export ☐ sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31998: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 03-11-2022
	The proposed proprietary name / brand name	CLOXXIN 500mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cloxacillin (as sodium monohydrate).....500mg
	Pharmaceutical form of applied drug	hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Anaclosil 500 mg hard capsules CIMA Spain Approved
	For generic drugs (me-too status)	Cloxacilan 500mg Capsule by Zafa
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:		Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)		Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin capsule without specifying name of manufacturer and brand name. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin capsule without specifying name of manufacturer and brand name.
	Analytical method validation/verification of product		Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00022/054/2021		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C-01	C-02	C-03
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	25-02-2022	25-02-2022	25-02-2022

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Product manufacturer is required.” You have only submitted the specifications of API from the drug Drug product manufacturer. - Provide verification studies of drug substance from drug product manufacturer. - Specify whether the drug substance used is in compacted form or micronized. - Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence and CDP studies have been performed. - Justify why pharmaceutical equivalence and CDP studies are not performed against innovator / reference product. - Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided. - Provide COA of reference standard / working standard actually used in the analysis of drug product. Provide description of container closure system whether Alu-Alu blister or otherwise. - Submit copy of invoice for procurement of drug substance from Pharmagen. - Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. - Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		
Decision of M-323 (held on 6th to 8th December, 2022) Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
Response of the firm: The applicant has submitted replies vide General Request TID NP1-N9A-6S7T submitted on 02 Jan 26.		
Observation/Document Required		Response of the Firm
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance		Drug product manufacturer Specifications and analytical procedure attached. Annexure A

	specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.” You have only submitted the specifications of API from the drug product manufacturer.		
	Provide verification studies of drug substance from drug product manufacturer.	verification studies of drug substance from drug product manufacturer. Annexure B	
	Specify whether the drug substance used is in compacted form or micronized.	Compacted form material used Attached in Annexure C.	
	Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence and CDP studies have been performed.	Attached in Annexure D. RiteMed Batch number X425, Exp Date: 09-2023	
	Justify why pharmaceutical equivalence and CDP studies are not performed against innovator / reference product.	Firm has not provided any justification, however, attached CDP report which was performed against RiteMed Cloxacillin Sodium.	
	Provide results of comparative dissolution profile (CDP) in three dissolution mediums since only a single table result is provided.	Annexure-E, Provided	
	Provide COA of reference standard / working standard actually used in the analysis of drug product.	Annexure-F, the firm has provided COA from Pharmagen for Cloxacillin Batch 00022/054/2021, Mfg on 22.08.2021 and tested on 28.08.2021.	
	Provide description of container closure system whether Alu-Alu blister or otherwise.	Alu-Alu blister in unit caron.	
	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing attached Attached in Annexure G.	
	Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers	Record of Digital data logger for temperature and humidity monitoring of both stability chambers attached. Annexure H.	
	Decision: Rejected being not submitted within due time and submission of same data for products at S.No. 62 & 63.		
63.	Name, address of Applicant / Marketing Authorization Holder	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.	
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.	
	Status of the applicant	☒ Manufacturer Importer ☐ Is involved in none of the above (contract giver)	
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.	

Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) Dry Powder Injection • (Penicillin) Injection (Carbapenem) •
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 32000: 07-11-2022
Details of fee submitted	PKR 30,000/- : 03-11-2022
The proposed proprietary name / brand name	CLOXXIN 250mg/5ml Suspension
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cloxacillin (as sodium monohydrate).....250mg
Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle
Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Could not be confirmed
For generic drugs (me-too status)	Cloxacillin suspension 250mg by Zafa
Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.		
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.		
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin suspension without specifying the name of manufacturer or brand name.		
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.		
STABILITY STUDY DATA			
Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00022/054/2021		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	25-02-2022	25-02-2022	25-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Product manufacturer is required." You have only submitted the specifications of API from the drug Drug product manufacturer. - Provide verification studies of drug substance from drug product manufacturer. - Specify whether the drug substance used is in compacted form or micronized. - Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence and CDP studies have been performed. - Justify why pharmaceutical equivalence and CDP studies are not performed against innovator / reference product. - Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided. - Provide COA of reference standard / working standard actually used in the analysis of drug product. Provide description of container closure system whether Alu-Alu blister or otherwise. - Submit copy of invoice for procurement of drug substance from Pharmagen. - Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. - Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		

Decision of M-323 (held on 6th to 8th December, 2022)

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

Response of the firm:

The applicant has submitted replies vide General Request TID NP1-N9A-6S7T submitted on 02 Jan 26.

Observation/Document Required	Response of the Firm										
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.	Drug product manufacturer Specifications and analytical procedure attached. Annexure A.										
Provide verification studies of drug substance from drug product manufacturer.	verification studies of drug substance from drug product manufacturer. Annexure B <u>Evaluator Remarks: (Critical concern)</u> A comparative review of the raw data reveals a significant temporal (time) discrepancy within the API verification (Day 1) sequences for Cloxacillin compacted and micronized. <table border="1"> <thead> <tr> <th>Sample Description</th><th>Material Form</th><th>Reported Acquisition Time (PKT)</th></tr> </thead> <tbody> <tr> <td>Sample Blank 2</td><td>Cloxacillin (Compacted)</td><td>2/10/2022 1:22:11 PM</td></tr> <tr> <td>Sample Blank 2</td><td>Cloxacillin (Micronized)</td><td>2/10/2022 8:22:11 AM</td></tr> </tbody> </table> In the above table, while the hours differ, the seconds and milliseconds (11:00) are identical across two supposedly independent analytical runs. In a high-performance liquid chromatography (HPLC) environment, the probability of two injections initiating at the exact same second across different material validations is statistically negligible. Hence, this indicates a potential "save-as" event or the repurposing of a single raw data file for two different verification reports and requires a full audit trail review.	Sample Description	Material Form	Reported Acquisition Time (PKT)	Sample Blank 2	Cloxacillin (Compacted)	2/10/2022 1:22:11 PM	Sample Blank 2	Cloxacillin (Micronized)	2/10/2022 8:22:11 AM	
Sample Description	Material Form	Reported Acquisition Time (PKT)									
Sample Blank 2	Cloxacillin (Compacted)	2/10/2022 1:22:11 PM									
Sample Blank 2	Cloxacillin (Micronized)	2/10/2022 8:22:11 AM									
Specify whether the drug substance used is in compacted form or micronized.	Compacted form material used Attached in Annexure C.										

Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence and CDP studies have been performed.	Attached in Annexure D. RiteMed Batch number X425, Exp Date: 09-2023	
Justify why pharmaceutical equivalence and CDP studies are not performed against innovator / reference product.	Firm has not provided any justification, however, attached CDP report which was performed against RiteMed Cloxacillin Sodium.	
Provide results of comparative dissolution profile (CDP) in three dissolution mediums since only a single table result is provided.	Annexure-E, Provided	
Provide COA of reference standard / working standard actually used in the analysis of drug product.	Annexure-F, the firm has provided COA from Pharmagen for Cloxacillin Batch 00022/054/2021, Mfg on 22.08.2021 and tested on 28.08.2021.	
Provide description of container closure system whether Alu-Alu blister or otherwise.	Alu-Alu blister in unit caron.	
Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing attached Attached in Annexure G.	
Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers	Record of Digital data logger for temperature and humidity monitoring of both stability chambers attached. Annexure H.	

Decision: Rejected being not submitted within due time and submission of same data for products at S.No. 62 & 63.

64.	Name, address of Applicant / Marketing Authorization Holder	M/s Unimark Pharmaceutical (Pvt.) Ltd., Plot No. 7-A Street No. S-7, National Industrial Zone Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufr ☐ importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07- 2012 mentioning ampoule (general) section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale Export ☐ sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25820; dated 13-09-2022.
	Details of fee submitted	PKR 75,000/-: vide slip No. 5458813402 dated 19-08- 2022.
	The proposed proprietary name / brand name	Unilac 30mg Injection.

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine 30mg
Pharmacotherapeutic Group of (API)	NSAID
Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule
Reference to Finished product specifications	USP specifications.
Proposed Pack size	1ml x 5's.
Proposed unit price	As per SRO.
The status in reference regulatory authorities	US FDA approved.
For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, – Haryana, 134109 India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. KTM180021, Mfg. date 15-08-18) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 ° ± 2 ° C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 ° C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)		
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure, verification studies, batch analysis and justification of		
		specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – Indi a. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.			
API Lot No.	KTM180021.			
Description of Pack (Container closure system)	Multi-colour unit carton having ALU/PVC tray containing 5 Glass ampoules filled with almost colorless to slight yellow sterile solution.			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period	Real time: 24 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)			
Batch No.	A-745	A-737	A-703	
Batch Size	30,000 Ampoules	30,000 Ampoules	30,000 Ampoules	
Manufacturing Date	10-2019	10-2019	10-2019	
Date of Initiation	26-10-2019	26-10-2019	26-10-2019	
No. of Batches	03			

Administrative Portion	
1. Reference of previous approval of applications with stability study data of the firm (if any)	NA
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. Drugs (3) Pb. 2021/3124 dated 25-06-2021 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 25-06-2023.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. SCL/2019-20/087 dated 25-07-2019 mentioning 15kg of ketorolac Tromethamine USP with B. No. KTM180021 attested by Assistant Director I&E, DRAP, Islamabad dated 02-08- 2019.
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1.	1.4.3	- Valid copy of DML of the applicant shall be submitted. - Valid copy of GMP certificate of the applicant as well as contract acceptor shall be submitted.	Please see Attached Annex 01
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Please see Attached Annex 02
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Table for Literature reference is USP for drug substance which is correct and the SAP is provided as per USP for your reference. Please see Attached Annex 03
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	The USP monograph hasn't specify the run time for drug substance but mention the retention time of Ketorolac is about 08 to 12 minutes so in the submitted chromatograms the peak of Ketorolac has the RT as per USP monograph.

5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	We have followed the same ingredients except ethanol according to well established study on the use of ethanol in injections describe that containing organic vehicles such as ethanol have a certain degree of toxicity, which can easily cause irritation upon injection, thereby due avoid any adverse/harmful effect we replace them with Citric Acid..
6.	3.2.P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	The method of terminal sterilization mistakenly not mentioned in the initial submission. After extensive search at product development stage we did not found any innovator document either recommending terminal sterilization or prohibiting from it, but we chose a safe combination of sterilization procedure for applied product i.e Filtration along with terminal sterilization.
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	As per product label claim 30mg/ml, the concentration could be 0.048mg/ml which is nominally 0.05mg/ml However, analysis was performed with manual injector with fixed loop of 20ul instead of 100ul hence the higher concentration 0.06mg/ml was preferred
8.	3.2.P.8	- Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted chromatograms for the stability data reflects 20µl injection volume. - Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	At that time we have performed analysis with the Shimadzu isocratic manual injector and it has fixed loop of 20ul so we did not used 100µl. Compliance Record of HPLC software 21CFR & audit trail reports are attached. Please see Attached Annex 04 Digital data logger please see Attached Annex 04
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
The firm has submitted reply via General Request Form TID ETU-7BG-Y4RM dated 21-05-2025.			
Decision: Approved.			

Agenda of Adil Saeed PEC-IX

Form 5F deferred Cases

65.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1,

	RCCI Industrial Estate, Rawat. DML No. 000882
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No 3224 dated 03.02.2023
Details of fee submitted	PKR 30,000/- Slip No. 94847755 Dated 01.01.2023
The proposed proprietary name / brand name	ROSTA 5mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin.....5mg
Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
Pharmaceutical form of applied drug	White, round, biconvex film coated Tablets.
Reference to Finished product specifications	USP Specifications.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
For generic drugs (me-too status)	Rovista Tablet 5mg Reg No. 044043 M/s Getz Pharma (Pvt.) Ltd. Karachi.
Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) and drug product.

Module-III Drug Substance:		Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted pharmaceutical equivalence of their product against product Rovista 5mg Tablet Batch No. F05008, mfg date: 04.2022, Exp date: 04.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 96, Acetate buffer F2: 98, Phosphate buffer F2: 97 Pictorial evidence of pack of Reference product is not attached
Analytical method validation/verification of product		Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.	
API Lot No.	RT12-9058	
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10's further packed in bleach card unit carton along with Leaflet.	
Stability Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	

Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6(Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted New DML DML was issued in Feb 2023
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh India. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schedule M of the Drugs & Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from WNSFEILD Pharmaceuticals Hattar. Quantity: 4kg Batch No. RT12-9058 Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution and what is its strength.
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.

5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.
7.		Only a list of previous approval of applications with stability study data in tablet section is required.

Decision of 330th RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
8.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	Firm has submitted response in eapp (general request form) vide tracking ID 28T-G11-JMNY. Rovista 5mg Tablet B. No. F05008 M/s Getz
9.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	Its acceptable to use comparator product as per CTD guidance issued by DRAP.
10.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution and what is its strength.	SAP is submitted.
11.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	Submitted.
12.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	Submitted
13.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	HPLC log is submitted
14.		Only a list of previous approval of applications with stability study data in tablet section is required.	Dexqin 30mg and 60mg Tablets

Decision: Approved.

66.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat. DML No. 000882

Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No 3124 dated 02.02.2023
Details of fee submitted	PKR 30,000/- Slip No. 82189200836 Dated 31.01.2023
The proposed proprietary name / brand name	ROSTA 10mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin.....10mg
Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
Pharmaceutical form of applied drug	White, round, biconvex film coated Tablets.
Reference to Finished product specifications	USP Specifications.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
For generic drugs (me-too status)	Rovista Tablet 10mg Reg No. 044044 M/s Getz Pharma (Pvt.) Ltd. Karachi.
Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data

		related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$ for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$ for 36 months. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against product Rovista 10mg Tablet Batch No. F06026, mfg date: 04.2022, Exp date: 04.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 93, Acetate buffer F2: 97, Phosphate buffer F2: 95. Pictorial evidence of pack of Reference product is not attached
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.	
API Lot No.	RT12-9058	
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10's further packed in bleach card unit carton along with Leaflet.	
Stability Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6(Months)	

Batch No.	T-04	T-05	T-06
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted New DML DML was issued in Feb 2023
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh India. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schedule M of the Drugs & Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from WNSFEILD Pharmaceuticals Hattar. Quantity: 4kg Batch No. RT12-9058 Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required

6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.
7.		Only a list of previous approval of applications with stability study data in tablet section is required.

Decision of 330th RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	Firm has submitted response in eapp (general request form) vide tracking ID 28T-G11-JMNY. Rovista 10mg Tablet B. No. F06026 M/s Getz
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	Its acceptable to use comparator product as per CTD guidance issued by DRAP.
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.	SAP is submitted.
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	Submitted.
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	Submitted
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	HPLC log is submitted
7.		Only a list of previous approval of applications with stability study data in tablet section is required.	Dexqin 30mg and 60mg Tablets

Decision: Approved

67.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat. DML No. 000882
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.

Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No 3125 dated 02.02.2023
Details of fee submitted	PKR 30,000/- Slip No. 895013356553 Dated 31.01.2023
The proposed proprietary name / brand name	ROSTA 20mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin.....20mg
Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
Pharmaceutical form of applied drug	White, round, biconvex film coated Tablets.
Reference to Finished product specifications	USP Specifications.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
For generic drugs (me-too status)	Rovista Tablet 20mg Reg No. 044045 M/s Getz Pharma (Pvt.) Ltd. Karachi.
Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 36 months. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted pharmaceutical equivalence of their product against product Rovista 20mg Tablet Batch No. F06042, mfg date: 02.2022, Exp date: 02.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 92, Acetate buffer F2: 96, Phosphate buffer F2: 93. Pictorial evidence of pack of Reference product is not attached
Analytical method validation/verification of product		Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.		
API Lot No.	RT12-9058		
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10's further packed in bleach card unit carton along with Leaflet.		
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6(Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted New DML DML was issued in Feb 2023
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh India. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schedule M of the Drugs & Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from WNSFEILD Pharmaceuticals Hattar. Quantity: 4kg Batch No. RT12-9058 Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted
Remarks of Evaluator:		
Sr. No.	Section	Observation
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.
7.		Only a list of previous approval of applications with stability study data in tablet section is required.

Decision of 330th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
8.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	Firm has submitted response in eapp (general request form) vide tracking ID 28T-G11-JMNY. Rovista 20mg Tablet B. No. F06036 M/s Getz
9.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	Its acceptable to use comparator product as per CTD guidance issued by DRAP.
10.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.	SAP is submitted.
11.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	Submitted.
12.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	Submitted
13.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	HPLC log is submitted
14.		Only a list of previous approval of applications with stability study data in tablet section is required.	Dexqin 30mg and 60mg Tablets
Decision: Approved.			

68.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15401: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023

The proposed proprietary name / brand name	CELEFOLD 200mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib...200mg
Pharmacotherapeutic Group of (API)	NSAID
Reference to Finished product specifications	BP Specifications.
The status in reference regulatory authorities	MHRA Approved
For generic drugs (me-too status)	Celbexx capsule by Getz
Proposed Pack size	As per SRO
Evaluation by PEC³:	
Sr. No Shortcomings	
The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
Submit COA of reference / working standard actually used in analysis of drug substance.	
Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
Justify why test for uniformity of dosage unit is not included in drug product specification.	
Submit valid GMP certificate of API manufacturer	
Submit documents for procurement of API including DRAP clearance certificate.	
Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. Firm has submitted their response on eapp CMS vide tracking ID 2NX-A8P-ZL1T	
Sr. No Shortcomings	Response by the firm
The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	Specifications are revised to BP.
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted

Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted, working standard used is also of M/s Aarti drug company India. Batch No. CEB/WRS/00124
Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	Submitted, performed against Celbexx 200mg capsule
Justify why test for uniformity of dosage unit is not included in drug product specification.	Revised specifications are submitted.
Submit valid GMP certificate of API manufacturer	GMP issued by FDA Maharashtra India valid till 06.09.2025 is submitted.
Submit documents for procurement of API including DRAP clearance certificate.	Form 6 is submitted.

Decision: Approved. Letter shall be issued after submission of fee for preregistration variation.

69.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15400: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	CELEFOLD 100mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib...100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP Specifications.
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Celbexx capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC³:

Shortcomings

The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
Submit COA of reference / working standard actually used in analysis of drug substance.	
Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
Justify why test for uniformity of dosage unit is not included in drug product specification.	
Submit valid GMP certificate of API manufacturer	
Submit documents for procurement of API including DRAP clearance certificate.	
Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. Firm has submitted their response on eapp CMS vide tracking ID 2NX-A8P-ZL1T	
Shortcomings	Response by the firm
The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	Specifications are revised to BP.
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted, working standard used is also of M/s Aarti drug company India. Batch No. CEB/WRS/00124
Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	Submitted, performed against Celbexx 100mg capsule
Justify why test for uniformity of dosage unit is not included in drug product specification.	Revised specifications are submitted.
Submit valid GMP certificate of API manufacturer	GMP issued by FDA Maharashtra India valid till 06.09.2025 is submitted.
Submit documents for procurement of API including DRAP clearance certificate.	Form 6 is submitted.

Decision: Approved. Letter shall be issued after submission of fee for preregistration variation.

70.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15402: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	CELEFOLD 400mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib...400mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP Specifications.
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Celbexx capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC³:

Shortcomings
Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.
Submit evidence of me-too status
The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.
Submit COA of reference / working standard actually used in analysis of drug substance.

Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.
Justify why test for uniformity of dosage unit is not included in drug product specification.
Submit valid GMP certificate of API manufacturer
Submit documents for procurement of API including DRAP clearance certificate.

Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm has submitted their response on eapp CMS vide tracking ID 2NX-A8P-ZL1T

Shortcomings	Response by the firm
Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275 th meeting.	USFDA approved.
Submit evidence of me-too status	Celbexx 400mg Capsule
The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	Specifications are revised to BP.
Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted, working standard used is also of M/s Aarti drug company India. Batch No. CEB/WRS/00124
Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	Submitted, performed against Celbexx 400mg capsule
Justify why test for uniformity of dosage unit is not included in drug product specification.	Revised specifications are submitted.
Submit valid GMP certificate of API manufacturer	GMP issued by FDA Maharashtra India valid till 06.09.2025 is submitted.
Submit documents for procurement of API including DRAP clearance certificate.	Form 6 is submitted.

Decision: Approved. Letter shall be issued after submission of fee for pre-registration variation.

71.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3139 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 331736067
	The proposed proprietary name / brand name	MYTAKRO 0.5mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate... 0.5mg
	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immunomodulating Agents, Calcineurin inhibitors.
	Reference to Finished product specifications	USP Specs
	The status in reference regulatory authorities	VIVADDEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/0103/DC MHRA Approved.
	For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Observation	
2.3.P.1.(a) Description of the FPP has been mentioned as ' <i>White to off white color powder filled in yellow body white cap hard gelatin capsule shell</i> ' as well as ' <i>White to off white color powder filled in white body white cap hard gelatin capsule shell</i> '. Please justify	
3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5)	
Avg. Weight has been mentioned as 100mg $\pm$ 5%, 150mg $\pm$ 5% as well as 100mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.	
Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	

Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API			
Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-01-2022 .			
Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing			
Decision of 336th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The firm has submitted their response on eapp case management system vide tracking ID 7H8-E1T-E9JU.			
	Observation	Response	
	2.3.P.1.(a) Description of the FPP has been mentioned as ' <i>White to off white color powder filled in yellow body white cap hard gelatin capsule shell</i> ' as well as ' <i>White to off white color powder filled in white body white cap hard gelatin capsule shell</i> '. Please justify	The firm has stated that it was typographic error. The correct description is White to off white color powder filled in white body white cap hard gelatin capsule shell.	
	3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5)	USP Dissolution Test-1 is performed. Revised analytical procedure submitted	
	Avg. Weight has been mentioned as 100mg $\pm$ 5%, 150mg $\pm$ 5% as well as 100mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.	It was a typo mistake Correct and accurate average weights in respective sections is 150mg $\pm$ 10%.	
	Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	Firm has submitted pictorial evidence of Inograf 0.5mg Capsule B. no. 54, Mfg M/s Platinum Pharma.	
	Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API	Form 6 is submitted.	
	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-01-2022 .	Copy of GMP certificate issued by FDA Gujrat state India is submitted.	
	Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing	HPLC Log is submitted.	
Decision: Approved.			
72.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.	
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.	

Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3140 dated 02 FEB 2023
Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 29967435581
The proposed proprietary name / brand name	MYTAKRO 1mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate... 1mg
Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immunomodulating Agents, Calcineurin inhibitors.
Reference to Finished product specifications	USP Specs
The status in reference regulatory authorities	VIVADDEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/0103/DC MHRA Approved.
For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO

Evaluation by PEC

Observation	
3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).	
Avg. Weight has been mentioned as 100mg $\pm$ 5%, 150mg $\pm$ 5% as well as 100mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.	
Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	
Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.	
Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-012022	
Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.	

Decision of 336th meeting:

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

The firm has submitted their response on eapp case management system vide tracking ID 7H8-E1T-E9JU.

Evaluation by PEC

Observation	Response
3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).	USP Dissolution Test-1 is performed. Revised analytical procedure submitted

Avg. Weight has been mentioned as 100mg $\pm$ 5%, 150mg $\pm$ 5% as well as 100mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.	It was a typo mistake Correct and accurate average weights in respective sections is 150mg $\pm$ 10%.	
Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP.	Pictorial evidence of Inograf 1mg B. No. 138 Mfg Platinum Pharma is submitted.	
Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.	Form 6 is submitted.	
Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-012022	Copy of GMP certificate issued by FDA Gujarat state India is submitted.	
Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.	HPLC Log is submitted.	

Decision: Approved.

73.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3122 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 27-01-2023 Challan / Receipt # 759489500668
	The proposed proprietary name / brand name	MYTAKRO 5mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Tacrolimus as Monohydrate... 5mg
	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immunomodulating Agents, Calcineurin inhibitors.
	Reference to Finished product specifications	USP Specs
	The status in reference regulatory authorities	VIVADDEX 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/0103/DC MHRA Approved.

	For generic drugs (me-too status)	INOGRAF Capsule of M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC (XXI):		
Observation		
3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).		
Avg. Weight has been mentioned as 215mg $\pm$ 5% as well as 215mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.		
Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP		
Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.		
Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-012022 .		
Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.		
Decision of 336th meeting:		
Registration Board deferred the case for submission of reply to the above cited shortcomings.		
The firm has submitted their response on eapp case management system vide tracking ID 7H8-E1T-E9JU.		
Evaluation by PEC (IX):		
	Observation	Response
	3.2.P.5.1 Please specify USP Dissolution Test adopted (1,2,3,4 or 5).	USP Dissolution Test-1 is performed. Revised analytical procedure submitted
	Avg. Weight has been mentioned as 215mg $\pm$ 5% as well as 215mg $\pm$ 10% on separate instances in Sections 3.2.P.2.2, 3.2.P.5.1, 3.2.P.5.4 and 3.2.P.8.1. Please justify.	It was a typo mistake Correct and accurate average weights in respective sections is 150mg $\pm$ 10%.
	Please provide evidence of Reference / Innovator / Comparator Packs used for Pharmaceutical Equivalence and CDP	Inograf 5mg capsule, M/s Platinum Pharma.
	Please provide AD (I&E) DRAP clearance for Commercial Invoice No. TR120051 dated January 10, 2022 for import of 50grams of API.	Form 6 is submitted.
	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid till 29-012022 .	Copy of GMP certificate issued by FDA Gujrat state India is submitted.
	Please provide 21CFR Compliance Record of HPLC software & audit trail reports on product testing.	HPLC Log is submitted.
Decision: Approved.		
Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.	
Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, PhaseII, Industrial Area, Hattar.	

Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7697 dated 17-03-2023.
Details of fee submitted	Rs.30,000/- vide slip No. 30810134648 dated 27-012023.
The proposed proprietary name / brand name	Thiofold 4mg/2ml Injection.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Thiocolchicoside 4mg
Pharmacotherapeutic Group of (API)	Muscle relaxant.
Reference to Finished product specifications	Innovator's Specifications.
The status in reference regulatory authorities	ANSM France approved.
For generic drugs (me-too status)	Chicowin 4mg/2ml Injection, Wnsfield Pharmaceuticals, Reg. No. 093890.
Proposed Pack size	As per SRO.
Proposed unit price	As per SRO.

Decision of 343rd meeting: Deferred for following;

- Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.
- Specifications of the drug substance from drug substance manufacturer shall be submitted.
- Justification shall be submitted for provision of changed method verification results from that of the initially submitted in the dossier.
- Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other

Evaluation by PEC:

The firm has submitted reponse on eapp CMS vide tracking ID 8YD-N6Y-ANXE

Observation	Response	
Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate issued by Food Safety and drugs administration authority Uttarakhand India is submitted. Its valid till 06.02.2025	
Specifications of the drug substance from drug substance manufacturer shall be submitted	Submitted	
Justification shall be submitted for provision of changed method verification results from that of the initially submitted in the dossier	As Thiocholchicoside peak time is 2.8-3 min and we have no impurities, we run standard and sample one injection up to 30min and found no peak, also validation performed and found no other peak, therefore selection of runtime is different as per our validation process.	
Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other.	Terminal sterilization was not mentioned in the dossier mistakenly. Revised process validation protocols are submitted.	
Submission of 9000/- fee for pre-registration variation as per SRO 1324(I)2024 dated 30-08-2024	Fee of Rs. 9400/- is submitted vide slip No. 152271896085	

Decision: Deferred for submission of complete method validation (3.2.P.5) along with chromatograms and other relevant supporting data.

Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, PhaseII, Industrial Area, Hattar.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7698 dated 17-03-2023.
Details of fee submitted	Rs.30,000/- vide slip No. 8064730870 dated 27-01-2023
The proposed proprietary name / brand name	Thiofold 4mg Tablet.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Thiocolchicoside 4mg
Pharmacotherapeutic Group of (API)	Muscle relaxant.
Reference to Finished product specifications	Innovator's Specifications.
The status in reference regulatory authorities	ANSM France approved.
For generic drugs (me-too status)	Wodlink 4mg tablets, Martin Dow, Reg. No. 081138.
Proposed Pack size	As per SRO.
Proposed unit price	As per SRO.

Decision of 343rd meeting: Deferred for following;

- ☐ ☐ **Submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- ☐ ☐ **Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.**
- ☐ ☐ **Specifications of the drug substance from drug substance manufacturer shall be submitted.**
- ☐ ☐ **Justification shall be submitted for changing the qualitative composition of the applied formulation as initially at the time of submission of dossier it was different from innovator and after shortcoming it is aligning with the innovator product.**
- ☐ ☐ **Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other.**
- ☐ ☐ **Raw data sheets for calculation of assay and dissolution as per calculation formula for each time interval shall be submitted.**

Evaluation by PEC:

The firm has submitted reponse on eapp CMS vide tracking ID A15-HEB-PTLN

Observation	Response	
Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate issued by Food Safety and drugs administration authority Uttarakhand India is submitted. Its valid till 06.02.2025	
Specifications of the drug substance from drug substance manufacturer shall be submitted	Submitted	
Justification shall be submitted for changing the qualitative composition of the applied formulation	It was Typographical Mistake Correct one can be confirmed from BMR which was according to innovator. Hence we corrected this in Qualitative composition too.	

as initially at the time of submission of dossier it was different from innovator and after shortcoming it is align with the innovator product.		
Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other.	Wrong Analytical procedure was mistakenly attached. Now corrected analytical procedure is submitted.	
Raw data sheets for calculation of assay and dissolution as per calculation formula for each time interval shall be submitted.	Raw data sheets are submitted.	
Submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.	Fee of Rs. 9000/- is submitted vide slip No. 393509369	

Decision: Deferred for submission of complete method validation (3.2.P.5) along with chromatograms and other relevant supporting data.

76.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 26274 : 31-10-2023
	Details of fee submitted	PKR 30,000/- : 0312690979
	The proposed proprietary name / brand name	CLOZZA 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Clozapine...50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Cannot be verified from database
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):		
Serial No.	Module/ Section	Shortcomings
1.	1.5.9	Submit me-too status of 50mg strength
2.	3.2.S.7	Long term stability data is submitted for 2 batches only. Submit long term stability data for at least three batches.
Decision of 343rd meeting: Deferred for satisfactory response to afore-mentioned shortcomings.		
Evaluation by PEC-IX.		
Firm has submitted response on eapp CMS vide tracking ID MSM-TLH-XWRE		
1.5.9	Submit me-too status of 50mg strength	No response submitted.
3.2.S.7	Long term stability data is submitted for 2 batches only. Submit long term stability data for at least three batches.	Stability data of 3 batches as per Zone IVa conditions is submitted up to 24 months.
Decision: Deferred for submission of me-too reference or fee for registration of new drug product.		
77.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot # 69/2, PhaseII, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21690 dated 01-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 94078660903 dated 04-08-2023.
	The proposed proprietary name / brand name	Finrox 10mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerone 10mg
	Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other PotassiumSparing Agents.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.

For generic drugs (me-too status)	N/A.
Proposed Pack size	10's, 14's, 20's & 30's. As per SRO.
Proposed unit price	As per SRO.

Decision of 343rd meeting: Deferred for following;

- **Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.**
- **Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.**
- **Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.**

Evaluation by PEC:

Firm has submitted their response on eapp CMS vide tracking ID UGS-GPB-LQ3L

Observation	Response	
Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.	Fee of Rs. 9000/- is submitted vide slip No.	69750357
Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.	Submitted upto 24 months as per Zone IVa conditions.	
Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.	12 th month time point stability data as per new SAP is submitted.	
Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.	Calculations sheets and chromatograms are submitted.	

Decision: Approved.

78.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals, Plot # 69/2, PhaseII, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21691 dated 01-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 3812073763 dated 04-08-2023.

The proposed proprietary name / brand name	Finrox 20mg Tablet.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone 20mg
Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other PotassiumSparing Agents.
Reference to Finished product specifications	Innovator's Specifications.
The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.
For generic drugs (me-too status)	N/A.
Proposed Pack size	10's, 14's, 20's & 30's. As per SRO.
Proposed unit price	As per SRO.

Decision of 343rd meeting: Deferred for following;

- **Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.**
- **Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.**
- **Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.**

Evaluation by PEC:

Firm has submitted their response on eapp CMS vide tracking ID UGS-GPB-LQ3L

Observation	Response	
Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.	Fee of Rs. 9000/- is submitted vide slip No. 361917902760	
Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.	Submitted upto 24 months as per Zone IVa conditions.	
Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.	12 th month time point stability data as per new SAP is submitted.	
Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.	Calculations sheets and chromatograms are submitted.	

Decision: Approved.

79.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Infusion Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25757 dated 25.10.2023
	Details of fee submitted	PKR 30,000/- Slip No. 36362201985 dated 20.10.2023
	The proposed proprietary name / brand name	Gen-Zole 4mg/5ml Concentrate for solution for infusion.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Zolidronic acid as monohydrate....4mg
	Pharmacotherapeutic Group of (API)	Bisphosphonates ATC Code: M05BA08
	Pharmaceutical form of applied drug	Clear colourless solution filled in glass vial with flip-off seal.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOMETA 4MG/5ML CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	For generic drugs (me-too status)	Zoledronic acid Normon 4mg/5ml Injection Reg No. 082059 M/s Merixil Pharma Islamabad (Importer).
	Name and address of API manufacturer.	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. 69020422 dated 13.03.2023
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$ for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$ for 36 months. Batch No. ZLA/FPR/001/18, ZLA/FPR/002/18, ZLA/FPR/003/18
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product Macdronic 4mg/5ml Injection batch no. _____ exp. _____. manufactured by _____. Pictorial evidence is not submitted. Tests: Description, identification, particulate matter, pH, Assay, BET, Sterility.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Synnat Pharma Pvt. Ltd. Plot No. 60A, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakhapatnam, Andhra Pradesh, India.	
API Lot No.	69020422	
Description of Pack (Container closure system)	Clear colourless solution filled in glass vial with flip-off seal.	
Stability	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$	

Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	03.2023	03.2023	03.2023
Date of Initiation	15.03.2023	15.03.2023	15.03.2023
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section, NA	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. E-1844451/DD/DCA/VSP/2022 dated 02.11.2022 valid till 01.11.2023, issued by Drug control administration Andhra Pradesh India.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Batch No.: Mfg date: Exp date: Quantity: Invoice No.: Invoice date: Cleared by AD I&E	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Remarks of Evaluator:			
Sr. No.	Section	Observation	Reply by the firm
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Macdronic) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm vide letter No. nil dated 02.12.2023 has submitted pictorial evidence of the reference product macdronic 4mg/5ml injection, Batch No. 23004, mfg date: 05.2023 exp: 04.2025.

			Manufactured by M/s Macter International Ltd.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Copies of BMR of batches T001, T002 and T003.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	The firm has submitted that drug substance is taken loan from M/s Medisave Pharma. Copy of clearance certificate and loan agreement is submitted. Batch No. 69010122 mfg 01.01.2022 exp: 31.12.2024. Invoice No. DP-378/2021-22 cleared by AD I&E DRAP Lahore on 18.03.2022
4	-	The product is a liquid vial (SVP), section approval is of infusion section. Justify.	Firm has submitted letter of issuance of DML vide No. 1-2/2019-Lic dated 14.02.2020, wherein Ampoule section SVP (General) is mentioned.

Decision of 333rd meeting of RB: The Board Deferred the case for verification of manufacturing facility for Liquid Vial SVP of the firm M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.

Remarks of evaluator: The firm vide letter No. nil dated 12.02.2024 has submitted reply in response to decision of the Registration Board.

The firm has shared a copy of inspection report for grant of DML, conducted on 12.12.2019. In the inspection report Infusion section is mentioned as SVP General.

In section approval letter, SVP is not mentioned with infusion section.

Decision of 336th meeting: The Board deferred the case for verification of manufacturing facility of the firm from Licensing Division.

Evaluation by PEC-IX:

The firm has submitted their response on eapp CMS vide tracking ID Y5Q-27V-GV9U
The DML of firm has been renewed vide letter No. 1-2/2019-Lic dated 26.09.2025. AS per renewal letter firm's Liquid Vial (general) section has been regularized as both SVP/LVP (general).

Decision: Approved.

80.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	g Manufacturer un Importer un Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5260 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 1415475365
	The proposed proprietary name / brand name	TUGLIF-M 2.5/1000mg Tablet

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyrogutamic acid«PJ Metformin Hydrochloride «PJ
Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
Reference to Finished product specifications	,QQRYDWRU¶V6SHFLILFDWLRQV
The status in reference regulatory authorities	SEGLUROMET Tablet 2.5/1000mg (USFDA Approved).
For generic drugs (me-too status)	LOZGIL-M Tablet 2.5/1000mg of M/s Genix Pharma (Private) Limited.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
Evaluation by PEC (XXI):	
The following deficiencies / shortcomings have been communicated to the firm:	

Sr. No.	Observations	Reply
i.	Ertugliflozin L-Pyrogutamic acid: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Admistration, China.
ii.	Metformin Hydrochloride: Please provide valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid until 12-03-2024 .	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06 th Month (Accelerated) testing interval from initial test results of Ertugliflozin, Batch No. 058B22. Please justify.	Firm have submitted justification as follows: - x When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. x In the case of small batch sizes, it is important to acknowledge that the results obtained from the stability testing may not fully reflect the true stability profile of the product. x Despite the challenges, all other parameters were satisfactory that shows variation is not as significant.

iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22 nd February, 2023.

Decision of 336th meeting: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accelerated stability studies of Batch no. 058B22 decided to defer the case for submission of stability studies of newly formulated batches.

Evaluation by PEC-IX
The firm has submitted their response on eapp CMS vide tracking ID MMX-QG3-TJNR
Firm has manufactured 3 new trial batches. Details of batches is tabulated below;

B. No.	Size	Mfg Date
216B24	2500 tablets	09-2024
236B24	2500 tablets	09-2024
237B24	2500 tablets	09-2024

As per submitted stability data of new batches, the variation in assay results of Ertugliflozin is now less than 3% over time period of 6 months accelerated conditions. Firm has submitted real time stability studies up to 6th month time point also. Supporting data like calculations and chromatograms are also submitted.

Decision: Approved.

81.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	g Manufacturer un Importer un Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5259 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 4043535505
	The proposed proprietary name / brand name	TUGLIF-M 7.5/1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyrogutamic acid«PJ Metformin Hydrochloride «PJ
	Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	,QQRYDWRU¶V6SHFLILFDWLRQV
	The status in reference regulatory authorities	SEGLUROMET Tablet (USFDA Approved).

For generic drugs (me-too status)	LOZGIL-M Tablet 7.5/1000mg of M/s Genix Pharma (Private) Limited.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO

Evaluation by PEC (XXI):

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

Sr. No.	Observations	Response
i.	Ertugliflozin L-Pyrogutamic acid: Please provide approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Administration, China.
ii.	Metformin Hydrochloride: Please provide valid approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid until 12-03-2024 .	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06 th Month (Real Time) testing interval from initial test results of Metformin, Batch No. 060B22. Please justify.	xn have submitted justification as follows: - When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. In the case of small batch sizes, it is important to acknowledge that the results obtained from the stability testing may not fully reflect the true stability profile of the product. Despite the challenges, all other parameters were satisfactory that shows variation is not as significant. x
iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22 nd February, 2023.

Decision of 336th meeting: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accelerated stability studies of Batch no. 060B22 decided to defer the case for submission of stability studies of newly formulated batches.

Evaluation by PEC-IX

The firm has submitted their response on eapp CMS vide tracking ID TUU-HB8-2JXG

Firm has manufactured 3 new trial batches. Details of batches is tabulated below;

B. No.	Size	Mfg Date
233B24	2000 tablets	09-2024
234B24	2000 tablets	09-2024
235B24	2000 tablets	09-2024

As per submitted stability data of new batches, the variation in assay results of Ertugliflozin is now less than 3% over time period of 6 months accelerated conditions. Firm has submitted real time stability studies up to 6th month time point also. Supporting data like calculations and chromatograms are also submitted.

Decision: Approved.

82.	Name, address of Applicant / Importer	M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan
	Details of Drug Sale License of importer	License No.: 0002 Address: 246-B, Block-6, PECHS, Karachi Validity: 15-08-2022 Status: License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	South Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. 2020-D1-3552) dated 23-10- 2020 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. <u>The name of importing country on CoPP is mentioned as Pakistan.</u> GMP: Firm has submitted legalized GMP certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein prefilled syringe dosage form has not been mentioned.
	Details of letter of authorization / sole agency agreement	Firm has submitted Legalized NOC from M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea which authorises M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan to register their products in Pakistan. The authorization letter is valid till 09-112022.

Status of the applicant	. Manufacturer . Importer . Is involved in none of the above (contract giver)
Status of application	. New Drug Product (NDP) . Generic Drug Product (GDP)
Intended use of pharmaceutical product	. Domestic sale . Export sale . Domestic and Export sales
For imported products, specify one the these	. Finished Pharmaceutical product import . Bulk import and local repackaging . Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No 10553 dated 06-04-2021
Details of fee submitted	Rs.100,000/- dated 24-03-2021
The proposed proprietary name / brand name	Hyal Forte Pre Filled Syringe
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe (2ml) Contains 20mg of Sodium Hyaluronate
Pharmaceutical form of applied drug	Pre-filled syringe
Pharmacotherapeutic Group of (API)	Hyaluronic acid
Reference to Finished product specifications	Innovator specifications
Proposed Pack size	1's; AS per SRO
Proposed unit price	AS per SRO
The status in reference regulatory authorities	Hyalgan PFS 20mg/2ml approved by ANSM of France
For generic drugs (me-too status)	Hyalgan PFS of M.s Matrix Pharma Reg.# 031340
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea

Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 °C±2. The stability study data is till 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence Euflexxa
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	Pre-filled syringe
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batchesT he accelerated stability study data is conducted at
	25°C ±2°C / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5°C ±3°C / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.
Evaluation by PEC: - x The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate 10mg - x Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022. - x Firm has submitted legalized GMP certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwongu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned. - x Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25°C.	
Decision of 333 rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.	
Submission by the firm:	

Sr. No	Reason for deferment	Response by the firm
1.	The submitted COPP does not clarify the description of applied product whether prefilled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate 10mg	Firm has submitted copy of CoPP certificate (No. 2024-D1-0199) dated 08-02- 2024 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection (pre-filled syringe). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years.
2.	Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.	Firm has submitted copy of NOC from M/s Shin Poong Pharmaceutical Co., Ltd. which authorises M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan to register their products in Pakistan. The authorization letter is issued on 29-01-2024.
3.	Firm has submitted legalized GMP certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.	Firm has submitted copy of GMP certificate (No. 2024-D1-0201) dated 08-02-2024 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has been mentioned in injections.
4.	Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25°C.	Firm has not submitted any written justification instead a chart is submitted which does not specify any product.
Decision of 336 th RB meeting: Deferred for following:		
x Justification for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25°C.		
Response by the firm: We, Shin Poon Pharm. Co., Ltd., would like to justify the reason of performing stability studies as per refrigerating conditions since the reference product recommends storage condition of store below 25°C. While developing the product, our R&D team found a potential risk of viscosity reduction due to an increase in temperature. Therefore, we conducted stability studies as per refrigerating conditions and set the storage condition as 2~8°C.		
Decision of 339 th RB meeting: Registration Board deferred for clarification as the product is not stable at/below 25 ⁰ C, since the reference product recommends the storage condition below 25 ⁰ C		

Response by the firm: Firm has submitted that innovator's product recommend storage condition at room temparture while our product is recommended at 2-8degree because: Molecular weight of innovator hyalgan is: 500k – 730k Dalton Molecular weight of our product: 2500 K Dalton. A research study used highly purified hyaluronic acid with molecular weight 2000K Da obtained by fermentation and autoclaved at 118 degree for 5 mins. These are similar to preparation of our product. Degradation is one of the important properties required for visco supplementation. From this study when compared to hydrogels after 24 hours stored at 5 degree and 25 degree. Samples at 5 degree have no change while smples kept at 25 degree show a clear effect on rate of degradation. Hyal forte also show a decrease in viscosity under storage condition of 25 degree. Decision of 343rd meeting: Deferred for clarification regarding regulatory status of the applied product whether regulated as drug product or medical device and relevant clinical data considered by relevant NRA. Evaluation by PEC: The firm has submitted their response on eapp CMS vide tracking ID W2S-JRU-N44T The firm has given following justifications for considering their product as a Drug; 1. According to the FDA regulations, a medical device is a product which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 2. The active ingredient of Hyalforte, hyaluronic acid, exerts its therapeutic effects through biochemical actions. This has been demonstrated through numerous studies. 3. The Hyal forte injection is registered as pharmaceutical product in Mongolia, Uzbekistan, Georgia, Sri Lanka, Tanzania, and Vietnam, including South Korea. Hyalgan PFS (RRA reference) is available in ANSM France drug database and its status is valid. Decision: Approved as per policy for inspection abroad.	

83.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	IX Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) IX Generic Drug Product (GDP)
	Intended use of pharmaceutical product	IX Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2629 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient	Each tablet contains: Nebivolol HCl equivalent to Nebivolol

(API) per unit	2.5mg
Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
Reference to Finished product specifications	Manufacturer's Specification
Proposed Pack size	1x10's , 3x 10's and 2x 7's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
For generic drugs (me-too status)	Nabil 2.5mg Tablet by M/s Getz Pharma, Reg. No. 061344
GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.	
STABILITY STUDY DATA			
Manufacturer of API		Jiangsu Weiqida Pharmaceutical Co., Ltd.	
API Lot No.		NBB-19070031M	
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's , 3x 10's and 2x 7's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 12 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)	
Batch No.	NEB2.5-TR002	NEB2.5-TR003	NEB 2.5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leader approved in Pakistan.

4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.
Decision of 324th meeting of Registration Board: Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.		
Response of the Firm:		

S.no.	Sections	Observations/Deficiencies/Shortcomings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted”. Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance	Firm replied it is an error which was rectified an correct COA of drug substance by drug product manufacturer has submitted.

		manufacturer calculated the assay on anhydrous basis only.	
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead o pharmaceutical equivalence report including the te of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure o drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure i which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl ra material in production of our trial batches as pe Innovator's specifications not Nebivolol base as it i evident from our COA of raw material attached her but since international and our claim is Nebivolol a HCl (Nebivolol base) that's why we had used onl Nebivolol in our chromatograms. The peak i chromatograms is of Nebivolol HCl but to justify your claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.

		brand approved in USFDA.	
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl
Decision of 329th meeting of Registration Board: Deferred for submission of following shortcomings: Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product. Response of the Firm: Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product. Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.			
Decision of 336th meeting of Registration Board: Deferred for submission of following: x Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. x Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.			
Response of the Firm: x Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. x Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product			
Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.			
Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.			

Decision OF 339 th meeting: The Registration Board deferred the application as last chance to submit the reply for the shortcomings already communicated. their submitted responses were still deemed unsatisfactory after evaluation.		
Evaluation by PEC-IX; Firm has submitted their response on eapp CMS vide tracking ID T8G-ES8-WPSY Firm was asked to submit dissolution testing performance data as per new revised method (3.2.P.5). Firm has again not submitted the required documents/data. Firm has submitted a summary page of CDP of all 3 strengths, Method of analysis(MOA) and internal factory specifications(IFS). The dissolution testing data that was required from the firm (chromatograms/ UV absorbance values, calculations etc) are not submitted.		
Decision: The Board deliberated on the matter that firm has failed to dissolution testing performance data despite being asked multiple times. The Board rejected the case.		
84.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	IX Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) IX Generic Drug Product (GDP)
	Intended use of pharmaceutical product	IX Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2630 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol.....5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 5mg Tablet by M/s Getz Pharma, Reg. No. 061345
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd

		Address: No.1, Linjiang Avenue, Nantong, China
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure
		system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)		Official monograph of Nebivolol HCl is not present in Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies		Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NEB5-TR002, NEB5-TR003, NEB5-TR004)
Module-III (Drug Product):		The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile		Pharmaceutical Equivalence have been established against the brand leader that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd. in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product		Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.
STABILITY STUDY DATA		
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.	
API Lot No.	NBB-19070031M	

Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's3x 10's and 2x 7's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 12 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)	
Batch No.	NEB5 - TR00 2	NEB5-TR003	NEB5- TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator:			
S.n	Secti ons	Observations/Deficiencies/ Short-comings	
1.	3.2.S. 4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted”. Since you have only submitted the requisite information	

		provided by drug substance manufacturer.	
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.	
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	
Decision of 324th meeting of Registration Board: Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.			
Response of the Firm:			
S.no.	Sections	Observations/Deficiencies/ Shortcomings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.

		information provided by drug substance manufacturer.	
2.	3.2.S .4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P .2.2. 1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P .5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P .5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P .5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write

			only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.	
7.	3.2.P .5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.	
8.	3.2.R .1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.	

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm: Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.		
Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product. Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.		
Decision of 339th meeting: The Registration Board deferred the application for last chance to submit reply to the communicated shortcomings as their submitted responses were still deemed unsatisfactory after evaluation.		
Evaluation by PEC-IX; Firm has submitted their response on eapp CMS vide tracking ID T8G-ES8-WPSY Firm was asked to submit dissolution testing performance data as per new revised method (3.2.P.5). Firm has again not submitted the required documents/data. Firm has submitted a summary page of CDP of all 3 strengths, Method of analysis(MOA) and internal factory specifications(IFS). The dissolution testing data that was required from the firm (chromatograms/ UV absorbance values, calculations etc) are not submitted.		
Decision: The Board deliberated on the matter that firm has failed to dissolution testing performance data despite being asked multiple times. The Board rejected the case.		
85.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	IX Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) IX Generic Drug Product (GDP)
	Intended use of pharmaceutical product	IX Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.9330 dated 12/04-2022
	Details of fee submitted	PKR 30,000/-: dated 17/03/2022
	The proposed proprietary name / brand name	Nevol 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol.....10mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's

Proposed unit price	As per SRO
The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
For generic drugs (me-too status)	Bynevol 10mg Tablet by Atco Laboratories, Reg. No. 081562
GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to
	nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any Pharmacopoeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bynevol 10mg tablet by Atco Laboratories. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bynevol 10mg tablet by Atco Laboratories. in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

Analytical method validation/verification of product		Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.	
STABILITY STUDY DATA			
Manufacturer of API		Jiangsu Weiqida Pharmaceutical Co., Ltd.	
API Lot No.		NBB-19070031M	
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's, 3x 10's and 2x 7's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 12 months	
		Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)	
Batch No.	NEB10-TR002	NEB10-TR003	NEB10-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Administrative Portion			
1. Reference of previous approval of applications with stability study data of the firm (if any)		The firm has not submitted any document.	
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate issued by DCA valid till 17/01/2024.	
3. Documents for the procurement of API with approval from DRAP (in case of import).		Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.	
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted	
5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Submitted	
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted	
Remarks of Evaluator:			
S. no.	Sections	Observations/Deficiencies/ Short-comings	

1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted”. Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leader approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.
		Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

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

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.

		non- compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacture r calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.

6.	3.2.P. 5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P. 5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R. 1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product. Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.
Decision of 336th meeting of Registration Board: Deferred for submission of following: - Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. - Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.
Response of the Firm: - Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria. - Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product. Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.
Decision of 339th meeting: The Registration Board deferred the application for last chance to submit the reply to the communicated shortcomings, as their submitted responses were still deemed unsatisfactory after evaluation.
Evaluation by PEC-IX; Firm has submitted their response on eapp CMS vide tracking ID T8G-ES8-WPSY Firm was asked to submit dissolution testing performance data as per new revised method (3.2.P.5). Firm has again not submitted the required documents/data. Firm has submitted a summary page of CDP of all 3 strengths, Method of analysis(MOA) and internal factory specifications(IFS). The dissolution testing data that was required from the firm (chromatograms/ UV absorbance values, calculations etc) are not submitted.
Decision: The Board deliberated on the matter that firm has failed to dissolution testing performance data despite being asked multiple times. The Board rejected the case.

Form 5D deferred Cases

86.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 5/500 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin..... 5mg Metformin Hcl...500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38729 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39304 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs

		ATC Code: A10BD15		
	Type of Form	Form 5D.		
	Finished product Specifications	Innovator Specifications		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in Reference Regulator Authorities			
	Me-too status			
	GMP status			
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug	Daplo-M XR 5/500 mg Tablet			
Manufacturer of API	<u>Dapagliflozin:</u> M/s. <u>Metformin HCl:</u> M/s			
API Lot No.	<u>Dapagliflozin:</u> D5290-22-005 <u>Metformin HCl:</u> MEF/11030557			
Description of Pack (Container closure system)	Alu-Alu blister			
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%			
Time Period	Real time: 9 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)			
Batch No.	TDM-019	TDM-020	TDM-021	
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets	
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022	
Date of Initiation	06.01.2022	10.01.2022	11.01.2022	
No. of Batches	03			
Date of Submission	Dy. No.: 39304 dt. 29.12.2022			
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	Documents to Be Provided	Status		
1.	Reference of previous approval of applications with stability study data of the firm	NA		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted		
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.		
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of both drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.		

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

Remarks of Evaluator:

Sr. No.	Observation
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

Decision of 344th meeting: Deferred for submission of reply addressing above mentioned deficiencies.

Remarks of Evaluator:

Firm has submitted response on eapp CMS vide tracking ID 4AH-6HY-LPUQ

Sr. No.	Observation	Response
1.	Copy of GMP certificates of both drug substance manufacturers are required.	Copy of DML of drug substance manufacturer issued by Zhejiang Medical products administration is submitted. Copy of GMP certificate of M/s Aarti Drugs limited issued by FDA Maharashtra India is submitted.

2.	Copy of GMP certificate of drug product manufacturer is required.	Copy of last GMP inspection dated 03.03.2022 is submitted.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.	PE & CDP against Xigduo XR 5mg-500mg Batch No. AX-457-021 Mfg Asrazeneca AB USA is performed. As per submitted data both metformin and Dapagliflozin are being released slowly over a time period of 12 hours. Its indicated in both test and reference product. But the innovator product should have an immediate release coat (or bilayer) of dapagliflozin
4.	Copies of BMR of trial batches are required	BMR submitted. As per BMR firm has not made bilayer tablet. Both Dapagliflozin and metformin HCl are included in single core.
5.	Method of analysis of drug substance (both) is required	Submitted.
6.	Copies of AD attested invoices are required.	Form 6 are submitted.
7.	Differential fee is required.	Fee of Rs. 17000/- is submitted vide slip No. 7637287248
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required	HPLC Log not submitted.
9.	Label claim needs revision as per innovator product.	Revised.
10.	Drug excipient compatibility studies are required.	Not submitted.
11.	Detailed testing method of finished drug product is required.	Submitted
12.	Evidence of RRA reference and me-too product is also required.	Submitted.

Decision: The Board rejected the case due to variation in release profile of applied product and the Innovator.

87.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo-M XR 10/500 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin...10mg Metformin HCl...500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38730 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39305 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Daplo-M XR 10/500 mg Tablet		
Manufacturer of API	<u>Dapagliflozin:</u> M/s. <u>Metformin HCl:</u> M/s		
API Lot No.	<u>Dapagliflozin:</u> D5290-22-005 <u>Metformin HCl:</u> MEF/11030557		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-022	TDM-023	TDM-024
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39306 dt. 29.12.2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm	NA	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of both drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>Dapagliflozin:</u> <u>Metformin HCl:</u>	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	<u>Dapagliflozin:</u> <u>Metformin HCl:</u>	
7.	Protocols followed for conduction of stability study	Submitted	
8.	Method used for analysis of FPP		
9.	Drug-excipients compatibility studies (where applicable)		

10.	Complete batch manufacturing record of three stability batches.	
11.	Record of comparative dissolution data (where applicable)	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

Decision of 344th meeting: Deferred for submission of reply addressing above mentioned deficiencies.

Remarks of Evaluator:

Firm has submitted response on eapp CMS vide tracking ID TUE-UGT-7H51

Sr. No.	Observation	Response
13.	Copy of GMP certificates of both drug substance manufacturers are required.	Copy of DML of drug substance manufacturer issued by Zhejiang Medical products administration is submitted. Copy of GMP certificate of M/s Aarti Drugs limited issued by FDA Maharashtra India is submitted.
14.	Copy of GMP certificate of drug product manufacturer is required.	Copy of last GMP inspection dated 03.03.2022 is submitted.
15.	Pharmaceutical equivalence and CDP studies data is required along with protocols.	PE & CDP against Xigduo XR 10mg-500mg Batch No. MR-927-021 Mfg Asrazeneca AB USA is performed. As per submitted data both metformin and Dapagliflozin are being released slowly over a time period of 12 hours. Its indicated in both test and reference product. But the innovator product should have an immediate release coat (or bilayer) of dapagliflozin
16.	Copies of BMR of trial batches are required	BMR submitted.

		As per BMR firm has not made bilayer tablet. Both Dapagliflozin and metformin HCl are included in single core.
17.	Method of analysis of drug substance (both) is required	Submitted.
18.	Copies of AD attested invoices are required.	Form 6 are submitted.
19.	Differential fee is required.	Fee of Rs. 17000/- is submitted vide slip No. 7637287248
20.	Compliance record of HPLC software with CFR 21 and audit trial report is required	HPLC Log not submitted.
21.	Label claim needs revision as per innovator product.	Revised.
22.	Drug excipient compatibility studies are required.	Not submitted.
23.	Detailed testing method of finished drug product is required.	Submitted
24.	Evidence of RRA reference and me-too product is also required.	Submitted.

Decision: The Board rejected the case due to variation in release profile of applied product and the Innovator.

88.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Daplo-M XR 10/1000 mg Tablet
	Composition	Each Tablet Contains: Dapagliflozin...10mg Metformin Hcl...1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38732 dated 26-11-2018 Rs.20,000/- dated 26-11-2018 Stability: 39307 dt. 29.12.2022
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form 5D.
	Finished product Specifications	Innovator Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	
	Me-too status	
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Daplo-M XR 10/1000 mg Tablet
Manufacturer of API	<u>Dapagliflozin:</u> M/s. <u>Metformin HCl:</u> M/s
API Lot No.	<u>Dapagliflozin:</u> D5290-22-005 <u>Metformin HCl:</u> MEF/11030557
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 9 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TDM-028	TDM-029	TDM-030
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	06.01.2022	10.01.2022	11.01.2022
Date of Initiation	06.01.2022	10.01.2022	11.01.2022
No. of Batches	03		
Date of Submission	Dy. No.: 39305 dt. 29.12.2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm	NA	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of both drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>Dapagliflozin:</u> <u>Metformin HCl:</u>	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	<u>Dapagliflozin:</u> <u>Metformin HCl:</u>	
7.	Protocols followed for conduction of stability study	Submitted	
8.	Method used for analysis of FPP		
9.	Drug-excipients compatibility studies (where applicable)		
10.	Complete batch manufacturing record of three stability batches.		
11.	Record of comparative dissolution data (where applicable)		
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		

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

Remarks of Evaluator:

Sr. No.	Observation
1.	Copy of GMP certificates of both drug substance manufacturers are required.
2.	Copy of GMP certificate of drug product manufacturer is required.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.
4.	Copies of BMR of trial batches are required
5.	Method of analysis of drug substance (both) is required
6.	Copies of AD attested invoices are required.
7.	Differential fee is required.
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required
9.	Label claim needs revision as per innovator product.
10.	Drug excipient compatibility studies are required.
11.	Detailed testing method of finished drug product is required.
12.	Evidence of RRA reference and me-too product is also required.

Decision of 344th meeting: Deferred for submission of reply addressing above mentioned deficiencies.
Remarks of Evaluator:

Firm has submitted response on eapp CMS vide tracking ID RL6-H1A-HARS

Sr. No.	Observation	Response
1.	Copy of GMP certificates of both drug substance manufacturers are required.	Copy of DML of drug substance manufacturer issued by Zhejiang Medical products administration is submitted. Copy of GMP certificate of M/s Aarti Drugs limited issued by FDA Maharashtra India is submitted.
2.	Copy of GMP certificate of drug product manufacturer is required.	Copy of last GMP inspection dated 03.03.2022 is submitted.
3.	Pharmaceutical equivalence and CDP studies data is required along with protocols.	PE & CDP against Xigduo XR 10mg-1000mg Batch No. EX-829-021 Mfg Asrazeneca AB USA is performed. As per submitted data both metformin and Dapagliflozin are being released slowly over a time period of 12 hours. Its indicated in both test and reference product. But the innovator product should have an immediate release coat (or bilayer) of dapagliflozin
4.	Copies of BMR of trial batches are required	BMR submitted. As per BMR firm has not made bilayer tablet. Both Dapagliflozin and metformin HCl are included in single core.
5.	Method of analysis of drug substance (both) is required	Submitted.
6.	Copies of AD attested invoices are required.	Form 6 are submitted.
7.	Differential fee is required.	Fee of Rs. 17000/- is submitted vide slip No. 7637287248
8.	Compliance record of HPLC software with CFR 21 and audit trial report is required	HPLC Log not submitted.
9.	Label claim needs revision as per innovator product.	Revised.
10.	Drug excipient compatibility studies are required.	Not submitted.

11.	Detailed testing method of finished drug product is required.	Submitted
12.	Evidence of RRA reference and me-too product is also required.	Submitted.

Decision: The Board rejected the case due to variation in release profile of applied product and the Innovator.

89.	Name and address of manufacturer / Applicant		M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar	
	Brand Name +Dosage Form + Strength		Daplo 5mg Tablets	
	Composition		Each Film Coated Tablet Contains; Dapagliflozin As Propanediol Monohydrate...5mg	
	Diary No. Date of R& I & fee		Form-5 Dy.No 38599 dated 23-11-2018 Rs.20,000/- dated 23-11-2018	
	Pharmacological Group		Blood glucose Lowering drugs ATC Code: A10BK01	
	Type of Form		Form 5-D.	
	Finished product Specifications		Manufacturer's Specification	
	Pack size & Demanded Price		Pack size and MRP as per SRO.	
	Approval status of product in Reference Regulator Authorities		Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals.	
	Me-too status		Dapa 5mg tablet, by Hilton Pharmaceuticals Pvt Ltd.	
	GMP status		Not Submitted	
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		Daplo 5mg Tablets		
Manufacturer of API		Not submitted		
API Lot No.		Not submitted		
Description of Pack (Container closure system)		Not submitted		
Stability Storage Condition		Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period		Real time: 6 months		
		Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.		TD-013	TD-014	TD-015
Batch Size		1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date		06-01-2022	06-01-2022	06-01-2022

Date of Initiation				
No. of Batches		03		
Date of Submission		Dy. No. 39302 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	Documents to Be Provided	Status		
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.		
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.		
4.	Stability study data of API from API manufacturer	Not submitted.		
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.		
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.		
7.	Protocols followed for conduction of stability study	Submitted.		
8.	Method used for analysis of FPP	Not submitted.		
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.		
10.	Complete batch manufacturing record of three stability batches.	Not submitted.		
11.	Record of comparative dissolution data (where applicable)	Not submitted.		
12.	Data of 03 batches will be supported by attested respective documents like	Firm has submitted stability data sheets for three batches. Respective documents like chromatograms,		
	chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets, COA, summary data sheets etc. are required by the firm.		
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.		

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

Remarks of Evaluator:

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

Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Firm has submitted response on eapp CMS vide tracking ID No. H4G-48T-Z3JL

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	No response submitted.
2.	Certificate of Analysis of drug substance from respective drug substance manufacturer shall be submitted.	Submitted. B. No. D5290-21-001
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Method of analysis is submitted.
4.	Stability study data of API from API manufacturer shall be submitted.	Submitted but its as per Zone II conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued	Submitted.

	by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted..	Form 6 is submitted.
7.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
8.	Method used for analysis of Finished Product shall be submitted.	Submitted.
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Firm has stated that they are using same formulation as that of brand leader.
10.	Complete batch manufacturing record of three stability batches shall be submitted..	BMRs are submitted.
11.	Record of comparative dissolution data shall be submitted.	Submitted. Performed against Farxiga Tablet 5mg B. No. AFG-519-021 Mfg M/s Astrazeneca AB USA. Its performed only in 0.1N HCl medium.
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	HPLC log is not submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms are submitted. But height of every peak in every chromatogram is same (Peak 1 14426, Peak 2 832984), other parameters like area, titles, date and time are changed. This indicates issue of data integrity.
14.	Submit valid GMP certificate of M/s Navegal Laboratories.	GMP inspection report dated 03.03.2022 is submitted.

Proceeding of 353rd meeting:

The chromatograms submitted by the firm in different applications of different molecules were observed to be visually identical and had similar values of peak area and peak height. Following chromatograms were extracted from individual applications and were presented before the board.



Analysis Report

Sample Name : Brexpiprazole std1
 Sample ID : Brexpiprazole sample 1
 Data Filename : Brexpiprazole std.lcd
 Method Filename : Brexpiprazole.lcm
 Batch Filename :
 Vial # : 1-1

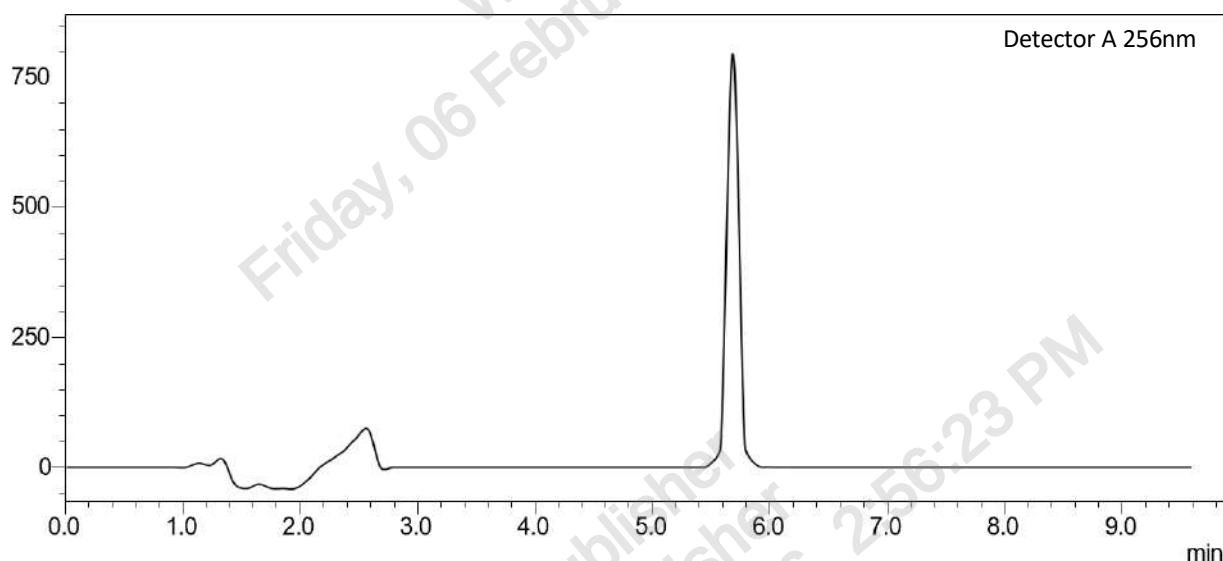
Sample Type : Unknown

Injection Volume : 20 uL
 Date Acquired : 01/05/2022 09:34:48 AM
 Administrator Date Processed : 01/05/2022
 System Administrator

Acquired by : System
 09:44:45 AM Processed by :

<Chromatogram>

mV



<Peak Table>

Detector A 256nm

Peak#	Ret. Time	Area	Height	Conc.	Unit	Mark	Name
1	2.459	370537	14426	0.000		V	
2	5.668	4801158	832984	0.500		SV	Brexpiprazole
Total		5171695	847410				

C:\Users\Track Computers\Desktop\Brexpiprazole std.lcd



Analysis Report

<Sample Information>

Sample : Dapagliflozin std1
 Name : Dapagliflozin sample 1
 Sample ID : Dapagliflozin std.lcd
 Data : Dapagliflozin.lcm
 Filename :
 Method :
 Filename : 1-1 Sample Type : Unknown
 Batch :
 Filename Vial :
 # :

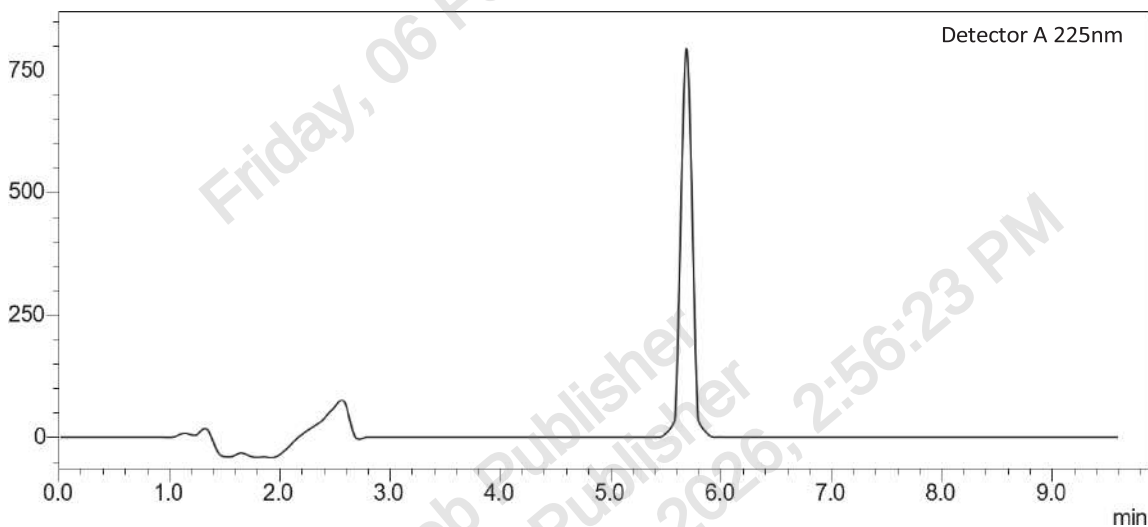
Injection Volume : 20 uL

Date Acquired : 01/05/2022 09:34:48 AM Acquired by : System Administrator

Date Processed : 01/05/2022 09:44:45 AM Processed by : System Administrator

<Chromatogram>

mV



<Peak Table>

Detector A 220nm

Peak #	Ret. Time	Area	Height	Conc.	Unit	Mark	Name
1	2.459	370537	14426	0.000		V	
2	5.668	4801158	832984	0.500		SV	Dapagliflozin
Total		5171695	847410				

C:\Users\Track Computers\Desktop\Dapagliflozin std.lcd

<Sample Information>

Sample : Empagliflozin std4
Name : Empagliflozin sample 1
Sample ID : Empagliflozin std.lcd
Data : Empagliflozin.lcm
Filename :
Method :
Filename : 1-1
Batch
Filename Vial
#

Sample Type : Unknown

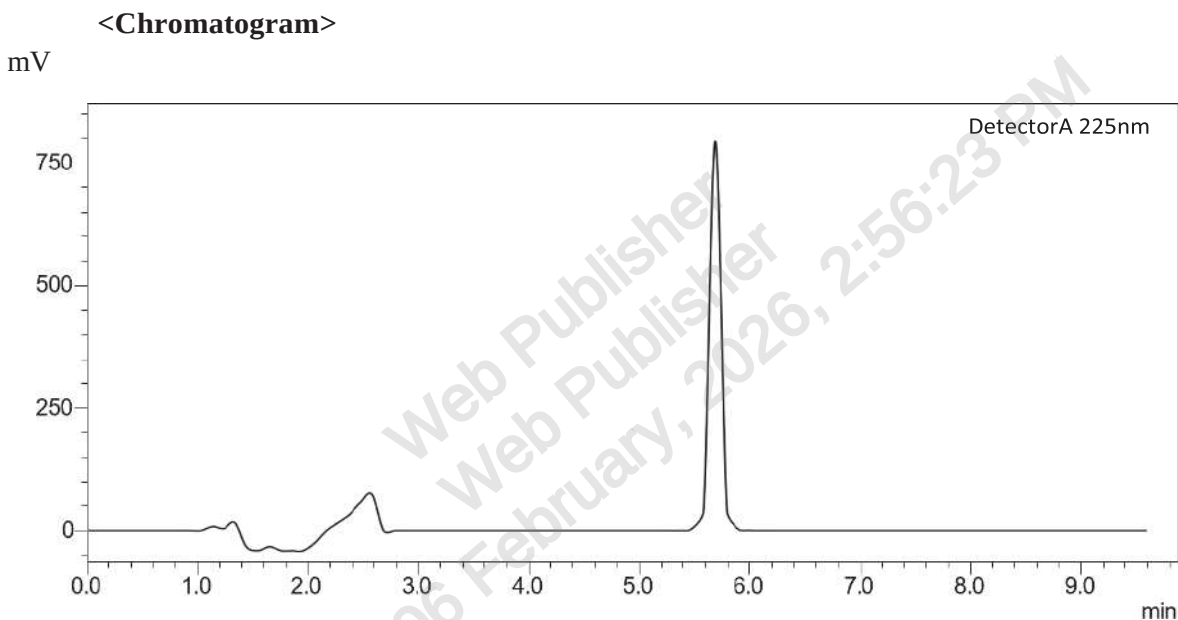
Injection Volume: 20 μ L

Date Acquired : 12/29/2021 11:26:41 AM

Acquired by : System Administrator

Date Processed : 12/29/2021 11:36:46 AM

Processed by : System Administrator



<Peak Table>

Detector A 225nm

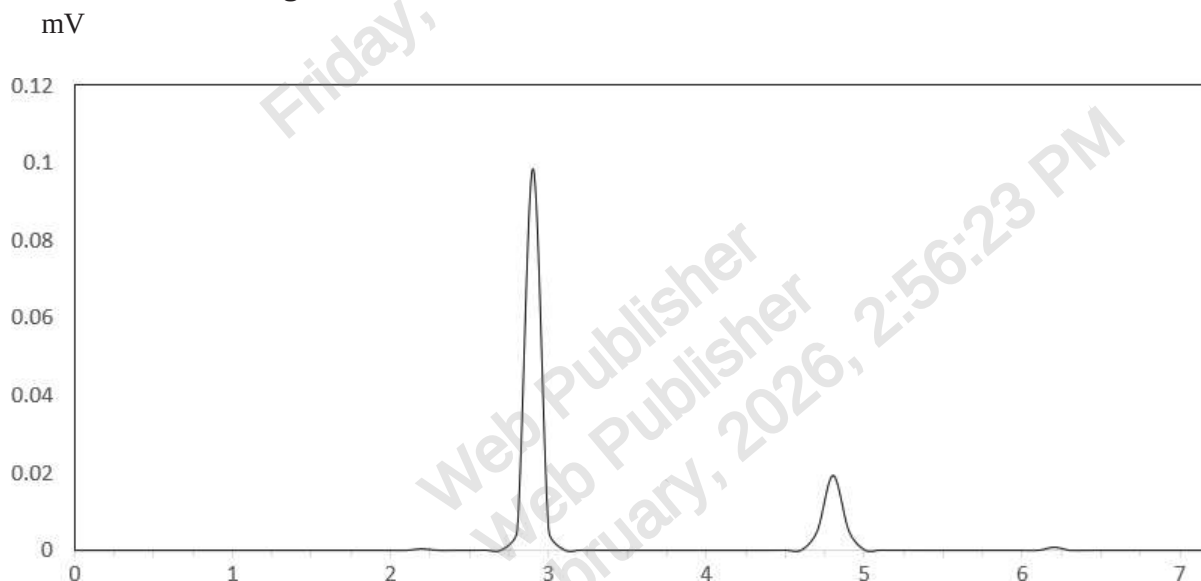
Peak #	Ret. Time	Area	Height	Conc.	Unit	Mark	Name
1	2.459	370527	14426	0.000		V	
2	5.668	4801158	832984	0.500		SV	Empagliflozin
Total		5171685	847410				

C:\Users\Track Computers\Desktop\Empagliflozin std.lcd

<Sample Information>

Sample Name Sample ID Data Filename
Method Filename
Batch Filename Vial #
: Emplina smp2
: Lina.Empa sample 2
: Emplina smp1.lcd
: Emplina.lcm
:
: 1-1 Sample Type : Unknown
Injection Volume : 20 uL
Date Acquired : 01/06/2022 09:35:26 AM Acquired by : System Administrator
Date Processed : 01/06/2022 09:45:29 AM Processed by : System Administrator

<Chromatogram>



<Peak Table>

Peak #	Ret. Time	Area	Height	Conc.	Unit	Mark	Name
1	2.784	1058957	14426	1.500		SV	Empagliflozin
2	5.668	4813643	832984	0.015		SV	Linagliptin
Total		5872600	878736				

Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

90.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Daplo 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate...10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38598 dated 23-11-2018 Rs.20,000/- dated 23-11-2018
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals.
	Me-too status	Dapa 10mg tablet, by Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Daplo 10mg Tablets		
Manufacturer of API	Not submitted		
API Lot No.	Not submitted		
Description of Pack (Container closure system)	Not submitted		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TD-016	TD-017	TD-018
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 39303 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	

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

Remarks of Evaluator:

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

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8.	Method used for analysis of Finished Product shall be submitted.
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.
10.	Complete batch manufacturing record of three stability batches shall be submitted..
11.	Record of comparative dissolution data shall be submitted.
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
14.	Submit valid GMP certificate of M/s Navegal Laboratories.

Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:
Firm has submitted response on eapp CMS vide tracking ID No. H4G-48T-Z3JL

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	No response submitted.
2.	Certificate of Analysis of drug substance from respective drug substance manufacturer shall be submitted.	Submitted. B. No. D5290-21-001
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Method of analysis is submitted.
4.	Stability study data of API from API manufacturer shall be submitted.	Submitted but its as per Zone II conditions.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted..	Form 6 is submitted.
7.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
8.	Method used for analysis of Finished Product shall be submitted.	Submitted.
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Firm has stated that they are using same formulation as that of brand leader.

10.	Complete batch manufacturing record of three stability batches shall be submitted..	BMRs are submitted.
11.	Record of comparative dissolution data shall be submitted.	Submitted. Performed against Farxiga Tablet 10mg B. No. AXR-479-021 Mfg M/s Astrazeneca AB USA. Its performed only in 0.1N HCl medium.
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	HPLC log is not submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms are submitted. But height of every peak in every chromatogram is same (Peak 1 14426, Peak 2 832984), other parameters like area, titles, date and time are changed. The chromatograms submitted for both strengths 5mg and 10mg are same. This indicates issue of data integrity.
14.	Submit valid GMP certificate of M/s Navegal Laboratories.	GMP inspection report dated 03.03.2022 is submitted.

Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

Agenda of Evaluator PEC-XI (Dr. Farhad Ullah)

Case No. 01; Deferred registration applications of Human Drugs

91.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals. Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat

Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals. Plot No. 23 & 24, Phase S-I, Industrial Estate, Rawat
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 486,: 05-01-2023
Details of fee submitted	PKR 30,000/- : 13-12-2022
The proposed proprietary name / brand name	DIAZEN 5mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Desloratadine...5mg
Pharmacotherapeutic Group of (API)	Antihistamine
Reference to Finished product specifications	USP
Proposed Pack size	As per SRO

Evaluation by PEC³:

Sr. No	Shortcomings communicated
1.	Revise your label claim as per innovator's product along with submission of requisite fee
2.	Submit API specifications and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.
3.	Submit verification studies of the analytical method of API from drug product manufacturer
4.	Submit details against which CDP and PE studies are conducted
5.	Submit GMP certificate of the API manufacturer.
6.	Submit evidence of purchase of API.

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response;

Sr. No	Deferment Reason	Firm's Response
1.	Revise your label claim as per innovator's product along with submission of requisite fee	Each Film Coated Tablet Contains: Desloratadine.....5mg Firm has submitted fee Rs. 9400/- on deposit slip#3588068069 for revision of label claim
2.	Submit API specifications and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
3.	Submit verification studies of the analytical method of API from drug product manufacturer	Verification studies of the analytical method of API is submitted
4.	Submit details against which CDP and PE studies are conducted	Firm has submitted pictorial evidence of product Kadisdin 5mg by M/s Kanel Pharma against which CDP and pharmaceutical equivalence studies is performed

5.	Submit GMP certificate of the API manufacturer.	Firm has submitted cGMP certificate of API manufacturer issued by Food and Drug Administration Maharashtra State India valid upto 05-09-2026.
6.	Submit evidence of purchase of API.	Firm has submitted copy of loan intimation, form 6 attested by AD (I&E) DRAP and invoice.

**Decision; Approved with following label claim;
Each Film Coated Tablet Contains:
Desloratadine.....5mg**

92.	Name and address of manufacturer/ Applicant	M/s. Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat (contract giver) (DML No.000882) Contract with M/s. Welwink Pharmaceuticals GT Road Industrial Estate Gujranwala (Contract Acceptor) (DML No.000751) Liquid Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	Ketozen 30mg/1mL Injection
	Composition	Each 1ml Ampoule Contains; Ketorolac Tromethamine (USP).....30mg
	Diary No. Date of R & I & fee	Dy. No. 16312 dated 07.03.2019 Fee paid Rs. 50,000/- vide slip No. 1901600 dated 06.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	Acetic acid derivatives and related substances (NSAIDs)
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved.
	Me-too status	Ketometa 30mg Injection Reg. No. 108436 M/s Lahore Chemical & Pharmaceutical Works Lahore.
	GMP status	GMP certificate dated 25.08.2022 valid till 26.07.2025 is submitted, vide letter dated 20.01.2023
	Remarks of the Evaluator	i. Innovator specifications are applied when monograph in pharmacopoeia is available. Revision of spec along with fee of Rs. 7500/- is required. The firm has revised specs of the product vide letter No. Nil dated 20.01.2023 and have paid fee of Rs. 7500/- vide slip No. 072566430939 dated 20.01.2023
	Previous Decision (M-324 th -RB)	Deferred for details for sterilization method for applied formulation.
	Firms Response	Firm has submitted that terminal sterilization performed for applied product
	Decision: Deferred for submission of evidence of reply of the deferred cases as per decision of Registration Board in DRAP R&I within notified time.	

93.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S- 5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lurbi tablet 100mg
	Composition	Each film- coated tablet contains: Flurbiprofen... 100mg
	Diary No. Date of R& I & fee	Dy.No.27233; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Analgesic/ NSAID
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's, 2x 10's, 6x 5's & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as sugar- coated
	Me-too status	Biofen 100mg tablet of M/s Mission Pharma Kar (Reg. # 081600)
	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • Film- coated tablet is applied while it is available in RRA as sugar- coated.
	Previous Decision (M-292 nd -RB)	• Deferred for revision of formulation as per reference product along with submission of requisite fee.
	Firm's Response	• The firm has stated that film coated tablet previously approved in registration board meeting-326th M/s Espoir Pharmaceuticals Karachi. • The firm has also provided evidence of applied formulation in Health Canada as film coated tablet. Details are; Flurbiprofen 50mg, 100mg film coated tablets by AA PHARMA INC 1165 Creditstone Road, Unit #1 Vaughan, Ontario L4K 4N7 Health Canada Approved. • Firm has submitted evidence of reply submission in DRAP R&I dated 26-07-2022
Decision: Approved.		

94.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Molyfax Ointment
	Composition	Each gram cream contains: Polymyxin B sulfate.....1000units Bacitracin Zinc.....500units
	Dairy No. date of R &I fee	Form-5 Dy.No 9428 dated 01-03-2019 Rs.20,000/- 01-3-2019
	Pharmacological Group	Antibacterial
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10gm, 20gm; As per SRO

Approval status of product in Reference Regulatory Authorities	
Me-too-status	JD-Fax Ointment by M/s Bloom Pharmaceuticals (Reg#82300) (10000IU/500IU... international units)
GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
Previous Remark of Evaluator ^{XI}	- The firm did not provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting - The firm have revised the label claim from each gram cream contains to each gram of ointment contains and submitted revised form 5 and master formulation. Furthermore, the firm have revised the strength of polymyxin B sulfate. The revised label claim is as under Each gram of ointment contains: Polymyxin B sulfate.....10,000IU Bacitracin Zinc.....500IU The firm did not submit fee for revision of label claim and strength of polymyxin B sulfate in label claim - The firm submitted panel inspection report for grant of DML conducted on 30.01.2015 confirming the presence of semi-solid general section
Previous Decision (297-DRB)	Deferred for following: - Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting - Submission of requisite fee for revision of label claim and strength of polymyxin B sulfate in label claim
Evaluation by PEC	- The firm submitted Rs. 30000/- on deposit slip#74705374820 for revision of label claim and strength of polymyxin B sulfate in label claim. - The firm provided evidence of approval of product in USFDA. However, the product is discontinued
Previous Decision (307-DRB)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

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	Firm's Response	• Firm has provided evidence of RRA of the product Polyfax Ointment, 10,000 IU Polymyxin B Sulphate + 500 IU Bacitracin Zinc, HPRA Approved. However, the status of product is withdrawn (Not Currently Available). • Firm has submitted evidence of me-too product. Polyfax Skin Ointment (Reg#000371) by M/s GlaxoSmithKline Pakistan Limited • Firm has submitted evidence of reply submission in DRAP R&I dated 31-01-2024
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

Sr. No.	Name and address of Manufacturer / Applicant	Brand Name (Proprietary name + Dosage form + Strength) Composition Pharmacological Group Finished product specification	Type of Form Initial date, diary. Fee including differential fee Demanded Price / Pack size	International status in stringent regulatory agencies Me-too status GMP status as depicted in inspection report (dated)	Previous Decision (M-249 th -RB)
95.	M/S LINTA Pharmaceuticals (Pvt) Limited plot No 03, Street No S-5, National Industrial Zone Rawat, Islamabad. DMLNo 000810 dated 02-04-2015 Capsule Cephalosporin No.F. 1-4/2011-Lic (DML No-000810) Dated 03-04-2015	Zix Capsules 200 mg Each hard gelatin capsule contains:- Cefixime trihydrate eq. to Cefixime 200mg. (Cephalosporin) (Manufacturer's Spec.s)	Form 5 17-04-2015 (992) Rs.20,000/- As per SRO/5's	Not provided/Not confirmed Cefim 200 mg capsules (Hilton Pharma Private Limited) Grant For registration of drugs of new license dated 02-04-2015	Deferred for confirmation of formulation in reference drug agencies.
	Firm's Response	Firm has provided evidence of applied product in RRA. Details are;			

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	Cefixime Normon 200mg hard capsule by Normon Laboratories, SA Ronda de Valdecarrizo, 6 28760 Tres Cantos — Madrid Spain, CIMA Spain Approved
	Decision; Deferred for submission of evidence of reply of the deferred cases as per decision of Registration Board in DRAP R&I within notified time.

96.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 12213 dated 18-05-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#128181087419)
	The proposed proprietary name / brand name	Sulrid 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride.....100mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 100mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Nexpride 100mg Tablet by M/s Medcraft Pharmaceutical (Reg.No# 95949)
	Proposed Pack size and unit price	As per SRO

Evaluation by PEC^{XI}:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	
Previous Decision (M-339th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings		
Firm's Response;		
Section	Deferment Reason	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of application submitted for renewal of DML.
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm submitted that our inspection has been held, we are waiting for the report. Firm has requested to please consider the case in DRB meeting, letter may be subjected to submission of GMP Report as this will be received in few days.
1.6.5	• 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 cGMP certificate of API manufacturer issued by Food and Drugs Control Administration Gandhinagar, Gujarat State, India, valid upto 20-04-2027
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Was mistakenly not added in COA. Revised API COA is submitted.

3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	• Performed against Lesulp Tab 100mg of Glitz Pharma. Batch No. 478, Manufacturing date; 06-2021, expiry date; 06-2023. • Submitted
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	• Mistakenly not added. Revised Finished product specifications are Attached • The sample spectrum should be matched with the working standard as obtain in the assay • Mistakenly not added. Revised Finished product specifications are Attached • Standard Analytical Procedure Attached • Analytical method for assay test is performed by HPLC. Revised Analytical Procedure Attached • Submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of loan intimation, invoice cleared, clearance certificate by AD (I&E) DRAP is submitted.
Decision; Approved. Registration Board further decided that the registration letter shall be issued after submission of the requisite Pre-Registration Variation fee.		

97.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3126 dated 02-02-2023

Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#90918757972)
The proposed proprietary name / brand name	Sulrid 25mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride.....25mg
Pharmacotherapeutic Group of (API)	Antipsychotic
Reference to Finished product specifications	Innovator's Specifications
The status in reference regulatory authorities	Levopraid 25mg Tablet AIF Italy Approved
For generic drugs (me-too status)	Levopaid 25mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99723)
Proposed Pack size	As per SRO
Proposed unit price	As per SRO

Evaluation by PEC^{XI}:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of application submitted for renewal of DML.
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of grant of additional section letter dated 30-12-2020 specifying tablet (general) section • Firm submitted that our inspection has been held, we are waiting for the report. Firm has requested to please consider the case in DRB meeting, letter may be subjected to submission of GMP Report as this will be received in few days.
1.6.5	• 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 cGMP certificate of API manufacturer issued by Food and Drugs Control Administration Gandhinagar, Gujarat State, India, valid upto 20-04-2027
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Was mistakenly not added in COA. Revised API COA is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted

3.2.P.2	- Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted - Complete comparative dissolution studies shall be submitted	- Performed against L-Pride tablet 25mg of M/s Wnsfeild Pharma. Batch No. 556, expiry date; 11-2023. - Submitted
3.2.P.5	- Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications - Description of test for identification test in finished product specifications shall be submitted - Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications - Analytical procedure for all the tests given in finished product specifications shall be submitted - Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. - Analytical method validation protocols shall be submitted	- Mistakenly not added. Revised Finished product specifications are Attached - The sample spectrum should be matched with the working standard as obtain in the assay - Mistakenly not added. Revised Finished product specifications are Attached - Standard Analytical Procedure for all test is submitted - Analytical method for assay test is performed by HPLC. Revised Analytical Procedure Attached - Submitted - Firm has also submitted fee Rs. 9400/- for revision of specifications vide deposit slip# 1445779765
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
3.2.P.8	- Submit documents for the procurement of API with approval from DRAP (in case of import). - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	- Firm has submitted copy of loan intimation, invoice cleared, clearance certificate by AD (I&E) DRAP is submitted. - Submitted

Decision: Approved.

98.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3127 dated 02-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023

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		(Deposit slip#9927068333)
	The proposed proprietary name / brand name	Sulrid 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride.....50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC^{XI}:		
Section	Observations	
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of application submitted for renewal of DML.
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of grant of additional section letter dated 30-12-2020 specifying tablet (general) section • Firm submitted that our inspection has been held, we are waiting for the report. Firm has requested to please consider the case in DRB meeting, letter may be subjected to submission of GMP Report as this will be received in few days.
1.6.5	• 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 cGMP certificate of API manufacturer issued by Food and Drugs Control Administration Gandhinagar, Gujarat State, India, valid upto 20-04-2027
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Was mistakenly not added in COA. Revised API COA is submitted.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical	• Performed against L-Pride tablet 50mg of M/s Wnsfeild Pharma. Batch No. 557,

	equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted	manufacturing date; 11-2021, expiry date; 11-2023. • Submitted
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted	• Mistakenly not added. Revised Finished product specifications are Attached • The sample spectrum should be matched with the working standard as obtain in the assay • Mistakenly not added. Revised Finished product specifications are Attached • Standard Analytical Procedure for all test is submitted • Analytical method for assay test is performed by HPLC. Revised Analytical Procedure Attached • Submitted • Firm has also submitted fee Rs. 9400/- for revision of specifications vide deposit slip# 956688617
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of loan intimation, invoice cleared, clearance certificate by AD (I&E) DRAP is submitted. • Submitted

Decision: Approved.

99.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Form-5F Dy.No 21169 dated 27-07-2022
Details of fee submitted	Rs.30,000/- dated 22-07-2022 (Deposit slip#3869072841)
The proposed proprietary name / brand name	CipZen 250mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ciprofloxacin as HCl.....250mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Fluoroquinolones
Reference to Finished product specifications	USP Specifications
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	CIPRO 250mg film coated tablets USFDA Approved
For generic drugs (me-too status)	Jucip 250 Tablet of M/s Jupiter Pharma (Reg.No. 081914)
Name and address of API manufacturer.	CITI Pharma (Pvt.) Ltd., 3.5km, Head Baloki Road, Phool Nagar, Kasur-Pakistan
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at

		30°C ± 2°C / 65% ± 5% RH for 24 months.		
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis justification of specifications, reference standard or materials, container closure system and stability study.		
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Cipesta 250mg tablets by performing quality tests (Description, weight/tab, identification, CDP) Firm has submitted CDP results of their product against the product Cipesta 250mg tablets in acid media 0.1N HCl (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.		
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, Repeatability, linearity,/range, LOD, LOQ, robustness.		
STABILITY STUDY DATA				
Manufacturer of API		CITI Pharma (Pvt.) Ltd., 3.5km, Head Baloki Road, Phool Nagar, Kasur-Pakistan		
API Lot No.		CPH2110109		
Description of Pack (Container closure system)		Alu-alu blister packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 06 months Accelerated: 06 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T01	T02	T03
Batch Size		1200 tablets	1200 tablets	1200 tablets
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		17-12-2021	17-12-2021	17-12-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		

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2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan dated 06-01-2021 based on inspection conducted on 17-12-2020 valid upto two years from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note date 11/11/2021 from M/s Citi Pharma Ltd., for purchase of 20kg Ciprofloxacin HCl in the name of M/s Wezen Pharmaceuticals
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator ^{XI}:

Section	Observations
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years • Provide evidence of approval of manufacturing facility / Approved Section from Licensing division
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product • Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Justification shall be submitted for not including the time in dissolution test in finished product specifications • Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets • Submit complete analytical verification protocol and analytical method verification studies of the applied product

3.2.P.6	• COA of reference standard or material used in stability study shall be submitted	
3.2.P.8	• Submit documents for the procurement of API • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	
Previous Decision (M-331 st -RB): Registration Board deferred the case for submission of reply to the above cited shortcomings		
Firm's Response;		
Section	Deferment Reason	Firm's Response
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years • Provide evidence of approval of manufacturing facility / Approved Section from Licensing division	• Not submitted. • Firm has submitted copy of grant of additional section letter dated 30-12-2020 specifying tablet (general) section
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of M/s Citi Pharma (Pvt.) Ltd., Pakistan issued based on inspection dated 03-03-2023
3.2.S.4	• Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted • Copies of the Drug substance analytical procedures of the Drug substance by Drug substance manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product • Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)	• Revised pharmaceutical equivalence studies and CDP against the Cipro 250mg tablet is submitted • Performed against Cipro 250mg tablet (innovator) • Revised pharmaceutical equivalence studies as per USP monograph is submitted

3.2.P.5	- Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications - Justification shall be submitted for not including the time in dissolution test in finished product specifications - Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets - Submit complete analytical verification protocol and analytical method verification studies of the applied product	- As the applied strength is greater than 25mg Test for uniformity of dosage units is applied on weight variation in finished product specifications is performed. Revised finished product specifications is Attached - Revised finished product specifications Attached - Revised analytical method of dissolution test and assay test of ciprofloxacin tablets is attached - Analytical method protocol and summary report is submitted - Firm has also submitted fee Rs. 9400/- for revision of specifications vide deposit slip# 3717722909
3.2.P.6	COA of reference standard or material used in stability study shall be submitted	Submitted
3.2.P.8	- Submit documents for the procurement of API - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	- Firm has submitted copy of delivery note from M/s Citi Pharma Ltd specifying 20kg Ciprofloxacin in the name of M/s Wezen Pharma - Submitted
	Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	No justification is submitted. Firm has again submitted same CDP studies

Decision; Deferred for submission of;

- Justification for using six units for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles**

100.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 21170 dated 27-07-2022

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Details of fee submitted	Rs.30,000/- dated 22-07-2022 (Deposit slip#2027464350)
The proposed proprietary name / brand name	CipZen 500mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ciprofloxacin as HCl.....500mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Fluoroquinolones
Reference to Finished product specifications	USP Specifications
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	CIPRO 500mg film coated tablets USFDA Approved
For generic drugs (me-too status)	Jucip 500 Tablet of M/s Jupiter Pharma (Reg.No. 081915)
Name and address of API manufacturer.	CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Cipesta 500mg tablets by performing quality tests (Description, weight/tab, identification, CDP) Firm has submitted CDP results of their product against the product Cipesta 500mg tablets in acid media 0.1N HCl (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.	
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, Repeatability, linearity,/range, LOD, LOQ, robustness.	
STABILITY STUDY DATA			
Manufacturer of API		CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan	
API Lot No.		CPH2110109	
Description of Pack (Container closure system)		Alu-alu blister packed in unit carton	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 06 months Accelerated: 06 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		T04	T05 T06
Batch Size		1200 tablets	1200 tablets
Manufacturing Date		12-2021	12-2021
Date of Initiation		17-12-2021	17-12-2021
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan dated 06-01-2021 based on inspection conducted on 17-	

		12-2020 valid upto two years from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note date 11/11/2021 from M/s Citi Pharma Ltd., for purchase of 20kg Ciprofloxacin HCl in the name of M/s Wezen Pharmaceuticals
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator ^{XI}:

Section	Observations
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted within last three years • Provide evidence of approval of manufacturing facility / Approved Section from Licensing division
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product • Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Justification shall be submitted for not including the time in dissolution test in finished product specifications • Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets • Submit complete analytical verification protocol and analytical method verification studies of the applied product
3.2.P.6	• COA of reference standard or material used in stability study shall be submitted
3.2.P.8	• Submit documents for the procurement of API

	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	
Previous Decision (M-331 st -RB): Registration Board deferred the case for submission of reply to the above cited shortcomings		
Firm's Response:		
Section	Deferment Reason	Firm's Response
1.3.5	- Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years - Provide evidence of approval of manufacturing facility / Approved Section from Licensing division	- Not submitted. - Firm has submitted copy of grant of additional section letter dated 30-12-2020 specifying tablet (general) section
1.6.5	Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of M/s Citi Pharma (Pvt.) Ltd., Pakistan issued based on inspection dated 03-03-2023
3.2.S.4	- Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. - Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. - Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted - Copies of the Drug substance analytical procedures of the Drug substance by Drug substance manufacturer is submitted. - Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	- Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product - Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted - Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)	- Revised pharmaceutical equivalence studies and CDP against the Cipro 500mg tablet is submitted - Performed against Cipro 500mg tablet (innovator) - Revised pharmaceutical equivalence studies as per USP monograph is submitted

3.2.P.5	- Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications - Justification shall be submitted for not including the time in dissolution test in finished product specifications - Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets - Submit complete analytical verification protocol and analytical method verification studies of the applied product	- As the applied strength is greater than 25mg Test for uniformity of dosage units is applied on weight variation in finished product specifications is performed. Revised finished product specifications is Attached - Revised finished product specifications Attached - Revised analytical method of dissolution test and assay test of ciprofloxacin tablets is attached - Analytical method protocol and summary report is submitted - Firm has also submitted fee Rs. 9400/- for revision of specifications vide deposit slip# 7113003316
3.2.P.6	COA of reference standard or material used in stability study shall be submitted	Submitted
3.2.P.8	- Submit documents for the procurement of API - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	- Firm has submitted copy of delivery note from M/s Citi Pharma Ltd specifying 20kg Ciprofloxacin in the name of M/s Wezen Pharma - Submitted
	Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	No justification is submitted. Firm has again submitted same CDP studies

Decision; Deferred for submission of;

- Justification for using six units for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles**

101.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, S-I, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Form-5F Dy.No 21171 dated 27-07-2022
Details of fee submitted	Rs.30,000/- dated 22-07-2022 (Deposit slip#2402760228)
The proposed proprietary name / brand name	CipZen 750mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ciprofloxacin as HCl.....750mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Fluoroquinolones
Reference to Finished product specifications	USP Specifications
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	CIPRO 750mg film coated tablets USFDA Approved <i>Discontinued** Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**</i>
For generic drugs (me-too status)	Cipropar Tablets 750mg of M/s Neomedix (Reg.No. 81412)
Name and address of API manufacturer.	CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.	
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Ciprox 750mg tablets by performing quality tests (Description, weight/tab, identification, CDP) Firm has submitted CDP results of their product against the product Ciprox 750mg tablets in acid media 0.1N HCl (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range.	
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, Repeatability, linearity,/range, LOD, LOQ, robustness.	
STABILITY STUDY DATA			
Manufacturer of API	CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan		
API Lot No.	CPH2110109		
Description of Pack (Container closure system)	Alu-alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T07	T08	T09
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	17-12-2021	17-12-2021	17-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s CITI Pharma (Pvt.) Ltd., 3.5km, Head Balloki Road, Phool Nagar, Kasur-Pakistan dated 06-01-2021 based on inspection conducted on 17-12-2020 valid upto two years from the date of inspection
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note date 11/11/2021 from M/s Citi Pharma Ltd., for purchase of 20kg Ciprofloxacin HCl in the name of M/s Wezen Pharmaceuticals
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted
Remarks of Evaluator ^{XI}:		
Section	Observations	
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years • Provide evidence of approval of manufacturing facility / Approved Section from Licensing division	
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	
3.2.S.4	• Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product • Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)	

3.2.P.5	- Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications - Justification shall be submitted for not including the time in dissolution test in finished product specifications - Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets - Submit complete analytical verification protocol and analytical method verification studies of the applied product
3.2.P.6	COA of reference standard or material used in stability study shall be submitted
3.2.P.8	- Submit documents for the procurement of API - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-331st-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.5	- Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years - Provide evidence of approval of manufacturing facility / Approved Section from Licensing division	- Not submitted. - Firm has submitted copy of grant of additional section letter dated 30-12-2020 specifying tablet (general) section
1.6.5	Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of M/s Citi Pharma (Pvt.) Ltd., Pakistan issued based on inspection dated 03-03-2023
3.2.S.4	- Signed copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. - Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. - Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted - Copies of the Drug substance analytical procedures of the Drug substance by Drug substance manufacturer is submitted. - Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.

3.2.P.2	- Justification shall be submitted for not performing pharmaceutical equivalence studies and CDP against the innovator product - Details of reference product i.e. manufacturer used in pharmaceutical equivalence studies shall be submitted - Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per USP monograph (dissolution, assay, uniformity of dosage units)	- Revised pharmaceutical equivalence studies and CDP against the Cipro 750mg tablet is submitted - Performed against Cipro 750mg tablet (innovator) - Revised pharmaceutical equivalence studies as per USP monograph is submitted
3.2.P.5	- Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications - Justification shall be submitted for not including the time in dissolution test in finished product specifications - Clarification is required as analytical method of dissolution test and assay test of ciprofloxacin suspension are submitted in application of ciprofloxacin tablets - Submit complete analytical verification protocol and analytical method verification studies of the applied product	- As the applied strength is greater than 25mg Test for uniformity of dosage units is applied on weight variation in finished product specifications is performed. Revised finished product specifications is Attached - Revised finished product specifications Attached - Revised analytical method of dissolution test and assay test of ciprofloxacin tablets is attached - Analytical method protocol and summary report is submitted - Firm has also submitted fee Rs. 9400/- for revision of specifications vide deposit slip# 1752691357
3.2.P.6	COA of reference standard or material used in stability study shall be submitted	Submitted
3.2.P.8	- Submit documents for the procurement of API - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	- Firm has submitted copy of delivery note from M/s Citi Pharma Ltd specifying 20kg Ciprofloxacin in the name of M/s Wezen Pharma - Submitted
	Justification shall be submitted for using six unit for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles	No justification is submitted. Firm has again submitted same CDP studies
Decision; Deferred for submission of; Justification for using six units for dissolution test in CDP studies instead of 12 units as recommended by WHO guideline for conducting comparative dissolution profiles		

Farooq Aslam:

Deferred Cases of Form 5F:

102.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK

Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26512 dated 02-11-2023
Details of fee submitted	Rs 30,000/- dated 04-05-2023 (Deposit slip#763295553574)
The proposed proprietary name / brand name	Tamsosin 6mg/0.4mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Solifenacin Succinate 6mg Tamsulosin HCl..... 0.4mg
Pharmacotherapeutic Group of (API)	Tamsulosin Alpha-adrenoreceptor antagonists Solifenacin succinate Antimuscarinic
Reference to Finished product specifications	Innovator's specifications
The status in reference regulatory authorities	Vecit 6mg/0.4mg Modified-release Tablets MHRA Approved Solifenacin succinate/Tamsulosin hydrochloride Milpharm 6mg/0.4mg modified release tablets MHRA Approved
For generic drugs (me-too status)	Tamsol-S 0.4mg/6mg Tablet by M/s Global Pharmaceuticals (Reg# 96667)
Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC^{XL}:

Section	Observations
1.1	• Submit differential fee of Rs. 270000/- for imported source of pellets
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Provide evidence of double layer tablet compression machine for applied product
1.5.2	• The reference formulation is bilayer, film coated modified release tablet while you have applied for film coated tablet. Revised the label claim as per reference formulation along with submission of applicable • Modified release layer of tamsulosine ??? pellets? Fee.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for drug substance Tamsulosin HCl and Solifenacin succinate issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance solifenacin succinate and Tamsulosin HCl by Drug Product manufacturer is required. • Copies of the complete analytical procedures used for routine testing of the Drug substance solifenacin succinate and Tamsulosin HCl by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance solifenacin succinate and Tamsulosin HCl shall be submitted. • Justification shall be submitted for not performing the test for sulphated ash/residue on ignition in batch analysis of drug substance solifenacin succinate and Tamsulosin HCl by drug product manufacturer as per drug substance manufacturer • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by both drug substance manufacturer and drug product manufacturer for solifenacin succinate shall be submitted
3.2.S.5	• COA of primary / secondary reference standard solifenacin succinate including source and lot number shall be provided.
3.2.P.1	• The reference formulation is bilayer, film coated modified release tablet containing modified release layer of Tamsulosin HCl and immediate release layer of solifenacin succinate while the applied formulation does not contain modified release component, clarify?
3.2.P.2	• Submit details of comparator product including batch number, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed • Submit complete results of CDP studies of applied product against the reference product • Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product
3.2.P.5	• Justification is required for not mentioning the dissolution limits of both solifenacin succinate and tamsulosin hydrochloride separately in finished product specifications as solifenacin is available in immediate layer and tamsulosin hydrochloride is available in modified release layer • Analytical procedure for all the tests given in finished product specifications shall be submitted
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP. • Stability study data of drug product at 6th month time point shall be submitted
Decision of 343rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The firm has submitted the reply through General Request ID No. 7ND-SN7-JUJ2.	
Reason for deferment	Observations
• Submit differential fee of Rs. 270000/- for imported source of pellets	No pellets have been used in the formulation. c36f6c3d92570c968b25fa690fc6e167057df890

• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Provide evidence of double layer tablet compression machine for applied product	Tablet General Section is approved. As per inspection report dated 13-04-2022, the panel verified following facilities: Tablet in Tablet Bi-layered tablet Combokits dies for co-blistering Semi automatic vial filling machine
• The reference formulation is bilayer, film coated modified release tablet while you have applied for film coated tablet. Revised the label claim as per reference formulation along with submission of applicable • Modified release layer of tamsulosine ??? pellets? Fee.	The firm has revised the label claim as follows: Each Modified release tablet contains: Solifenacin Succinate.....6mg (Eq. to Solifenacin 4.5mg) Tamsulocin HCl.....0.4mg (Eq. to 0.37mg Tamsulocin) However the correct label claim is: Each Modified Release, Bi Layer Film Coated Tablet Contains: Solifenacin Succinate (Immediate release layer).....6mg (Eq. to Solifenacin 4.5mg) Tamsulocin HCl (extended release layer).....0.4mg (Eq. to 0.37mg Tamsulocin) *The firm shall submit the applicable fee for revision of label claim.
• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for drug substance Tamsulosin HCl and Solifenacin succinate issued by relevant regulatory authority of country of origin is required	Manufacturer: Hema Pharmaceuticals Pvt. Ltd. India GMP certificate No 2404494 valid till 18-04-2027 (Solifenacin) Union Quimco Farmaceutica S.A Spain GMP certificate No. M00686 valid till 31-01-2026.
Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Submitted
Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance solifenacin succinate and Tamsulosin HCl by Drug Product manufacturer is required.	Submitted.
Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance solifenacin succinate and Tamsulosin HCl shall be submitted.	Submitted
Justification shall be submitted for not performing the test for sulphated ash/residue on ignition in batch analysis of drug substance solifenacin	<i>“Initially it was typographical mistake which has been rectified and revised COA attached.”</i>

succinate and Tamsulosin HCl by drug product manufacturer as per drug substance manufacturer.	
Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by both drug substance manufacturer and drug product manufacturer for solifenacin succinate shall be submitted	Submitted. B.No. 15001825003 (Solifenacin) B.No. 20TM0005 (Tamsulosin)
COA of primary / secondary reference standard solifenacin succinate including source and lot number shall be provided.	Tamsulosin: 20WTM001 Solifenacin: 1500017001WS
The reference formulation is bilayer, film coated modified release tablet containing modified release layer of Tamsulosin HCl and immediate release layer of solifenacin succinate while the applied formulation does not contain modified release component, clarify?	The firm has revised the master formulation. However, the stability was performed on old formulation. The firm was asked to submit clarification the firm replied as under: With reference to this observation, it is clarified that there was only a discrepancy in the formulation description mentioned in Module 3.2.P.5.1. However, as can be verified from the Batch Manufacturing Record (BMR), the formulation composition and manufacturing steps were strictly followed in accordance with our revised master formulation. The stability studies were performed on batches manufactured using this same formulation.
Submit details of comparator product including batch number, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed	PE and CDP studies have been performed against comparator's product i.e. Tamsolin by Getz Pharma but analytical record has not been provided.
Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	<i>The Correct Formulation has been attached along with which is according to Innovator and can be verified from BMR hence no Compatibility studies required.</i>
Justification is required for not mentioning the dissolution limits of both solifenacin succinate and tamsolucin hydrochloride seperately in finished product specifications as solifenacin is available in immediate layer and tamsulosin hydrochloride is available in modifies release layer.	<i>Typographical Mistake. Rectified Finished Product Specification Attached.</i>
Analytical procedure for all the tests given in finished product specifications shall be submitted	Submitted
Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from	Tamsuolsin: Form 6 dated 16-07-2021 for 0.1KG material is submitted alongwith unattested invoice No. EXP-046/21-22 dated 07-07-

DRAP.	2021 and airway bill. Solifenacin: Form 6 dated 04-02-2022 for 300grams of material alongwith unattested invoice dated 12-30-2021.	
Stability study data of drug product at 6th month time point shall be submitted	Submitted.	
Decision: Deferred for Product Specific Inspection (PSI) for verification of authenticity of submitted stability data. The Board authorized the Chairman Registration Board for constitution of the panel for PSI.		
103.	Name, address of Applicant / Marketing Authorization Holder	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21697 dated 01-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 893024395056 dated 04-08-2023.
	The proposed proprietary name / brand name	Anestro 1mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Anastrozole...1mg
	Pharmacotherapeutic Group of (API)	Aromatase inhibitors. (L02BG)
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	ARIMIDEX® (Anastrozole) tablet, USFDA Approved.
	For generic drugs (me-too status)	Arimisol 1mg Tablet, Swiss Pharmaceuticals, Reg. No. 091125.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:			
Sr.	Section the firm No.	Observation	Reply by
1.	1.3.4	Valid copy of DML and GMP DML No. certificate of the applicant shall be w.e.f. 13-04-2022. submitted.	Firm has submitted copy of 000610 renewed
2.	1.3.5	Evidence of manufacturing facility/section approval from 2/2006-Lic (Vol-II) dated 11-06-2024 licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3- specifying Tablet (General) section
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	1 x 14's.
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by No. K Dis. No. 16478/D1/4/2021 dated 31- relevant/concerned regulatory by Department of Food authority shall be submitted. Drug Control Administration	Firm has submitted copy of GMP No. 05-2022 issued Safety and
			Govt. of Tamilnadu valid till 31-12-2024. <i>However, address of the DS in module 3 is different from the address mentioned in the submitted GMP certificate.</i>
5.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted	Submitted.
7.	3.2.S.4.4	COA of the drug substance submitted by the drug product manufacturer has pH limits while USP monograph and COA submitted by the drug substance manufacturer has no pH limits. Clarification shall be submitted	No clarification is submitted by the firm against this point. They just submitted revised COA wherein they removed pH.
8.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted	Submitted.
9.	3.2.S.7	☐ Limits of water content test mentioned in stability data sheets is NMT 1.0% while specification provided by the drug substance manufacturer has	Firm has submitted revised stability data sheets wherein they have changed the limits of water content test from NMT 1.0% to

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		mentioned NMT 0.3%. Clarification shall be submitted.	NMT 0.3%.
		□□ Stability data sheets have mentioned pH limit of 5-6 while COA of the drug product manufacturer has mentioned 5-6.5. clarification shall be submitted	Firm has removed pH limit from their specifications as per USP method.
10.	3.2.P.2.2.1	Complete CDP studies with each time point dissolution of both reference and test product with analytical record shall be submitted. Pictorial evidence of the innovator product with visible details of the batch number, expiry date and name of manufacturer shall be submitted	Submitted. Firm has submitted pictorial evidence of innovator product Arimidex 1mg tablets, B. No. RB739, manufacturing date 03-2019 manufactured by M/s AstraZeneca USA. However, the data submitted in the dossier and now submitted data is totally different from each other. F2 values calculated in the new data and previously submitted data are totally changed. Firm has submitted revised specifications wherein they added the said test.
11.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph	Submitted.
12.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted	Firm once again submitted the analytical method wherein they have prepared standard and sample solutions as per USP pharmacopoeia. <i>But again the raw data sheets and analytical method are in contrast to each other. And if we put the value of 0.04mg/ml in raw data sheets then the values of assay are totally out of specifications</i>
13.	3.2.P.8	Stability data sheets as per decision of Registration Board with inclusion of API lot number shall be submitted.	Submitted along with inclusion of API lot No. ABANSNF003.

	Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.04mg/mL while raw data sheets have 0.1mg/mL. Chromatograms also does not reveal any wavelength. Clarification shall be submitted. Compliance record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that it was a typo error and corrected concentration is 0.1mg/mL and they also submitted revised analytical procedures. However, concentration is different from that mentioned in USP. No justification submitted by the firm. Submitted
Decision of 343rd meeting: The firm has submitted the reply through General Request ID No. EXG-LJB-QAQB. Deferred for the following; - Valid copy of GMP certificate of the drug substance manufacturer (as per information submitted in Module I and Module III) issued by relevant/concerned regulatory authority shall be submitted. - Justification shall be submitted for provision of changed data from that of the initially submitted data in Comparative Dissolution studies. - Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted again in reply wherein the analytical method has mentioned 0.04mg/ml while raw data sheets have 0.1mg/ml. - Chromatograms also does not reveal any wavelength. Clarification shall be submitted. - Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.		
Response by the firm: The firm has not submitted the reply to the above-mentioned points but has referred to the decision of 348th meeting. The Board approved the application submitted by M/s Weather Folds Pharmaceuticals , Hattar manufactured by M/s Wnsfeild Pharmaceuticals, Hattar vide application ID 963-QMY-AJG1, 2024-03-06.		
Decision: The Board deferred the case for submission of reply against each point as mentioned in the decision of 343rd meeting of Registration Board.		
104.	Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant Application Form Dy. No / Tracking ID & date of submission	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E- 127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi. Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi. ☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) Form 5F: Dy. No. 25553 dated 23-10-2023.

Details of fee submitted	Rs.75,000/- vide slip No. 328149207380 2023.	dated 03-10-
The proposed proprietary name / brand name	Dexketo 12.5mg/gram Gel.	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Dexketoprofen Trometam eq. to Dexketoprofen 12.5mg.	
Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti Rheumatic Products, Non- Steroids. ATC code M01AE17.	
Reference to Finished product specifications	Innovator's Specifications.	
The status in reference regulatory authorities	Enangel 12.5 mg/g gel, Menarini Laboratories, S.A, CIMA Spain approved.	
For generic drugs (me-too status)	N/A.	
Proposed Pack size	60 gram Tube (As per S.R.O.)	
Proposed unit price	As per SRO.	
Evaluation by PEC:		
Sr. No.	Section	Observation
		Reply by the firm
1.	1.5.2	Justify the label claim with respect to the reference product.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.
3.	3.2.S.4.1	Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content. Clarification shall be submitted.
4.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.
5.	3.2.P.8	- Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted. - Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable. - Justify the batch size of the trial batches as only 10 tubes are manufactured in each trial batch.
Decision of 343 rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. Evaluation by PEC: Reply received through General Request ID 63T-GVZ-VJW		

Reason for deferment		Response
Justify the label claim with respect to the reference product.		“The submitted label claim contains the typographic error, please not the corrected label claim. Each gram contains: Dexketoprofen.....12.5mg”
Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.		GMP certificate of drug substance manufacturer dated 14-11-2022 (validity 5 ears from dated of issues) is submitted.
Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content. Clarification shall be submitted.		<i>“We did not perform R-enantiomeric content and Tromethamine content in the testing of drug substance, later we have performed these tests and also add them in the pecifications. Now we have submitted the revised soecificaitons along with COA of API.”</i>
COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.		Submitted (Dexketoprofen Trometamol: B/No. DKT-P/20016)
Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted.		Submitted.
Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable.		<i>“During the analytical method development stage, we conducted the assay using both UV spectrophotometric method and the HPLC method. The results from both procedures showed no differences. Therefore, we selected the UV test method as the final method. Additioanally, all required analytical method validation parameters were performed, confirming that the UV method used is accurate, specific and precise.”</i>
Justify the batch size of the trial batches as only 10 tubes are manufactured in each trial batch.		Trial batch weighing 600g was produced, each tube containing 40g with the cream distributed into 15 tubes which were more than sufficient for complete stability testing as per ICH guidelines. For long term stability, 6 tubes and for accelerated 2 tubes are required for 1 times testing. Therefore, the number of tubes meets the required testing specifications.”
Decision: Deferred for the following points: • Clarification for not performing the tests for R-enantiomer and Tromethamine content in the testing of drug substance. • Scientific justification regarding the distribution of each tube of finished product into 15 tubes for carrying out the stability studies since the stability studies are required to be performed on finished product along with its secondary packaging.		
105.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi

Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24301 dated 04-10-2023 Rs.75,000/- dated 14-09-2023
The proposed proprietary name / brand name	Nadiflox 1% Cream
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Nadifloxacin...10mg
Pharmacotherapeutic Group of (API)	Quinolone Antibiotics indicated for skin infection, deep skin infection, sores (purulent inflammation)
The status in reference regulatory authorities	Aquachim Cream 1% of M/s Otsuka Approved by PMDA of Japan
For generic drugs (me-too status)	--
Proposed Pack size & Price	As per SRO
Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Evidence of approval of required manufacturing facility i.e. "Cream section, from CLB shall be submitted.	Firm has submitted letter issued by Secretary CLB dated 03-03-2023 wherein renewal for DML has been granted for sections including "Oral Hygiene (Mouth Wash)/Semisolid & Toothpaste.
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted.
3.	Drug substance analytical procedure shall be submitted from M/s Kaizen.	Firm has submitted drug substance analytical procedure.
4.	Documents confirming import/procurement of Drug substance, issued by the DRAP I&E office shall be submitted.	Firm has submitted copy of commercial invoice attested by DRAP I&E Karachi dated 20-10-2020.

Decision of 343rd meeting:

Deferred for clarification regarding the manufacturing facility for applied dosage form, whether it will be manufactured in section of Mouthwash and Toothpaste or approved as separate section of “Cream/Ointment.”

Evaluation by PEC: (Reply received through G.R ID 1JG-Y14-R6NQ)

The firm has submitted Section approval letter No. F.2-5/2009-Lic(Vol-II) dated 19-06-2025 with the following title:

Topical Section (Cream/Ointment/Gel/Paste) (General/Steroidal) along with steroidal dispensing) (Revision/Regularization).

Decision: Approved.

106.	Name, address of Applicant / Marketing Authorization Holder	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of drug product manufacturer	GMP certificate: Inspection date 11-12- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22607: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 07-11-2022
	The proposed proprietary name / brand name	AVEBECTUM 1gm Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium...500mg Sulbactam ss Sodium...500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	PMDA Japan
	For generic drugs (me-too status)	Cebac Injection by Bosch
	Proposed Pack size	1's: As per SRO

Evaluation by PEC³:

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit GMP certificate / inspection report of product manufacturer	
2.	Submit API specifications and analytical method from API manufacturer as well as product manufacturer	
3.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	
4.	Submit details of the product including exp date and batch number against which PE studies were conducted.	
5.	Submit in-use stability studies.	
6.	Submit valid GMP certificate of API manufacturer.	
7.	Submit evidence of import of drug substance.	
8.	Submit BMR of stability batches.	
Decision of 343 rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The firm has submitted the reply through General Request ID No. <u>8N4-D37-7N3E</u> .		
	Reason for deferment	Response
	Submit GMP certificate / inspection report of product manufacturer	Inspection report dated 08-03-2024 for renewal of DML is submitted. (Wnsfeild)
	Submit API specifications and analytical method from API manufacturer as well as product manufacturer	Submitted
	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	Submitted
	Submit details of the product including exp date and batch number against which PE studies were conducted.	PE studies have been performed against the comparator's product i.e Cefkur by M/s Wemark Pharma. B.No. M5821 Mfg date: 12-22 Exp date: 12-24
	Submit in-use stability studies.	Submitted
	Submit valid GMP certificate of API manufacturer.	DML NO. Lu20160006 valid till 21-09-2030. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9YjRiZGNhYWY1MTlhZmE5NjNiYTQwZWVlNmU2NDhmZWImaXRlbUlKPWZmODA4MDgxOGI2NGIyNDIwMTIhN2ZhMjllYjgwYWRj
	Submit evidence of import of drug substance.	Clearance certificate dated 06-05-2021 for 50 kg material is submitted (Cefoperazone+Sulbactam) AD attested invoice No. JTRF210411-MQ dated 20-04-2021 is submitted.
	Submit BMR of stability batches.	Submitted
Decision: Approved subject to verification of loan letter.		
107.	Name, address of Applicant / Marketing Authorization Holder	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar

GMP status of drug product manufacturer	GMP certificate: Inspection date 11-12- 2020
Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22608: 14-09-2023
Details of fee submitted	PKR 75,000/- : 07-11-2022
The proposed proprietary name / brand name	AVEBECTUM 1gm Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium... 1000mg Sulbactam ss Sodium... 1000mg
Pharmacotherapeutic Group of (API)	Antibiotic
Reference to Finished product specifications	JP
The status in reference regulatory authorities	Approved in 03 European countries, i.e., Bulgaria: Sulcef 1g/1g powder for solution for injection Lithuania: Sulcef 1g/1g powder for solution for injection Slovakia: Sulcef 2g powder for solution for injection
For generic drugs (me-too status)	Cebac Injection by Bosch
Proposed Pack size	1's: As per SRO
Name and address of API manufacturer.	Suzhou dawnrays pharmaceutical Co., Ltd China.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Cebac injection of Bosch.
Details of stability studies of drug product	4000 vials / 3 batches
Documents for the procurement of API with approval from DRAP (in case of import).	Clearance certificate dated 01-09-2022
Evaluation by PEC ³ :	
Sr. No	Shortcomings communicated
	Response by the firm
	Submit GMP certificate / inspection report of product manufacturer Submit API specifications and analytical method from API manufacturer. Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3 Submit details of the product including exp date and batch number against which PE studies were conducted. Submit in-use stability studies. Submit valid GMP certificate of API manufacturer. Submit BMR of stability batches.
Decision of 343rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The firm has submitted the reply through General Request ID No. <u>8N4-D37-7N3E</u>.	

Reason for deferment		Response
Submit GMP certificate / inspection report of product manufacturer		Inspection report dated 08-03-2024 for renewal of DML is submitted. (Wnsfeild)
Submit API specifications and analytical method from API manufacturer as well as product manufacturer		Submitted
Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3		Submitted
Submit details of the product including exp date and batch number against which PE studies were conducted.		PE studies have been performed against the comparator's product i.e Cefkur by M/s Wemark Pharma. B.No. M5821 Mfg date: 12-22 Exp date: 12-24
Submit in-use stability studies.		Submitted
Submit valid GMP certificate of API manufacturer.		DML NO. Lu20160006 valid till 21-09-2030 is submitted. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9YjRiZGNhYWY1MTlhZmE5NjNiYTQwZWVlNmU2NDhmZWImaXRlbUlKZWZmODM4MDgxOGI2NGlyNDIwMTIhN2ZhMjllYjgwYWRj
Submit evidence of import of drug substance.		Clearance certificate dated 06-05-2021 for 50 kg material is submitted (Cefoperazone+Sulbactam) AD attested invoice No. JTRF210411-MQ dated 20-04-2021 is submitted.
Submit BMR of stability batches.		Submitted
Decision: Approved subject to verification of loan letter.		
108.	Name, address of Applicant / Marketing Authorization Holder	M/s Aspin Pharma Pvt Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 24688 dated 10-10-2023 Rs.75,000/- dated 05-12-2022
	The proposed proprietary name / brand name	Monsuka 4mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast Sodium Eq. to Montelukast...4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists

	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Myteka Sachet of M/s Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	BP specifications
Evaluation by PEC ^{II} :		
Sr.#	Observations	
1.	Justification shall be submitted for using Montelukast sodium working standard instead of montelukast dicyclohexylamine, as recommended by BP monograph for drug product Assay test.	
2.	As evident from submitted chromatograms, the chromatographic conditions of gradient mobile phase programme have not been followed for the performance of Assay test in drug product stability studies. Justification shall be submitted in this regard.	
Decision of 343 rd meeting: Deferred for submission of reply to above cited shortcomings. Evaluation by PEC: G.R tracking ID SDD-6B5-WRZY		
Sr.#	Observations	Firm's reply
1.	Justification shall be submitted for using Montelukast sodium working standard instead of montelukast dicyclohexylamine, as recommended by BP monograph for drug product Assay test.	The firm has submitted delivery challan dated 26-09-2023 as proof of procurement of Motelukast Dicyclohexylamine WS from M/s Javed Chemical Corporation Karachi whereas stability batches were manufactured in 2020.
2.	As evident from submitted chromatograms, the chromatographic conditions of gradient mobile phase programme have not been followed for the performance of Assay test in drug product stability studies. Justification shall be submitted in this regard.	The firm has not submitted any scientific justification regarding the selection of isocratic mobile phase whereas the recommended mobile phase system includes gradient system. The firm has submitted revised method of analysis and testing at 6 th month time point data of one batch for assay manufactured in May, 2024.
Decision: Deferred for Product Specific Inspection (PSI) for verification of authenticity of submitted stability data. The Board authorized the Chairman Registration Board for constitution of the panel for PSI.		
109.	Name, address of Applicant / Marketing Authorization Holder	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Status of the applicant	O Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24321 dated 04-10-2023 Rs.30,000/- dated 05-09-2023

Minutes of 353rd Meeting of Registration Board (14th – 15th January, 2026)

The proposed proprietary name / brand name	Linamet 2.5/1000 mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin...2.5mg Metformin HCl...1000mg
Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Lina-Met 2.5/500 of M/s CCL
Proposed Pack size & Price	As per SRO
Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Decision of 343rd meeting: Deferred for submission of reply to above cited shortcomings		
Sr.#	Observations	Firm's response
1	Submit valid DML/GMP certificate of the drug substance manufacturer of drug substance manufacturers issued by the relevant regulatory authority of country of origin.	License No. LIAO 20150233 valid till 17-11-2027.
2.	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as “practically insoluble”. Justification shall be submitted in this regard.	N.A
3.	Analytical Method Verification studies of drug substances including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.
4.	Justification shall be submitted for not including test of “Enantiomeric purity” in the drug substance specifications of Linagliptin	Declaration from APi manufacturer has been submitted stating that the enantiomeric purity of Linagliptin has been studied and based on the process validation of 03 batches and stability, enantiomeric impurity was not detected.
5.	Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation.	No seal coat has been applied on Metformin, Core tablet has been coated after Linagliptin.
6.	Justification shall be submitted for proposed quantity of Arginine in the formulation.	Maximum quantity was taken from FDA inactive ingredient database. The used quantity is 21.5mg/tablet for

		2.5mg/850mg and 25mg/tablet for 2.5/1000mg tablet.
7.	Justification shall be submitted on basis of performance based evidence for adding 10% overage of “Empagliflozin” & “Linagliptin” in the applied batch formulation.	N.A
8.	Justification shall be submitted for test of Arginine content in drug product specifications.	<i>Arginine will be tested in commercial batches.</i>
9.	Clearance certificate for the import of Linagliptin issued by DRAP I&E office shall be submitted.	Clearance certificate dated 19-09-2023 for 100 grams material is submitted.
10.	Justification shall be submitted for the ascending trend & significant change of Assay results of Empagliflozin and Linagliptin in drug product stability studies.	N.A
Decision: Deferred for clarification on above referred queries.		
110.	Name, address of Applicant / Marketing Authorization Holder	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24321 dated 04-10-2023 Rs.30,000/- dated 05-09-2023
	The proposed proprietary name / brand name	Linamet 2.5/850 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin...2.5mg Metformin HCl...850mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
Evaluation by PEC ^{II} :		
Decision of 343 rd meeting: Deferred for submission of reply to above cited shortcomings		
Observations		Firm's response

Submit valid DML/GMP certificate of the drug substance manufacturer of drug substance manufacturers issued by the relevant regulatory authority of country of origin.		License No. LIAO 20150233 valid till 17-11-2027.
In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as “practically insoluble”. Justification shall be submitted in this regard.		N.A
Analytical Method Verification studies of drug substances including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.		Submitted.
Justification shall be submitted for not including test of “Enantiomeric purity” in the drug substance specifications of Linagliptin		Declaration from APi manufacturer has been submitted stating that the enantiomeric purity of Linagliptin has been studied and based on the process validation of 03 batches and stability, enantiomeric impurity was not detected.
Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation.		No seal coat has been applied on Metformin, Core tablet has been coated after Linagliptin.
Justification shall be submitted for proposed quantity of Arginine in the formulation.		Maximum quantity was taken from FDA inactive ingredient database. The used quantity is 21.5mg/tablet for 2.5mg/850mg and 25mg/tablet for 2.5/1000mg tablet.
Justification shall be submitted on basis of performance based evidence for adding 10% overage of “Empagliflozin” & “Linagliptin” in the applied batch formulation.		N.A
Justification shall be submitted for test of Arginine content in drug product specifications.		<i>Arginine will be tested in commercial batches.</i>
Clearance certificate for the import of Linagliptin issued by DRAP I&E office shall be submitted.		Clearance certificate dated 19-09-2023 for 100 grams material is submitted.
Justification shall be submitted for the ascending trend & significant change of Assay results of Empagliflozin and Linagliptin in drug product stability studies.		N.A
Decision: Deferred for clarification on above referred queries.		
111.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar

Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 21698 dated 01-09-2023
Details of fee submitted	Rs.30,000/- vide slip no. 3070852160 dated 04-08- 2023
The proposed proprietary name / brand name	Tacrowin 0.1% Ointment
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Tacrolimus (as Monohydrate) 1mg (0.1%w/w)
Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immuno-modulating Agents, Calcineurin inhibitors.
Reference to Finished product specifications	Innovator's specification
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	MHRA Approved (Tacrolimus Monohydrate 0.1% Ointment)
For generic drugs (me-too status)	Aimus Ointment of M/s. Aims Pharmaceuticals (Reg.no. 069939)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that " <i>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted</i> ".
3.	3.2.S.7	Submit readable copy of stability datasheet of drug substance.
4.	3.2.P.2	Justify for using water in the applied formulation of ointment since the innovator/reference product has not been used water in their formulation.
5.	3.2.P.2.2.1	Justify for not including the microbiological analysis and pH test while performing the pharmaceutical equivalence against the comparator product.
6.	3.2.P.5.1	Justify for not including the microbiological analysis and content uniformity test in the specification of drug product.
7.	3.2.P.5.3	Assay method given in section 3.2.P.5.2 is different from the assay method on which verification has been performed ,clarification is required in this regard.

8.	3.2.P.5.4	Justify for not performing content uniformity and pH determination test while the batch analysis of finished product.
9.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.
10.	3.2.P.8	- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. - Justify for not performing microbiological analysis, content uniformity and pH determination test while conducting the stability study of drug product.
11.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision of 343rd meeting:

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

Response:

The firm has submitted the reply through General request ID No. 7A4-Q3W-U88U.

Reason for deferment	Response
Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Specifications along with analytical method for drug substance from drug product manufacturer is submitted.
Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that <i>"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"</i> .	Submitted. <i>However, system suitability has not been performed according to USP.</i>
Submit readable copy of stability datasheet of drug substance.	06 months accelerated and 24 months real time stability data according to the conditions of zone IV-A is submitted.
Justify for using water in the applied formulation of ointment since the innovator/reference product has not been used water in their formulation.	<i>"It was Typographical Error, which can be verified from the BMR."</i>
Justify for not including the microbiological analysis and pH test while performing the pharmaceutical equivalence against the comparator product.	The firm has stated that: <i>pH is not required for Ointment as it does not contain any water or preservative agent.</i> <i>Microbiological tests are performed during the pharmaceutical equivalence study and mentioned in the report.</i> The firm has submitted PE study report against the comparator's product i.e. Eczemus 0.1% Ointment by M/s Brookes Pharma which includes microbiological testing.

Justify for not including the microbiological analysis and content uniformity test in the specification of drug product.	However, content uniformity testing is mandatory for semisolids.
Assay method given in section 3.2.P.5.2 is different from the assay method on which verification has been performed; clarification is required in this regard.	The firm has submitted method of analysis and analytical method validation studies.
Justify for not performing content uniformity and pH determination test while the batch analysis of finished product. Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.	As per USP General Chapter, pH for Ointments is not mandatory unless specified in individual monograph and the applied product is non-pharmacopoeial. However, content uniformity testing is mandatory for semisolids.
Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.	COA of Batch No. TR21001-WRS is submitted.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. - Justify for not performing microbiological analysis, content uniformity and pH determination test while conducting the stability study of drug product.	Manufacturer of API: FISHFA Biogenics Limited, India GMP certificate No. 24044914 valid till 18-04-2027 is submitted. pH is not mandatory. CU test not performed. Microbiological testing has been performed as per submitted stability summary sheets.
Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.
Decision: Deferred for submission of system suitability studies for drug substance as per USP and Content Uniformity for drug product.	
112.	
Name and address of manufacturer/Applicant	M/s Wnsfeild Pharmaceuticals, Plot No.122, Block-A, Phase V, Industrial Estate, Hattar
Brand Name + Dosage Form + Strength	Nebival 5/80mg tablet
Composition	Each film coated tablet contains: Nebivolol 5mg valsartan 80mg
Diary No. Date of R & I & fee	From-5 Dy. No.2102 dated 07-12-2016 Rs. 50,000/- dated 07-12-2016
Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
Type of Form	Form-5D
Finished product Specification	Inhouse specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	BYVALSON (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, (USFDA approved Discontinued) (NDA) VYDUO (nebivolol and valsartan) 5mg;80mg tablets film-coated tablet, USFDA approved (ANDA)

	Me-too status	Could not be confirmed	
	GMP status		
	Remarks of the Evaluator	Stability list file. Form 5D needs to be verified	
STABILITY STUDY DATA			
Drug	Nebival 5/80mg tablet		
Manufacturer of API	Nebivolol HCl; Valsartan;		
API Lot No.	Nebivolol HCl; Valsartan;		
Description of Pack (Container closure system)	3x10's; Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	SV-01	SV-02	SV-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	05-01-2021	05-01-2021	05-01-2021
No. of Batches	03		
Date of Submission	Dy No. 27284 Dated; 04-10-2020		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Nebivolol HCl; Not submitted. Valsartan; Not submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nebivolol HCl; Not submitted. Valsartan; Not submitted.	

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

Decision of 344th meeting:

The Board deferred the case for the following points.

The applicant has submitted the following reply through General Request ID No. U2J-4R6-9UDL.

Sr. No.	Observation	Reply by the firm
1.	You have applied for label claim without considering the salt form of nebivolol. Revise the label claim as per reference formulation along with submission of applicable fee.	The firm has submitted revised label claim without submission of fee. Each film coated tablet contains: Nebivolol as HCl...5mg Valsartan.....80mg
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Dexlansoprazole Capsule, 297 th meeting
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	Submitted Nebivolol: (Hema Pharmaceuticas Pvt Ltd India) B.No. 20NB0007 Valsartan: (Zhuhai Rundu Pharmaceuticasl Co., Ltd., China) B.No. 67819070613
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted.

5.	Stability study data of API from both API manufacturer shall be submitted.	Nebivolol: 06 months accelerated and 60months real time stability data of 03 batches according to the conditions of zone IV-B. Valsartan: 06 months accelerated and 24 months real time stability studies for 03 batches according to the conditions of zone IV-A.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Nebivolol: (Hema Pharmaceuticas Pvt Ltd India) GMP certificate No. 24044914 valid till 18-04-2027. Valsartan: (Zhuhai Rundu Pharmaceuticasl Co., Ltd., China) License No. Guangdong 20160246 valid till 28-08-2030. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9OTY4MjY0Jml0ZW1JZD1mZjgwODA4MTgzY2FkNzUwMDE4NDM3NDAYzjE1MmYzYg==
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Nebivolol: AD attested invoice No. EXP-043 dated 2-10-2020 (Dy. No. 1831 dated 03-11-2020) Valsartan: Clearance certificate No.F.10-72/2019-DRAP/6369 dated 24-10-2019 is submitted.
8.	Protocols followed for conduction of stability study shall be submitted.	Submitted.
9.	Method used for analysis of Finished Product shall be submitted.	Submitted.
10.	Drug-excipients compatibility studies shall be submitted.	Excipients used are same as used in the formulation of innovator's product.
11.	Complete batch manufacturing record of three stability batches shall be submitted.	Submitted (NV-01, NV-02, NV-03)
12.	Record of comparative dissolution data shall be submitted.	CDP studies have been performed against Byvalson 5/80mg tablet by M/s Abbvie Pharma, USA. However, the product is not in product and discontinued in USFDA.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Batches were manufactured in 2021 while record of data loggers is submitted for the year 2023.
15.	Clarification shall be submitted as date of initiation of stability study in stability summary sheets is prior to the manufacturing	No clarification is submitted.

	of trial batches	
	Shortcomings communicated on 08-01-2026: Clarification shall be submitted as date of initiation of stability study in stability summary sheets is prior to the manufacturing of trial batches. the product against which CDP studies have been performed is not in production and discontinued as per USFDA, please clarify. Moreover, submit pictorial evidence and chromatograms. Compliance Record of HPLC software 21 CFR & audit trail reports on product testing shall be submitted.	Not submitted.
Decision: Deferred for the following points: - Clarification shall be submitted as date of initiation of stability study in stability summary sheets is prior to the manufacturing of trial batches. - the product against which CDP studies have been performed is not in production and discontinued as per USFDA, please clarify. Moreover, submit pictorial evidence and chromatograms. - Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.		

Deferred cases of form 5:

113.	Name and address of manufacturer / Applicant	M/s Epharm Laboratories.A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Ketomine 30mg/ml Injection
	Composition	Each ml Contains: Ketorolac Tromethamine...30mg
	Diary No. Date of R& I & fee	Dy.No 31972 dated 25-09-2018 Rs.20,000/- dated 25-09-2018
	Pharmacological Group	Anti-Inflammatory
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Toralac Injection 30mg/ml bt M/s Vision Pharma
	GMP status	27-4-2017, Overall GMP was satisfactory
	Remarks of Evaluator VI	Firm was asked why they did not perform terminal sterilization. Firm has revised the procedure and submitted that now they have performed terminal sterilization via autoclaving. But they did not submit fee for correction.

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Decision of RB in 316th Meeting: <i>Deferred for scientific rationale of performing terminal sterilization with reference to innovator product.</i>	
Remarks: The Firm has submitted that Terminal sterilization process is superior to filtration process as filtration is not a substitute for terminal sterilization. Product is heat stable this is the basis of performing terminal sterilization. Moreover, the firm has submitted fee challan of Rs. 7500/- for change in manufacturing method. In this context, it is submitted that the Innovator does not perform terminal sterilization of its formulation.	
Decision of 329th meeting: Deferred for scientific justification of using Terminal sterilization with reference to Innovator product being heat labile. Evaluation by PEC: (G.R Tracking ID P72-HXR-XJA8) The firm has stated that “we did not find any innovator documents either prohibiting from terminal sterilization process which is superior to filtration process”. Moreover, as per google patent, the manufacturing process includes the step of terminal sterilization.	
Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.	
114.	Name and address of manufacturer / Applicant
	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength
	Evolar 10mg Tablet
	Composition
	Each Tablet Contains: Everolimus..... 10mg
	Diary No. Date of R& I & fee
	Dy.No.26868 dated 06-08-2018, Rs.20,000/- dated 03-08-2018.
	Pharmacological Group
	Antineoplastic agent
	Type of Form
	Form-5
	Finished product Specification
	Manufacturer specifications
	Pack size & Demanded Price
	As per PRC
	Approval status of product in Reference Regulatory Authorities.
	approved by MHRA of UK
	Me-too status
	Afinitor by novartis
	GMP status
	GMP inspection report dated 04-02-2020 in which the panel concludes satisfactory level of cGMP compliance. The panel further reported that since the firm had upgraded the layout of anti-cancer section, therefore the firm was advised to get the anticancer section regularized and approved by DRAP, Islamabad after fulfilment of all codal formalities.
	Remarks of the Evaluator-II
	Decision of 297 th meeting: Deferred for consideration of applied formulation in the “anti-cancer section” since the applied product belongs to both L01 (Antineoplastic agents) & L04 (Immunosuppressants) class. Evaluation by PEC: The case has been process in response to the General Request No. 75Q-94S-JJQB. 1. DML renewal letter tacking ID No. 2N5-QNU-YX2W dated 1 st August, 2025 confirms the

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	availability of Tablet Section (Anti-Cancer). 2. Last inspection report dated 04-06-2025 confirms the approval of Tablet Section (Anti-Cancer). Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.	
115.	Name and address of manufacturer / Applicant	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Evolar 7.5mg Tablet
	Composition	Each Tablet Contains: Everolimus.....7.5mg
	Diary No. Date of R& I & fee	Dy.No 26867 dated 06-08-2018 Rs.20,000/- dated 03-08-2018
	Pharmacological Group	Antineoplastic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	approved by MHRA of UK
	Me-too status	Afinitor by novartis
	GMP status	GMP inspection report dated 04-02-2020 in which the panel concludes satisfactory level of cGMP compliance. The panel further reported that since the firm had upgraded the layout of anti-cancer section, therefore the firm was advised to get the anticancer section regularized and approved by DRAP, Islamabad after fulfilment of all codal formalities.
	Remarks of the Evaluator-II	
	Decision of 297th meeting: Deferred for consideration of applied formulation in the “anti-cancer section” since the applied product belongs to both L01 (Antineoplastic agents) & L04 (Immunosuppressants) class. Evaluation by PEC: The case has been process in response to the General Request No. 75Q-94S-JJQB. 1. DML renewal letter tacking ID No. 2N5-QNU-YX2W dated 1 st August, 2025 confirms the availability of Tablet Section (Anti-Cancer). 2. Last inspection report dated 04-06-2025 confirms the approval of Tablet Section (Anti-Cancer). Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.	
116.	Name and address of manufacturer / Applicant	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Evolar 5mg Tablet
	Composition	Each Tablet Contains: Everolimus.....5mg
	Diary No. Date of R& I & fee	Dy.No 26866 dated 06-08-2018 Rs.20,000/- dated 03-08-2018
	Pharmacological Group	Antineoplastic agent
	Type of Form	Form-5

	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	approved by MHRA of UK
	Me-too status	Afinitor by novartis
	GMP status	GMP inspection report dated 04-02-2020 in which the panel concludes satisfactory level of cGMP compliance. The panel further reported that since the firm had upgraded the layout of anti-cancer section, therefore the firm was advised to get the anticancer section regularized and approved by DRAP, Islamabad after fulfilment of all codal formalities.
	Remarks of the Evaluator-II	
	Decision of 297th meeting: Deferred for consideration of applied formulation in the “anti-cancer section” since the applied product belongs to both L01 (Antineoplastic agents) & L04 (Immunosuppressants) class. Evaluation by PEC: The case has been process in response to the General Request No. 75Q-94S-JJQB. 1. DML renewal letter tacking ID No. 2N5-QNU-YX2W dated 1st August, 2025 confirms the availability of Tablet Section (Anti-Cancer). 2. Last inspection report dated 04-06-2025 confirms the approval of Tablet Section (Anti-Cancer). Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.	
117.	Name and address of manufacturer / Applicant	M/s. Welmark Pharmaceuticals, Hattar
	Brand Name +Dosage Form + Strength	Clopix tablet
	Composition	Each Film coated tablet contains: Clopidogril.....75mg Aspirin.....75mg
	Diary No. Date of R& I & fee	Dy. No.30; 18-12-2010; Rs.8,000 Rs.12,000/- (21-10-2014)
	Pharmacological Group	Anti-Platelets
	Type of Form	Form-5
	Finished product Specification	Manufacturer’s Specification
	Pack size & Demanded Price	As per SRO; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DUOPALVIN by Sanofi (ANSM France Approved)
	Me-too status	Ascard Plus by Atco
	GMP status	Last inspection report 16-9-2017 Overall cGMP was satisfactory as per DRAP Guidelines.
	Previous remarks of the Evaluator.	• Fee challan photocopy is attached. • Internationally available as film coated tablet prepared by mixing granules of clopidogrel (prepared by wet granulation) and aspirin (prepared by dry granulation).
	Previous decision(s)	Deferred for deliberation on dosage form in

	comparison to reference product. (M-275) Deferred for clarification of manufacturing outline as per reference product. (M-284)																						
Evaluation by PEC	- Panel inspection conducted on 08-08-2018 unanimously recommends the renewal of DML. - The firm has submitted revised Form-5 with film coating composition and deposited fee challan of Rs.5000 /- (Deposit slip # 0793266) dated 17-07-2018. - The firm has submitted revised outline of method of manufacture with Clopidogrel prepared by wet granulation and aspirin prepared by dry granulation as per reference product.																						
Decision of 287th meeting: Deferred for review of formulation in view of reference product. Evaluation by PEC: (G.R application ID S6X-A5H-EVU6) The firm has submitted incorrect label claim: Each film coated bilayer tablet contains: Clopidogrel as Hydrogen Sulphate (enteric coated).....75mg Aspirin (outer immediate core).....75mg However, as per innovator's product review, the correct label claim is as under: Each film coated bilayer tablet contains: Clopidogrel (as Hydrogen Sulphate).....75mg Aspirin.....75mg The firm shall submit applicable fee for revision of label claim.																							
Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.																							
118.	<table> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhpura</td></tr> <tr> <td>Brand Name + Dosage Form + Strength</td><td>Calcium chloride Injection</td></tr> <tr> <td>Composition</td><td>Each 10ml contains: Calcium chloride 2H₂O.....2000mg</td></tr> <tr> <td>Diary No. Date of R&I & fee</td><td>Dy. No 28768 Dated 28-08-2018, Rs. 20,000/- 28-08-2018</td></tr> <tr> <td>Pharmacological Group</td><td>Electrolyte</td></tr> <tr> <td>Type of Form</td><td>Form-5</td></tr> <tr> <td>Finished product Specifications</td><td>USP specifications</td></tr> <tr> <td>Pack size & Demanded Price</td><td>10ml x 10 Ampoules, 10ml x 5 Ampoules & As per SRO</td></tr> <tr> <td>Approval status of product in Reference Regulatory Authorities</td><td></td></tr> <tr> <td>Me-too status (with strength and dosage form)</td><td>Calcium Chloride Injection of M/s LC&PW, Lahore</td></tr> <tr> <td>GMP status</td><td>DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018</td></tr> </table>	Name and address of manufacturer / Applicant	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhpura	Brand Name + Dosage Form + Strength	Calcium chloride Injection	Composition	Each 10ml contains: Calcium chloride 2H ₂ O.....2000mg	Diary No. Date of R&I & fee	Dy. No 28768 Dated 28-08-2018, Rs. 20,000/- 28-08-2018	Pharmacological Group	Electrolyte	Type of Form	Form-5	Finished product Specifications	USP specifications	Pack size & Demanded Price	10ml x 10 Ampoules, 10ml x 5 Ampoules & As per SRO	Approval status of product in Reference Regulatory Authorities		Me-too status (with strength and dosage form)	Calcium Chloride Injection of M/s LC&PW, Lahore	GMP status	DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018
Name and address of manufacturer / Applicant	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhpura																						
Brand Name + Dosage Form + Strength	Calcium chloride Injection																						
Composition	Each 10ml contains: Calcium chloride 2H ₂ O.....2000mg																						
Diary No. Date of R&I & fee	Dy. No 28768 Dated 28-08-2018, Rs. 20,000/- 28-08-2018																						
Pharmacological Group	Electrolyte																						
Type of Form	Form-5																						
Finished product Specifications	USP specifications																						
Pack size & Demanded Price	10ml x 10 Ampoules, 10ml x 5 Ampoules & As per SRO																						
Approval status of product in Reference Regulatory Authorities																							
Me-too status (with strength and dosage form)	Calcium Chloride Injection of M/s LC&PW, Lahore																						
GMP status	DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018																						

	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275 th meeting (M-292).
	Evaluation by PEC	The firm has submitted reference Baxter Healthcare corporation 15mg/100ml Calcium chloride : 1g /10ml ampoules Galenica MA (Italy)
	Remarks of the Evaluator	
	Decision of 321 st meeting of Registration Board: Deferred for evidence of approval of applied formulation in 10ml fill volume in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275 th meeting.	
Firm has revised the formulation Each ml contains: Calcium chloride dihydrate 100 mg/ml, elemental calcium 27.2mg/ml 10 ml ampoule Firm has provided requisite R.S. 30,000/- (66755258596). Firm has provided RRA status of the product in MHRA. Remarks of evaluator: Evidence Me-too status (with strength and dosage form) could not ascertained		
Decision of 324th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee and stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting. Evaluation by PEC: (G.R application ID 645-vt2-3rwu) The firm has submitted form 5D along with the annexures. However, as per notification No.F.15-1/2022-PEC dated 18-10-2024, all those applications requiring stability data (applied on form 5 / Form 5D) for which stability data has not been submitted till 30th June, 2023 shall be considered as disposed of. (This has been decided by DRAP Authority in its 184th meeting). For the instant case, the Board directed the firm to submit the data in 324th meeting held on 24-26th January, 2023. The date mentioned on letter head is 27-08-2024.		
Decision: Rejected as the firm failed to submit the data within the notified time as per the decision of Registration Board.		
119.	Name and address of manufacturer /Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V,Hattar Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Phosmin tablet 667mg
	Composition	Each uncoated tablet contains: Calcium acetate monohydrate 667mg eq. to elemental calcium 169mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 (Duplicate dossier) Dy. No 12692 dated 24-05-2022 Rs.8000/- dated 14-06-2010 (photo copy) to be verified from R&I No R&I and challan of 12,000/- submitted

	Pharmacological Group	Phosphate binders
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO; As per SRO
	RRA status	USFDA approved (as coated tablet)
	Me-too status	Lophos tablet of M/s English pharma (084829)
	GMP status	
	Remarks of the Evaluator	Shortcomings: • Fee challan for 8000/- and challan and R&I of RS. 12,000/- are not attached • Section approval from CLB is required
Decision of 344 th meeting (31 st Dec 2024 to 2 nd January, 2025): Registration Board deferred the case for submission of original receipt for submission of fee of Rs. 8,000 and Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. Evaluation by PEC: The firm has submitted the reply vide General Request No. Y8T-TYB-B6A6. The firm has not provided original fee receipts of Rs. 8000/- and Rs. 12000/-. However, the firm has provided receipt No. 56180510572 of fee of Rs. 37000/- dated 15-04-2025.		
Decision: Rejected as the firm failed to submit original receipts of Rs. 8000/- and Rs. 12,000/- within the time as decided by Registration Board.		
120.	Name and address of manufacture / Applicant	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ulpr 5mg Tablet
	Composition	Each Uncoated Tablet Contains: Ulipristal Acetate...5mg
	Dairy No. date of R &I fee	Dy.No 14561 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	Pharmacological Group	Other sex hormones and modulators of the genital system Ulipristal acetate is indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.
	Type of form	Form 5
	Finished product specifications	The firm has claimed manufacturer's specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ulipristal Acetate 5 mg tablets (MHRA) Approved
	Me-too-status	Could not be confirmed
	GMP Status	Firm has submitted copy of GMP certificate issued based on inspection dated 03-04-2023.
Date of submission of stability study data: 04-05-2021		

Evaluation:

- Evidence of already registered product by DRAP / me-too status or else application on Form 5D along with balance fee.
- Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.
- Submit stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting, since the submitted data is scattered and does not contain the information as required in the checklist of 293rd meeting of Registration Board.

Decision of 333rd meeting:

Deferred for following submissions:

- Evidence of already registered product by DRAP / me-too status or else application on Form 5D along with balance fee.
- Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.
- Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.

Reply:

The firm has submitted the reply vide General request ID number WYU-UQ2-79ZT.

- Evidence of already registered product by DRAP / me-too status or else application on Form 5D along with balance fee. (Me too could not be verified)
- Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP. (Tablet Hormonal Section is approved)
- Submission of stability study data as per the 14 points checklist approved by Registration Board in its 293rd meeting.

STABILITY STUDY DATA

Manufacturer of API	(Ulipristal Acetate) M/s Kaifeng Pharmaceutical (Group) Company Limited, Henan Province, China.		
API Lot No.	Ulipristal Acetate: HF190626		
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton		
Stability Storage Condition	Real time: 30°C ± 2 °C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0,3, 6 (months)		
Batch No.	UP-01	UP-02	UP-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	13-02-2020	13-02-2020	13-02-2020
No. of Batches	03		

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Date of Submission		09-06-2021 (16007)
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.	Documents to Be Provided	Status
No.		
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 297 th meeting dated 12-12-14 th January, 2021, decided to approve registration of Dexlansoprazole 30mg & 60mg Capsule. Inspection date: 01-09-2020 . The report shows that: • Conclusion: On risk-based approach, the genuineness /authenticity of stability data submitted by the firm for registration of Wnsodex 30mg DDR capsule, Wnsodex 60mg DDR capsules is verifiable to satisfactory level. And the panel recommends grant of registration for the above-mentioned products.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Productmanufacturer.	1. Copies of COAs (Batch No. HF190626) of API (Ulipristal Acetate) from M/s Kaifeng Pharmaceutical (Group) Company Limited, Henan Province, China. and M/S Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	<u>Ulipristal Acetate</u> : Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(031180401, 031180402, 031180403)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u>For Ulipristal Acetae</u> : Firm has submitted copy of drug production license certificate dated 1-01-2021 in the name of M/s Kaifeng Pharmaceuticals (Group) Co., Ltd issued by FDA from Henan Province Valid till 31-12-2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	<u>For Ulipristal Acetae</u> : The firm has submitted copy of invoice No. 190722AL01 dated Sep/04/2019 from exporter M/s Kaifeng Pharmaceutical (Group) Company Limited, Henan Province, China. for import of 30 gm's of Ulipristal Acetate (Batch No. HF190625) in name of M/S Wnsfeild Pharma Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar Kpk, Pakistan attested by AD (I&E) DRAP Peshawar dated 17-09-2019.

7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	https://www.medicines.org.uk/emc/product/3951/smpc#gr ef Excipients are according to Innovator, hence Drug excipients compatibility studies not required.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of 03 Batches.
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution and PE studies have been performed against Esmya 5mg Tablets Manufactured by: (Gedeon pharma UK) Batch No: E-24810 Exp Date: 09/2026 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8).
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

Decision: Deferred for the submission of following points:-

- **Chromatograms of CDP and PE studies.**
- **Clarification regarding the dates and time mentioned on the submitted chromatograms are not similar with the date of manufacturing of stability batches and the dates of testing of different time points considering the date of manufacturing.**

Deferred cases of Form 5D:

121.	Name and address of manufacturer / Applicant	M/s. Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Dagli 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate...5mg
	Diary No. Date of R& I & fee	Form 5 Dairy No. 37592 dated 13-11-2018 Rs.20,000/- dated 17-10- 2018.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification

	Pack size & Demanded Price	Pack size and MRP as per SRO.	
	Approval status of product in Reference Regulator Authorities	Forxiga 5mg Tablet, Manufactured by Astrazenica Pharmaceuticals. (CDP performed with this product) USFDA AProved	
	Me-too status	Dapa 5mg tablet, by Hilton Pharmaceuticals Pvt Ltd.	
	GMP status	Not Submitted	
	Remarks of the Evaluator		
STABILITY STUDY DATA			
Drug	Dagli 5mg Tablet		
Manufacturer of API	Fuxin Long Rui Pharmaceuticals Co. Ltd. Address : Fluoride Industrial Park, Fuxin City, Liaoning Provonce, China.		
API Lot No.	DG-20201201-D03-DG06-01		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	044DS04	044DS05	044DS06
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy. No. 21855 dated 02-08-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted	

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) Batch No. DGDZ202101 from M/s. Fuxin Long Rui Pharmaceuticals, Fuxin city, Liaoning province, China. Firm has also submitted COA of the drug substance with batch number DG-20201201-D03-DG06-01 and manufacturing date 25-12-2020. (Manufacturer's Specification)
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-vvoice attached. Invoice No. HN21042601-H, Invoice cleared by DRAP Karachi office. Dated, 07-05-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
3.	Complete batch manufacturing record of three stability batches shall be submitted..
4.	Submit valid GMP certificate of M/s. Aspin Pharma (Pvt) Ltd.
5.	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.

Decision 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

The firm has submitted the reply vide CMS application ID EDT-LTH-V9TD.

Sr. No.	Observation	Reply by the firm
1	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	DML No. LIAO 20150233 valid till 17-11-2027 is submitted.
3	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted
4	Submit valid GMP certificate of M/s. Aspin Pharma (Pvt) Ltd.	GMP certificate issued on the basis of inspection conducted on

		30-05-2025.
5	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.	Mfg date: 12-2021 Dated of initiation: 14-01-2022 for all the 03 batches 24 months stability data is submitted
Decision: Approved with innovator's specifications. The firm shall submit applicable fee for revision of specifications from manufacturer's to innovator's specifications.		
122.	Name and address of manufacturer / Applicant	M/s. Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Dagli 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate...10mg
	Diary No. Date of R& I & fee	Form-5 Dairy No. 37593 dated 13-11-2018 Rs.20,000/- dated 17-10- 2018.
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01
	Type of Form	Form 5-D.
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	Pack size and MRP as per SRO.
	Approval status of product in Reference Regulator Authorities	Forxiga 10mg Tablet, Manufactured by Astrazenica Pharmaceuticals. (CDP performed with this product) USFDA approved.
	Me-too status	Dapa 10mg tablet, by Hilton Pharmaceuticals Pvt Ltd.
	GMP status	Not Submitted
	Remarks of the Evaluator	
STABILITY STUDY DATA		
Drug	Dagli 10mg Tablet	
Manufacturer of API	Fuxin Long Rui Pharmaceuticals Co. Ltd. Address : Fluoride Industrial Park, Fuxin City, iaoning Provonce, China.	
API Lot No.	DG-20201201-D03-DG06-01	
Description of Pack (Container closure system)	Alu-Alu Blister	
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%	
Time Period	Real time: 06 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)	
Batch No.	045DS04	045DS05
Batch Size	2500 Tablets	2500 Tablets
Manufacturing Date	12-2021	12-2021
Date of Initiation		
No. of Batches	03	
Date of Submission	Dy. No. 21856 dated 02-08-2022.	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		

Sr. No.	Documents to Be Provided	Status
1	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate) Batch No. DGDZ202101 from M/s. Fuxin Long Rui Pharmaceuticals, Fuxin city, Liaoning province, China. Firm has also submitted COA of the drug substance with batch number DG-20201201-D03-DG06-01 and manufacturing date 25-12-2020. (Manufacturer's Specification)
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 23-08-2023. Issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone. (Not acceptable to DRAP)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached. Invoice No. HN21042601-H, Invoice cleared by DRAP Karachi office. Dated, 07-05-2021.
7.	Protocols followed for conduction of stability study.	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Submitted
10.	Complete batch manufacturing record of three stability batches.	submitted
11.	Record of comparative dissolution data (where applicable)	Submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted 3 months stability data (Accelerated and Real time).
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Sr. No.	Observation	Reply by the firm

1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.	Complete batch manufacturing record of three stability batches shall be submitted..	
4.	Submit valid GMP certificate of M/s. Aspin Pharma (Pvt) Ltd.	
5.	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.	

Decision 344th meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings.
The firm has submitted the reply vide CMS application ID EDT-LTH-V9TD.

Sr. No.	Observation	Reply by the firm
1	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	DML No. LIAO 20150233 valid till 17-11-2027 is submitted.
3	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted
4	Submit valid GMP certificate of M/s. Aspin Pharma (Pvt) Ltd.	GMP certificate issued on the basis of inspection conducted on 30-05-2025.
5	Provide the date of initialization of accelerated and real time stability studies. (Not mentioned in your firm's provided data), Also submit 06 moth time point data of chromatograms, stability data sheets.	Mfg date: 12-2021 Dated of initiation: 14-01-2022 for all the 03 batches 24 months stability data is submitted

Decision: Approved with innovator's specifications. The firm shall submit applicable fee for revision of specifications from manufacturer's to innovator's specifications.

Haleema Shareef

122	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 22437 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	Terbiwen 250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine as HCl...250mg

	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Terbiderm Tablet by Atco
Evaluation by PEC-XV:		
S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substances performed by drug product manufacturer.
3.	3.2.P.2.1.2	Excipients against which you analyze the compatibility of API is not same to the excipients mentioned in section composition table of section 3.2. P.1.
4.	3.2.P.2.2.1	- Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor “f2” and discussing its results. - Justify how you have performed the pharmaceutical equivalence and comparative dissolution profiling of applied strength of 125mg tablet against the comparator product of higher strength i.e. terbiderm forte tablet.
5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
7.	3.2.P.8.3	- Provide a scientific rationale for using a 20 µl injection volume while performing the assay of the drug product, despite the USP monograph for Terbinafine tablets recommending a 5 µl injection volume in the chromatography system for assay. - Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet.
8.	3.2.R.1.1	☐ Justify the use of 281.31 mg/tablet and 140.64 mg/tablet of terbinafine base in the manufacturing of trial batches for the 250 mg and 125 mg terbinafine tablets, respectively. - Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR. - Similarly, Explain along with calculation that how can 168.77 mg of Terbinafine HCl is equivalent to 125 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of BMR.
123	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan

Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22431 dated 12-09-2023
Details of fee submitted	Rs.30,000/- dated 10-07-2023
The proposed proprietary name / brand name	Terbiwen 125mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine as HCl... 125mg
Pharmacotherapeutic Group of (API)	Antifungal
Reference to Finished product specifications	USP specification
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved
For generic drugs (me-too status)	Terbiderm Tablet by Atco

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substances performed by drug product manufacturer.
3.	3.2.P.2.1.2	Excipients against which you analyze the compatibility of API is not same to the excipients mentioned in section composition table of section 3.2.P.1.
4.	3.2.P.2.2.1	- Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results. - Justify how you have performed the pharmaceutical equivalence and comparative dissolution profiling of applied strength of 125mg tablet against the comparator product of higher strength i.e. terbiderm forte tablet.
5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2. P.6.
7.	3.2.P.8.3	- Provide a scientific rationale for using a 20 µl injection volume while performing the assay of the drug product, despite the USP monograph for Terbinafine tablets recommending a 5 µl injection volume in the chromatography system for assay. - Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet.
8.	3.2.R.1.1	☐ Justify the use of 281.31 mg/tablet and 140.64 mg/tablet of terbinafine base in the manufacturing of trial batches for the 250 mg and 125 mg terbinafine tablets, respectively.

		- Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR. - Similarly, Explain along with calculation that how can 168.77 mg of Terbinafine HCl is equivalent to 125 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of BMR.

Response of firm for Terbiwin 250mg Tablet and Terbiwin 125mg Tablet:

Sr. No	Section Number	Observations	Reply of Firm
1	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance/Active Pharmaceutical Ingredient by drug product manufacturer.	The complete specifications and analytical procedures used for routine testing of the Drug substance is attached in Annexure-A
2	3.2.S.4.3	Submit analytical method verification report of both drug substances performed by drug product manufacturer.	Complete analytical method verification report is attached in Annexure- B
3	3.2.P.2.1.2	Excipients against which you analyze the compatibility of API is not same to the excipients mentioned in section composition table of section 3.2.P.1.	The compatibility study and formulation is revised attached in Annexure- C
4	3.2.P.2.2.1	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor “f2” and discussing its results.	The comparative dissolution profile (CDP) test in four medias i.e. 1. 0.1N HCl, 2. Acetate buffer pH 4.5 3. Phosphate Buffer pH= 6.8 4. Citrate Buffer pH (USP buffer) = 3 is studied at different time intervals i.e. 5, 10, 20, 30, 45 and further complete details is also attached in Annexure – D.
		Justify how you have performed the pharmaceutical equivalence and comparative dissolution profiling of applied strength of 125mg tablet against the comparator product of higher strength i.e. terbiderm forte tablet.	The product Terbiwin 250 mg tablet was compared against terbiderm fort 250mg (innovators). The terbiderm product complete detail (unit carton along with Batch No., Mfg. Date, Exp. Date) is provided through Pictorial Evidence attached in Annexure– E.

5	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.	The product is compared against innovators Specs, the retention time of our product and innovators product both are the same. There is no retention time mentioned in the USP monograph for terbinafine HCl. The recommended retention time is for risperidone instead of terbinafine (Active ingredient in Terbiwin 250mg). To evidence this		
			justification USP monograph is also attached in Annexure – F		
6	3.2.P.6	☐ Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.	Attached in Annexure-G		
7	3.2.P.8.3	☐ Provide a scientific rationale for using a 20 µl injection volume while performing the assay of the drug product, despite the USP monograph for Terbinafine tablets recommending a 5 µl injection volume in the chromatography system for assay.	Our HPLC system has fixed loop size i.e. 20µL, so, as per this condition we cannot adjust our injection volume at 5µL. The area of standard and sample increases three-times with 20µL injection volume. The retention time of both i.e. standard and sample (both) are same. Change in injection volume has no effect on system suitability (RSD, Flow rate, tailing factor and theoretical plate).		
8		☐ Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet	The concentration of standard and sample solutions for dissolution of 125mg and 250mg are the same.		
			Terbiwin 125mg Tablet		
			Solution	Dilution	Concentration
			Standard	25mg/50ml×1ml/50ml	0.01mg/mL
			Sample	125mg/500ml×1ml/25ml	0.01mg/mL
			Terbiwin 250mg Tablet		
			Solution	Dilution	Concentration
			Standard	25mg/50ml×1ml/50ml	0.01mg/mL
			Sample	250mg/500ml×1/50ml	0.01mg/mL
			3.2.R.1.1	☐ Justify the use of 281.31 mg/tablet and 140.64 mg/tablet of terbinafine base in the manufacturing of trial batches for the 250 mg and 125 mg terbinafine tablets, respectively.	We use 281.3mg of terbinafine base in the manufacturing of trial batches of 250 mg because 281.3mg of terbinafine is equivalent to 250mg of terbinafine as HCl (Terbinafine Factor = 1.125)
	☐ Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR.	Mistakenly written, Terbinafine Factor = 1.125 For Terbiwin 125 mg Tablet Terbinafine base = 140.64 Terbinafine HCl =125 ×1.125 =140.64mg			

		☐ Similarly explain along with calculation that how can 168.77mg of terbinafine HCl is equivalent to 125mg of terbinafine base, since you have mentioned the same quantity of active ingredient in composition tablet of BMR.	For Terbiwin 250 mg Tablet Terbinafine base = 281.3 Terbinafine HCl = $250 \times 1.125 = 281.3\text{mg}$ The amount of terbinafine HCl is correct and formulation is already attached in C.

Decision:

Registration Board deferred the case for product specific inspection of Terbiwin 250mg Tablet and Terbiwin 125mg Tablet for verification of authenticity of submitted stability studies data especially with reference to following points:-

Querries	Reply of Firm		
Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet.	The concentration of standard and sample solutions for dissolution of 125mg and 250mg are the same.		
	Terbiwin 125mg Tablet		
	Solution	Dilution	Concentration
	Standard	25mg/50ml×1ml/50ml	0.01mg/mL
	Sample	125mg/500ml×1ml/25ml	0.01mg/mL
	Terbiwin 250mg Tablet		
	Solution	Dilution	Concentration
	Standard	25mg/50ml×1ml/50ml	0.01mg/mL
	Sample	250mg/500ml×1/50ml	0.01mg/mL
Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR.	Mistakenly written Terbinafine Factor = 1.125 For Terbiwin 125 mg Tablet Terbinafine base = 140.64 Terbinafine HCl =125 ×1.125 =140.64mg		
Similarly explain along with calculation that how can 168.77mg of terbinafine HCl is equivalent to 125mg of terbinafine base, since you have mentioned the same quantity of active ingredient in composition tablet of BMR.	Mistakenly written For Terbiwin 250 mg Tablet Terbinafine base = 281.3 Terbinafine HCl =250 ×1.125 =281.3mg		

Saima Hussain

124.	Name, address of Applicant / Marketing Authorization Holder	Macter International Limited, F-216, S.I.T.E., Karachi.
	Name, address of Manufacturing site.	Macter International Limited, F-216, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23477 dated 22-09-2023
Details of fee submitted	PKR 30,000/- dated 11-08-2023 Challan / Receipt # 18431433 PKR 45,000/- dated 05-03-2024 Challan / Receipt # 605866247
The proposed proprietary name / brand name	ENDOGOLIX 150mg Tablets
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium 155.20 mg equivalent to Elagolix ... 150 mg
Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
Reference to Finished product specifications	Innovator's Specifications
The status in reference regulatory authorities	ORILISSA 150mg Tablets of M/s AbbVie USFDA approved.
For generic drugs (me-too status)	N/A
Proposed Pack size	7's, 14's and 28's
Proposed unit price	As per SRO

Decision of 343rd Meeting: The Registration Board deferred the case for submission of response to the cited shortcomings.

Evaluation by PEC (XXI):

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

Sr. No.	Observations	Firm's response
i.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP is from Jiaying Pharmaceutical Association, which is not the relevant authority for issuance of GMP Certificate.	Not submitted. Statement for non-issuance of GMP Certificate has been submitted.
ii.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-621272281258.	Clearance Certificate has not been submitted. Firm has again submitted Form 6 No. K-621272281258, for which the Clearance Certificate was requested.
iii.	3.2.S.7.1 Long Term Stability Study of API has been conducted at 30±2°C, 60±5% RH instead of 65±5% RH. Please justify.	Firm have submitted revised 3.2.S.7.1 Long Term Stability Studies Data of API conducted at 30±2°C, 65±5% RH.

Decision of 345th meeting of Registration Board:

Deferred for submission of following documents:-

- API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin
- Evidence of DRAP (I&E) Clearance / Procurement against Form 6 No. K-621272281258.

Response of the Firm:

API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin:

Firm submitted the Drug Manufacturing License issue dated 14th May, 2025 which is valid till 17th April, 2030.

Evidence of DRAP (I&E) Clearance / Procurement against Form 6 No. K-621272281258:

Firm submitted the good declaration certificate and commercial invoice mentioned the name of exporter only i.e. ECHEMI GLOBAL CO., LIMITED.

Decision: The Registration Board deferred the instant application for submission of the API procurement documents(DRAP attested commercial invoice, good declaration certificate) including the name of the API manufacturer.

125.	Name, address of Applicant / Marketing Authorization Holder	Macter International Limited, F-216, S.I.T.E., Karachi.
	Name, address of Manufacturing site.	Macter International Limited, F-216, S.I.T.E., Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 24552 dated 09-10-2023
	Details of fee submitted	PKR 30,000/- dated 11-08-2023 Challan / Receipt # 8749704588 PKR 45,000/- dated 05-03-2024 Challan / Receipt # 991985498179
	The proposed proprietary name / brand name	ENDO GOLIX 200mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix ... 200mg
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ORILISSA 200mg Tablets of M/s AbbVie USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	7's, 14's and 28's
	Proposed unit price	As per SRO

Decision of 343rd Meeting: The Registration Board deferred the case for submission of response to the cited shortcomings.

Evaluation by PEC (XXI):

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

Sr. No.	Observations	Firm's response
i.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP is from Jiaying Pharmaceutical Association, which is not the relevant authority for issuance of GMP Certificate.	Not submitted. Statement for non-issuance of GMP Certificate has been submitted.
ii.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-621272281258.	Clearance Certificate has not been submitted. Firm has again submitted Form 6 No. K-621272281258, for which the Clearance Certificate was requested.
iii.	3.2.S.7.1 Long Term Stability Study of API has been conducted at 30±2°C, 60±5% RH instead of 65±5% RH. Please justify.	Firm have submitted revised 3.2.S.7.1 Long Term Stability Studies Data of API conducted at 30±2°C, 65±5% RH.

Decision of 345th meeting of Registration Board:

Deferred for submission of following documents: -		
a) API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin		
b) Evidence of DRAP (I&E) Clearance / Procurement against Form 6 No. K-621272281258.		
Response of the Firm:		
API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin:		
Firm submitted the Drug Manufacturing License issue dated 14 th May, 2025 which is valid till 17 th April, 2030.		
Evidence of DRAP (I&E) Clearance / Procurement against Form 6 No. K-621272281258:		
Firm submitted the good declaration certificate and commercial invoice mentioned the name of exporter only i.e. ECHEMI GLOBAL CO., LIMITED.		
Decision: The Registration Board deferred the instant application for submission of the API procurement documents (DRAP attested commercial invoice, good declaration certificate) including the name of the API manufacturer.		
126.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26383: 01-11-2023
	Details of fee submitted	PKR 30,000/- : 961773622
	The proposed proprietary name / brand name	Formeco 500mcg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sugar Coated Tablet Contains: Mecobalamin...500µg
	Pharmacotherapeutic Group of (API)	Vitamin B12 (cyanocobalamin and analogues)
	Reference to Finished product specifications	JP Specifications
	The status in reference regulatory authorities	Neumethocol 500mcg Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vitobal 500mcg Tablet by Xenon Pharma. (Reg.No. 113718).
	Proposed Pack size	As per SRO
Evaluation by PEC (No.XXIII):		
Serial No.	Module/ Section	Shortcomings
1.	1.3.5	GMP report of applicant generated against inspection conducted in the last three years shall be submitted.
2.	3.2.P.8	Valid GMP and DML of API manufacturer (M/s Mahima Life Sciences, India) shall be submitted.
3.	---	Executed BMRs of stability batches shall be submitted.
Remarks of Evaluator:		

Decision of 343rd meeting of Registration Board : Deferred for satisfactory response to afore-mentioned shortcomings.

Response of the Firm:

Sr.no.	Observations	Response of the Firm
1.	GMP report of applicant generated against inspection conducted in the last three years shall be submitted.	Firm in their reply stated that “We would like to bring into your kind attention of that, subsequent to the issuance of our Drug Manufacturing License (DML) on dated 22-02-2021, we have not initiated any production activities. Notably, our initial registration letter was received on March 26, 2025. Prior to this, on March 14, 2025, we formally submitted a request for a Good Manufacturing Practice (GMP) inspection to the competent authority, a copy of which is enclosed herein. Unfortunately, the inspection has not been conducted to date and which is expected in next week. We wish to reiterate our unwavering commitment to adhering to GMP requirements and standards. We hereby undertake to submit the GMP inspection report/certificate upon completion of the inspection. Furthermore, we declare our intention to commence production operations only after the successful completion of the GMP inspection and receipt of the requisite certification.
2.	Valid GMP and DML of API manufacturer (M/s Mahima Life Sciences, India) shall be submitted.	Firm submit the GMP Certificate of API manufacturer (M/s Mahima Life Sciences, India) issued by Food & Drug Administration of Haryana and valid for 22-02-2029.
3.	Executed BMRs of stability batches shall be submitted.	Firm submit the BMRs of stability batches.

Decision: Approved.

127.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals, Plot # K/201, SITE, Super Highway Phase-II, Karachi.
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot # K/201, SITE, Super Highway Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000924) granted w.e.f. 22-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.2-3/2016-Lic dated 14 th June, 2021 for grant of DML specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15013 dated 14 JUN 2023
	Details of fee submitted	PKR 30,000/- dated 08-06-2023 (Fee Challan / Receipt # 89982021416).
	The proposed proprietary name / brand name	MOXINE 400mg Tablet
	Strength / concentration of drug of Active	Each Film Coated Tablet contains:

Pharmaceutical ingredient (API) per unit	Moxifloxacin as Hydrochloride..... 400mg (BP Specifications)
Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
Pharmaceutical form of applied drug	Oral Film Coated Tablet
Reference to Finished product specifications	BP
Proposed Pack size	5's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Avelox® 400mg Tablet by M/s Bayer Pharms, USA (USFDA approved).
For generic drugs (me-too status)	Moxiget 400mg Tablet (Reg. No. 047117) by M/s Getz Pharma, Karachi.
Name and address of API manufacturer.	M/s Shanku's Pharmaceuticals, Plot No. 9, 10, 11 Milan Industrial Estate, Vadsar Road, At Santej, Kajol- 382 721, District Gandhinagar Gujrat India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 Months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Avelox 400mg Tablet by Bayer Corporation.

		Firm has submitted CDP results of their product against the innovator's product Avelox 400mg Tablet in 3 dissolution media.	
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
STABILITY STUDY DATA			
Manufacturer of API	M/s Shanku's Pharmaceuticals, Plot No. 9, 10, 11 Milan Industrial Estate, Vadsar Road, At Santej, Kajol- 382 721, District Gandhinagar Gujrat India.		
API Lot No.	MOX21085		
Description of Pack (Container closure system)	Alu/Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MX-001	MX-002	N/A
Batch Size	5,000 Tablets	5,000 Tablets	N/A
Manufacturing Date	05-2022	05-2022	N/A
Date of Initiation	05/2022	05/2022	N/A
No. of Batches	02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. 2072077) dated 01-07-2020 issued by Commissioner Foods & Drug Control Administration, India. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial Invoice No. EXP/151 (20-21) dated 22-08-2021 cleared on 18-11-2021 by AD (I&E) DRAP, Karachi, specifying 04Kgs of Moxifloxacin Hydrochloride.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted. The Firm have mentioned that their HPLC system is not 21 CFR compliant.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Remarks of Evaluator: The following deficiencies / shortcomings have been communicated to the firm: -			

- i. Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as “M/s Fortune Pharmaceuticals” as well as “M/s Fortune Pharma (Pvt.) Ltd.” in your application dossier on separate instances.
- ii. Please provide Commitments / Undertakings as required vide Sections 1.5.15 – 1.5.20 of CTD application.
- iii. Please provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3, as required vide section ‘2.3.R.1.1 Executed Production Documents’.
- iv. Please provide evidence of Reference / Innovator’s pack used for Pharmaceutical Equivalence and CDP.
- v. Please provide calculations summary regarding utilization of 4Kgs of Moxifloxacin Hydrochloride (including but not limited to Production of Stability Batches / QC Testing / RND / Process loss etc.).

Decision of 330th Meeting:

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

Evaluation by PEC (XXI):

Sr. No.	Shortcomings	Firm’s response
i.	Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as “M/s Fortune Pharmaceuticals” as well as “M/s Fortune Pharma (Pvt.) Ltd.” in your application dossier on separate instances.	Topographical error The name of the Firm is Fortune Pharmaceuticals.
ii.	Please provide Commitments / Undertakings as required vide Sections 1.5.15 – 1.5.20 of CTD application	Not submitted. Commitments / Undertakings with Signatures / Seal has still not been submitted.
iii.	Please provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3, as required vide section ‘2.3.R.1.1 Executed Production Documents’	Not submitted.
iv.	Please provide evidence of Reference / Innovator’s pack used for Pharmaceutical Equivalence and CDP	Not submitted.
v.	Please provide calculations summary regarding utilization of 4Kgs of Moxifloxacin Hydrochloride (including but not limited to Production of Stability Batches / QC Testing / RND / Process loss etc.).	Not submitted.

Decision of 340th meeting of Registration Board:

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

Sr. No.	Shortcomings	Firm’s response
i.	Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as “M/s Fortune Pharmaceuticals” as well as “M/s Fortune Pharma (Pvt.) Ltd.” in your application dossier on separate instances.	Firm in their reply give clarification that “As identified by your good office, there was a Drafting mistake in mentioning the applicant firm name. The firm name is Fortune Pharmaceuticals. The DML & GMP certificate is enclosed as Annexure I , where the firm name could be verified.
ii.	Please provide Commitments / Undertakings as required vide Sections 1.5.15 – 1.5.20 of CTD application	Submitted

	iii.	Please provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3, as required vide section '2.3.R.1.1 Executed Production Documents'	Initially, the firm claimed that it manufactured two stability batches with a batch size of 5,000 tablets each. However, the submitted Batch Manufacturing Records (BMRs) reveal that the firm actually manufactured two stability batches with a batch size of 4,000 tablets each. This does not meet the requirement for two batches as per the CTD guidance document, which specifies a minimum batch size of 5,000 units per batch..
	iv.	Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence and CDP	Firm submitted the snapshot of reference product.
	v.	Please provide calculations summary regarding utilization of 4Kgs of Moxifloxacin Hydrochloride (including but not limited to Production of Stability Batches / QC Testing / RND / Process loss etc.).	The firm submitted the calculation indicating that two batches of 4,000 tablets each require 1.7452 kg of API per batch, and a total of 3.490 kg of API was utilized to manufacture both batches.
Decision: The Registration Board rejected the application because the firm did not meet the batch size requirements specified in the CTD guidance for stability studies. For oral solid dosage forms, a minimum of 5000 units per batch is required when developing two stability batches; however, the applicant developed two batches of 4,000 units each, which does not comply with the recommended batch size criteria.			
128.	Name, address of Applicant / Marketing Authorization Holder		Surge Laboratories (Pvt.) Ltd., 10 th Km, Faisalabadroad, Bikhi District, Sheikhupura Pakistan
	Name, address of Manufacturing site.		Surge Laboratories (Pvt.) Ltd., 10 th Km, Faisalabadroad, Bikhi District, Sheikhupura Pakistan
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer		Firm has submitted copy of GMP certificate dated 05-04-2022 based on inspection conducted on 05-10-2021
	Evidence of approval of manufacturing facility		Firm has submitted copy of letter No. F. 1-18/95-Lic(Vol-III) dated 11-01-2022 which specifies Dry powder injectable (cephalosporin)
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission		Dy. No. 25815 dated 13-09-2022
	Details of fee submitted		Rs.30,000/- dated 27-07-2022 (Deposit slip#38543763329)
	The proposed proprietary name / brand name		XTRAZID-AV 2g/0.5g Powder for solution for infusion

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime.....2g Avibactam sodium eq. to avibactam 0. 5g
Pharmaceutical form of applied drug	Intravenous infusion
Pharmacotherapeutic Group of (API)	Ceftazidime belongs to the group of antibiotics called "cephalosporin" Avibactam is "beta-lactamase inhibitor"
Reference to Finished product specifications	Innovators Specs.
Proposed Pack size	20ml vial of sterile dry for injection + 1 ampoule of 10ml Sterile Water for Injection to make 12ml clear solution in a single pack
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion MHRA Approved Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion TGA Approved AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved
For generic drugs (me-too status)	Zavicefta Injection 2g/0.5g (Powder for Concentrate for Solution for Infusion) by M/s Pfizer Pakistan Ltd (Reg#106848)
Name and address of API manufacturer.	M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District, Chifeng, Inner Mongolia, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing
	process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (180601, 180602, 180603)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drugproduct.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Zavicefta 2g/0.5g Powder forsolution for infusion IV by M/s Pfizer Limited., by performing quality tests (Description, pH, Sterility test and Assay).		
	Analytical method validation/verificationof product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China		
API Lot No.		2105001		
Description of Pack (Container closure system)		20ml clear glass vial tubular USP Type-I		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		CFA-2.5-001	CFA-2.5-002	CFA-2.5-003
Batch Size		15 vials	15 vials	15 vials
Manufacturing Date		17-8-2021	24-9-2021	24-9-2021
Date of Initiation		10-2022	10-2022	10-2022
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of thefirm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate ofAPI manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zoneof Hongshan District , Chifeng, China issued by		
		China Food and Drug Administration valid upto 21- 02-2022. Firm has also submitted copy of DML (certificate No#Nei20160028) in in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street,Economic development zone of Hongshan District , Chifeng, China valid upto 27-12-2025.		

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 17-06-2021 for import of 300gm of Avibactam and Ceftazidim sterile (Batch#2105001) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021. Firm has also submitted copy of form 6 dated 09-07-2021 for import of 300gm of Avibactam and Ceftazidim sterile powder (1:4) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Manual data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator ^{XI} : Letters of deficiency sent on 19 th May 2023 and reminder on 25 th August 2023 but no reply received		
Section	Observations	
1.5.10	Clearly mention the dosage form of applied drug	
1.6.5	Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	
2.3.R.1	- Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life - Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories. - Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product	
3.2.S.4	- Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance - Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume (20ul), flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance - Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	
3.2.P.1	Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	
3.2.P.2	Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit, particulate matter, water content, and bacterial endotoxins)	

3.2.P.5	- Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product review document - The limits of pH test for drug substance by drug product manufacturer was 5.5-7.5 while limits of pH test for drug product by drug product manufacturer was 5-7.5, clarify - Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document	
3.2.P.8	- Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document - Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 as august instead of October in in-use stability study	
Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings		
Response of firm:		
Section	Deferment Reason	Response of Firm
1.5.10	Clearly mention the dosage form of applied drug	Corrected dosage form according to innovator literature as Intravenous injection in section 1.5.10.
1.6.5	Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	- The firm submitted that after the amendment of the Drug Administration Law (DAL) of the People's Republic of China, the requirement for GMP has been abolished, and China no longer issues GMP certificates. The declaration by the National Medical Drugs Administration is submitted - Firm has also submitted copy DML# 20160028 of M/s Chifeng Addisun Pharmaceutical Co.,Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China valid upto 27- 12- 2025
2.3.R.1	Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelflife	- The firm submitted that Ceftazidime 2.0gm + Avibactam 0.5gm sterile ready-to-fill pre-mixed powder material provided by manufacturer to be filled in aseptic conditions and no formulation and manufacturing procedure (instead of aseptic filling) is involved, on the basis of this risk assessment we can rely on the stability studies (attached) provided by the manufacturer according to ICH Zone IVA conditions. - On the basis of above declaration, we have designed trials quantity as minimum as possible to do the necessary testing/studies. However, we commit to provide complete testing of Finished product till shelf life for commercial batches. - Three batches each of 15 vials were prepared to conduct testing upto 06 months for stability
		studies on the above mentioned rationale with necessary test studies. Justification letter and Undertaking is submitted

	Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories.	- The firm submitted that as per manufacturer COA of drug substance % potency of Ceftazidime as pentahydrate is 64.80% and Avibactam as sodium is 16.80% while on testing by Drug product manufacturer results obtained for Ceftazidime pentahydrate is 60.99% and Avibactam as sodium is 15.75% on as is basis. So the dispensed quantity of drug substance taken is 49.185gm/batch by considering 60.99% assay. <u>Calculation of proposed weight on the basis of Ceftazidime potency:</u> Assay of Ceftazidime (On as is basis) = 60.99% Fill weight = label claim x 100/ Assay % (on as such basis) = $2000 \times 100 / 60.99 = 3279 \text{mg/vial}$ <u>Calculation of proposed weight on the basis of Avibactam potency</u> Assay of Avibactam on as is basis = 15.75% Fill weight = label claim x 100/ Assay % (on as such basis) = $500 \times 100 / 15.75 = 3174 \text{mg/vial}$ - Fill weight of Ceftazidime + Avibactam injection has been selected 3279mg/vial to calculate the batch size which is maximum of both and have both API > 100%. - Justification letter is submitted
	Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product	Content of Sodium bi carbonate in premixed drug substance are not different as recommended by innovator product. Justification letter for the same is submitted.
3.2.S.4	- Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance - Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume (20ul), flow rate than that recommended by drug	- The firm submitted that we have done analytical method validation on our In-House method as per ICH Q2(R1) guidelines use in API testing. Since the API is non-compendia so our In-House validated method is also applicable for testing of API - Changes are made due to better elution of both API's. - Justification letter is submitted

	substance	
	manufacturer for assay of ceftazidime drug substance Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	- The firm submitted that test for particulate matter, bacterial endotoxin and sterility were performed on API but not reported in chemical test results. In-House COA as separate reports were generated by microbiology department which are submitted. - However, since this material was sterile ready to fill material and no addition of excipients or formulation has been carried at our site, so tests for content uniformity and pyridine content were performed on finished product testing. At API testing stage these tests were taken from API manufacturer COA. - Revise API COA is submitted.
3.2.P.1	Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	- The powder for Injection Ceftazidime 2gm+Avibactam 0.5gm is required to be reconstituted with 10ml of Water For Injection prior to mix with intravenous infusion. - Type of Diluent Used for Reconstitution: Water For Injection 10ml Filled in 10ml glass ampoule USP Type-I. - Composition: Each 10ml ampoule contains 10ml of Sterilized Water For Injection [BP Specs.] - Regulatory Status in Pakistan: This diluent (Water for Injection 10ml) having Drug Registration Number:026762 which will be provided with the applied drug product for registration
3.2.P.2	Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit, particulate matter, water content, and bacterial endotoxins)	- The firm submitted that we have again conducted pharmaceutical equivalence studies including complete testing of drug product manufactured by us and the innovator product. - Updated Pharmaceutical Equivalence studies with complete testing is submitted
3.2.P.5	- Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product review document - The limits of pH test for drug substance by drug product manufacturer was 5.5-7.5 while limits of pH test for	- The firm submitted that we have previously revised Finished Product Specifications mentioning all test as per innovator product review document including test for pyridine content and water content. - Updated Finished Product Specifications are submitted. - The firm submitted that the limits of pH for drug substance by API manufacturer was 5.5 – 7.5, while we have mentioned pH range 5.0 – 7.5 in submitted product specifications. It was a

	drug product by													
	drug substance manufacturer was 5-7.5, clarify	typographical error while compiling product specifications. The pH range 5.5 – 7.5 is the actual and all of our pH results provided in the submitted documents are in the range of 5.5 - 7.5. We have made necessary corrections in the specifications and related documents. • pH Data of All Trial Batches of Ceftazidime 2gm + Avibactam 0.5gm Injection and Reference Product is given below: <table><tr><th>Batch</th><th>Results</th></tr><tr><td>Innovator Batch</td><td>6.46</td></tr><tr><td>Trial Batch CFA-2.5-001</td><td>6.45</td></tr><tr><td>Trial Batch CFA-2.5-002</td><td>6.60</td></tr><tr><td>Trial Batch CFA-2.5-003</td><td>6.51</td></tr><tr><td>Trial Batch CFA-2.5-004</td><td>6.72</td></tr></table> • Above data shows that pH of the trial samples and innovator sample is comparable and well within the range (5.5 – 7.5).	Batch	Results	Innovator Batch	6.46	Trial Batch CFA-2.5-001	6.45	Trial Batch CFA-2.5-002	6.60	Trial Batch CFA-2.5-003	6.51	Trial Batch CFA-2.5-004	6.72
Batch	Results													
Innovator Batch	6.46													
Trial Batch CFA-2.5-001	6.45													
Trial Batch CFA-2.5-002	6.60													
Trial Batch CFA-2.5-003	6.51													
Trial Batch CFA-2.5-004	6.72													
	• Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document	• The firm submitted that we have manufactured another trial batch, Batch No: CFA-2.5-004 and complete testing was performed on said batch. • COA of said batch and justification letter is submitted.												
3.2.P.8	• Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document • Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA- 2.5-003 as august instead of October in in-use stability study	• Same justification letter as above. • The firm submitted that manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 was September 2021. Date mention on the report of In-Use stability studies as August is a typo- error. Corrected document /report is submitted												

Decision of 333rd meeting of Registration Board:

Deferred for submission of following:

- Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Justification of the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life
- Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance
- Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance
- Justification for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document.
- Justification for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document

Response of the Firm:

Sr.no.	Shortcomings	Response of the Firm
1.	Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm submitted the fee of Rs. 9400 in the head of pre-registration variation.
2.	Justification of the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	Firm replied that three new batches were manufactured having batch size of 250 vials sufficient enough to perform complete stability studies till shelf life of product.
3.	Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance	The chromatographic conditions and Method of Analysis used in analytical studies for AvibactAm drug substance and Ceftazidime drug substance by drug product manufacturer is same as provided by Drug substance manufacturer. Monograph of Drug Substance Manufacturer and Drug Product Manufacturer and comparison of chromatographic condition are submitted.
4.	Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance	
5.	Justification for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document.	Firm replied that Complete testing covering the test for description on reconstitution, reconstitution time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document has been performed. However, firm has submitted only the stability sheets without any supporting documents and BMR.

6.	Justification for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document	Complete testing covering the test for description on reconstitution, reconstitution time, pyridine content, water content, and particulate matter in stability study by drug product manufacturer as recommended by innovator product review document has been performed.

Decision: Registration Board deferred the product for submission of the BMR of new developed stability batches, Raw data sheets, Chromatograms and the procurement documents of API.

Previously Deferred Case of Finished Import:

129.	Name, address of Applicant / Importer	M/s. Hospital Supply Corporation
	Details of Drug Sale License of importer	License No:0013 Address: 42, Darul Aman Housing Society, Karachi Address of Godown: 46-E-2, Block-6, PECHS, Karachi Validity: 29-06-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	BIEM Ilac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey
	Name, address of manufacturer(s)	Mefar Ilac San A.S. Ramazanoglu Mahalles Ensar Caddesi No.2 Istanbul Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.2021/3007) dated 01-10-2021 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. <u>The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-10-2023.</u>
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from BIEM Ilac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey. The letter species that the manufacturer appoints M/s. Hospital Supply Corporation to register their products in Pakistan. The authorization letter is valid till 31-12-2024.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging

	☐ Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy.no.3416 Date: 04-02-2022
Details of fee submitted	PKR 150,000/ dated: 28-09-2021
The proposed proprietary name / brand name	Biemexol 350mgI/ml vial (100ml)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Iohexol.....755mg/ml (755mg Iohexol equivalent to 350mg I)
Pharmaceutical form of applied drug	Injectable
Pharmacotherapeutic Group of (API)	X-Ray Contrast Media
Reference to Finished product specifications	In-house specification/USP
Proposed Pack size	100ml vial
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved.
For generic drugs (me-too status)	Not confirmed in 100ml filled volume
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejiang Province Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 36 months. Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejiang Province Batch no. H18920080501, H18920080502, H18920080503 Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China Batch no.

		C006-0802003, C006-0802004, C006-0802005
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile		Pharmaceutical Equivalence established against Omnipaque 350mgI/ML Vial (100ml)
Analytical method validation/verification of product		Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product		Colorless type I Glass vial (100ml), bromobutyl closure, blue tear off cap
Stability study data of drug product, shelf life and storage conditions		Firm has submitted stability study data of 2 batches of 50ml. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

INDICATIONS AND USAGE:

OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen.

DOSAGE AND ADMINISTRATION:

The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings along with Response of the Firm
1.		Submit valid drug sale license of importer Hospital supply corporation, since the submitted DSL was expired on 29-06-2022. Firm submitted the copy of valid DSL issued in the name of M/s. Hospital Supply Corporation 42, Darul Aman Housing Society, Karachi (DSL no. 0237) and validity granted till 29/06/2024.
2.		According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard. Firm submit the explanation letter from Product License holder i.e. BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey, in which it is stated that “during pharmaceutical development and first application in country of origin, first DMF of API supplier Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China was in compliance of USP. Accordingly, batch formula was established according to USP specifications. Lately, starry pharmaceutical has update their specifications according to EP specifications and get approval for CEP. Biem has applied for CEP submission variation in 03-08-2016 and get approval for variation in 10.10.2016. Firm submitted the copy of variation letter issued from Turkish Medicines and Medical Agency for the approval of updated European Pharmacopeia certificate of conformity. However, the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug

		product manufacturer as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required”. Firm submit the specification table of drug substance which did not include the test of related substance, test of free aromatic amine, test of iodide and test of ionic compounds as per BP monograph. Further, firm submitted the analytical procedure used for routine testing of drug substance.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that <i>“Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted”</i>. Since you have submitted the validation report of drug substance manufacturer. Not submitted the requisite information instead submit the verification report of Bacterial Endotoxin test..
5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers. Firm replied that the parameter such as ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test are not susceptible to change during storage and are not likely to influence quality, safety and efficacy of iohexol, so they did not perform them in stability study. However, these test are included in the specification of API and also the part of BP monograph of API iohexol , further the shelf life specification may related to widened the limit of specifications but the critical test may remain same both in release specification and shelf life specification.
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product. - Product license holder replied that Product was developmental batches manufactured in non-sterile R&D Laboratory, because of this sterility test and bacterial endotoxin test was not performed. - Further, excipients used for manufacturing of Biemexol are standard excipient used in injectable solutions. Iohexol is very soluble in water. Trometamine dissolves in water and it is used for increasing solubility in our formulation. Therefore, particulate matter test was not performed in the developmental phase. - In the formulation of the drug product, the only source for free iodine is the API Iohexol. According to the analysis results (lower than 10 PPM) obtained from CoA of API, the free iodine was evaluated as low risk for effecting of product quality. Therefore, free iodine was not performed during the development phase. Also, it is confirmed by stability data that active ingredient has not got negative effects on free iodine and stability. However, test of free iodine, particulate matter, sterility and bacterial endotoxin test are the part of both BP and USP monograph.
7.	3.2.P.5.1	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Firm replied that for specifications which limits given In-house methods as related substances, assay and density-analysis methods are established following the USP monographs. Firm replied that for assay release and shelf life specification of Biemexol 350mg I/ml vial containing solution for IA, IV injection are proposed as 90%-110% according to the results obtained from analytical results of development batches, validation batches and reference product.

		However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.																																											
8.	3.2.P.5.1	Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%. Firm replied that the assay release and shelf life specifications of Biemexol 350mgI/ml vial containing solution for IA, IV Injection are proposed as 90.0%-110% according to the results obtained from analytical results of developmental batches, validation batches and reference product. However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.																																											
9.	3.2.P.8	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Submit the stability data of drug product of 100ml filled volume vials since you have submitted the data of 50ml and 200ml only. Firm claimed that they applied bracketing for BIEMEXOL 350mgI/100ml SOLUTION FOR Injection. The applied Bracketing Plan is as under: <table><tr><th colspan="2">Strength</th><th colspan="3">BIEMEXOL 350mgI/ml solution for Injection</th></tr><tr><th colspan="2">Batch</th><th>1</th><th>2</th><th>3</th></tr><tr><td rowspan="3">Ambalage</td><td>50ml</td><td>T</td><td>T</td><td>T</td></tr><tr><td>100ml</td><td></td><td></td><td></td></tr><tr><td>200ml</td><td>T</td><td>T</td><td>T</td></tr></table> <table><tr><th>Batch no.</th><th>Batch size (Litre)</th><th>Batch size (vials)</th><th>Submitted data</th></tr><tr><td>711001 (50ml)</td><td>80L</td><td>1,584</td><td>36-month real time 6 month accelerated</td></tr><tr><td>712002 (50ml)</td><td>80L</td><td>1,584</td><td>36-month real time 6 month accelerated</td></tr><tr><td>711001 (200ml)</td><td></td><td></td><td>36-month real time 6 month accelerated</td></tr><tr><td>712002 (200ml)</td><td></td><td></td><td>36-month real time 6 month accelerated</td></tr></table> However, the firm submit only the data of 2 batches of both volumes, while the Bracketing plan given by manufacturer is consisting of stability data of three batches of both volumes of 50ml and 200ml. Further, the Justification of application of bracketing may be required in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.	Strength		BIEMEXOL 350mgI/ml solution for Injection			Batch		1	2	3	Ambalage	50ml	T	T	T	100ml				200ml	T	T	T	Batch no.	Batch size (Litre)	Batch size (vials)	Submitted data	711001 (50ml)	80L	1,584	36-month real time 6 month accelerated	712002 (50ml)	80L	1,584	36-month real time 6 month accelerated	711001 (200ml)			36-month real time 6 month accelerated	712002 (200ml)			36-month real time 6 month accelerated
Strength		BIEMEXOL 350mgI/ml solution for Injection																																											
Batch		1	2	3																																									
Ambalage	50ml	T	T	T																																									
	100ml																																												
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711001 (200ml)			36-month real time 6 month accelerated																																										
712002 (200ml)			36-month real time 6 month accelerated																																										

Decision of 330th meeting of Registration:

Deferred for the submission of following shortcomings/justifications:

- Justify, how the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.
- Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.
- Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.
- Justification for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.
- Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.

- Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
- Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board. Further, submit the stability data of both 50ml and 200ml volumes in accordance with the given bracketing plan and Justification the bracketing plan in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.

Response of the Firm:

Sr.no.	Shortcoming	Response of the Firm
1.	Justify, how the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.	Firm replied that, during pharmaceutical development and first application in country of origin, first DMF of API supplier Zheiang Starry Pharmaceutical Co. Ltd was in compliance with USP. Accordingly, batch formula was established according USP specifications. Lately, Starry Pharmaceutical has update their specifications according the EP Specifications and get approval for CEP. Biem has applied for CEP Submission variation in 03.08.2016 and get approval for variation in 10.10.2016. The applicant, in their response, submitted a revised Certificate of Pharmaceutical Product (CoPP) indicating a label claim of Iohexol 755.0 mg/mL (equivalent to 350 mg of iodine per mL) but did not specify the corresponding filled volume.
2.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.	Firm submitted the specification and analytical procedure of drug substance under the document head of product license holder.
3.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.	Firm submitted the validation report of Bacterial Endotoxin test.
4.	Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.	Not submitted the response of this query
5.	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.	Firm replied that the test methods for Biemexol are adopted as USP monograph. For specifications Related substances, Assay and Density analysis methods are which limits given by In-house methods. The assay release and shelf-life specifications of Biemexol 350 mg I/ml vial containing solution for IA, IV injection are proposed as 90.0% - 110.0% according to the results obtained from analytical results of development batches, validation batches and reference product.
6.	Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP	

	monograph of iohexol injection i.e. 95-105%.	Also the stability results of validation batches were used for determination of the specifications. Biem developed Biemexol product in 2013 and received approval in 2015 year. During development of the product USP monograph was not available so Biem have approved limits according development batches, validation batches, reference product and stability results of validation batches. Along with reply firm submitted the COA of finished product manufactured back in year 2018 and 2019 in which limit were kept between 90-110%.
7.	Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board. Further, submit the stability data of both 50ml and 200ml volumes in accordance with the given bracketing plan and Justification the bracketing plan in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.	Long-term as per zone-IV and accelerated stability data for the batches of 712002(batch size 80L) (50ml), 711001(batch size 80L) (50ml), 712002(200ml) and 711001(200ml) are submitted. For 100ml batch no.121601: batch size (800l)

Decision: The Registration Board has decided to reject the instant application for the following reasons:

1. The firm has not submitted the assay verification report of the drug substance performed by the drug product manufacturer.
2. The drug product manufacturer has not provided justification from the drug substance manufacturer for not including the impurities test, sterility test, and bacterial endotoxin test during the stability studies of the drug substance.
3. The drug product manufacturer has applied widened assay limits (90-110%) for the drug product compared to those recommended in the USP monograph for Iohexol Injection (95-105%).
4. The drug product manufacturer has not submitted stability data for both applied volume size i.e.50ml and 100ml, in accordance with the CTD guidance approved by the Registration Board, nor in accordance with recognized international guidelines (WHO, ICH, etc.).

130.	Name, address of Applicant / Importer	M/s. Hospital Supply Corporation
	Details of Drug Sale License of importer	License No:0013 Address: 42, Darul Aman Housing Society, Karachi Address of Godown: 46-E-2, Block-6, PECHS, Karachi Validity: 29-06-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey
	Name, address of manufacturer(s)	Mefar Ilac San A.S. Ramazanoglu Mahalles Ensar Caddesi No.2 Istanbul Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.2021/3007) dated 01-10-2021 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. <u>The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-10-2023.</u>
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey. The letter specifies that the manufacturer appoints M/s. Hospital Supply Corporation to register their products in Pakistan. The authorization letter is valid till 31-12-2024.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.795 : 10-01-2022
	Details of fee submitted	PKR 150,030/-: 26-10-2021
	The proposed proprietary name / brand name	Biemexol 350mg/ml vial (50ml)

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Iohexol.....755mg/ml (755mg Iohexol equivalent to 350mg I)
Pharmaceutical form of applied drug	Injectable
Pharmacotherapeutic Group of (API)	X-Ray Contrast Media
Reference to Finished product specifications	In-house specification/USP
Proposed Pack size	50ml vial
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved.
For generic drugs (me-too status)	Monopague 350mg/ml Injection (063945) of M/s. Graton Pharma, Karachi.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejiang Province Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 36 months. Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejiang Province Batch no. H18920080501, H18920080502, H18920080503 Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China Batch no. C006-0802003, C006-0802004, C006-0802005
Module-III Drug Product:	Firm has submitted data of drug product

		including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established against Omnipaque 350mgI/ML Vial (Batch no. 14778967)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless type I Glass vial (50ml), bromobutyl closure, blue tear off cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 2 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

INDICATIONS AND USAGE:

OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen.

DOSAGE AND ADMINISTRATION:

The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.		Submit valid drug sale license of importer Hospital supply corporation ,since the submitted DSL was expired on 29-06-2022.
2.		According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard.
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required”.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “ <i>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted</i> ”. Since you have submitted the validation report of drug substance manufacturer.

5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.
7.	3.2.P.5.1	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
8.	3.2.P.8	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Submit the complete data of long term stability studies performed at zone IV-a conditions, since you have claimed shelf life of 36months and provide the data of 24 months.

Decision of 326th meeting of Registration Board:

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

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings along with Response of the Firm
1.		Submit valid drug sale license of importer Hospital supply corporation, since the submitted DSL was expired on 29-06-2022. Firm submitted the copy of valid DSL issued in the name of M/s. Hospital Supply Corporation 42, Darul Aman Housing Society, Karachi (DSL no. 0237) and validity granted till 29/06/2024.
2.		According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard. Firm submit the explanation letter from Product License holder i.e. BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey, in which it is stated that “during pharmaceutical development and first application in country of origin, first DMF of API supplier Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China was in compliance of USP. Accordingly, batch formula was established according to USP specifications. Lately, starry pharmaceutical has update their specifications according to EP specifications and get approval for CEP. Biem has applied for CEP submission variation in 03-08-2016 and get approval for variation in 10.10.2016. Firm submitted the copy of variation letter issued from Turkish Medicines and Medical Agency for the approval of updated European Pharmacopeia certificate of conformity.
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required”. Not submitted the requisite information.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that “ <i>Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted</i> ”. Since you have submitted the validation report of drug substance manufacturer.

		Not submitted the requisite information.									
5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers. Not submitted as the API supplier was on leave and commit to submit as soon as received.									
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product. - Product license holder replied that Product was developmental batches manufactured in non-sterile R&D Laboratory, because of this sterility test and bacterial endotoxin test was not performed. - Further, excipients used for manufacturing of Biemexol are standard excipient used in injectable solutions. Iohexol is very soluble in water. Trometamine dissolves in water and it is used for increasing solubility in our formulation. Therefore, particulate matter test was not performed in the developmental phase. - In the formulation of the drug product, the only source for free iodine is the API Iohexol. According to the analysis results (lower than 10 PPM) obtained from CoA of API, the free iodine was evaluated as low risk for effecting of product quality. Therefore, free iodine was not performed during the development phase. Also, it is confirmed by stability data that active ingredient has not got negative effects on free iodine and stability.									
7.	3.2.P.5.1	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Firm replied that for specifications which limits given In-house methods as related substances, assay and density-analysis methods are established following the USP monographs.									
8.	3.2.P.5.1	Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%. Firm replied that the assay release and shelf life specifications of Biemexol 350mg/ml vial containing solution for IA, IV Injection are proposed as 90.0%-110% according to the results obtained from analytical results of developmental batches, validation batches and reference product. However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.									
9.	3.2.P.8	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Firm submitted the following details: <table border="1"> <thead> <tr> <th>Batch no.</th> <th>Batch size (Litre)</th> <th>Batch size (vials)</th> </tr> </thead> <tbody> <tr> <td>711001 (50ml)</td> <td>80L</td> <td>1,584</td> </tr> <tr> <td>712002 (50ml)</td> <td>80L</td> <td>1,584</td> </tr> </tbody> </table> However, as per the CTD guidance document for selection of number and size of batches applicant may follow, any of the following options: - ICH/WHO guidelines. - At least 2 batches having the following minimum batch size considering the scientific reliability - OSDs: 5000 Units - Oral Liquid/Suspension: 2000 - Injectable: 2000 - Aerosol and any other specialized preparations: 500 - At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life.	Batch no.	Batch size (Litre)	Batch size (vials)	711001 (50ml)	80L	1,584	712002 (50ml)	80L	1,584
Batch no.	Batch size (Litre)	Batch size (vials)									
711001 (50ml)	80L	1,584									
712002 (50ml)	80L	1,584									

10	3.2.P.8	Submit the complete data of long term stability studies performed at zone IV-a conditions, since you have claimed shelf life of 36 months and provide the data of 24 months. Firm submitted the stability data of two batches of 50ml till the claimed shelf life of 36months.

Decision of 329TH meeting of Registration Board:

Deferred for the submission of following shortcomings/justifications:

- Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.
- Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.
- Justification for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.
- Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.
- Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
- Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board. Since you have submitted the stability data of drug product of batch sizes consist of 1584 vials while minimum requirement 2000 vials per batch.

Response of the Firm:

Sr.no.	Shortcoming	Response of the Firm
1.	Justify, how the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.	Firm replied that, during pharmaceutical development and first application in country of origin, first DMF of API supplier Zheiang Starry Pharmaceutical Co. Ltd was in compliance with USP. Accordingly, batch formula was established according USP specifications. Lately, Starry Pharmaceutical has update their specifications according the EP Specifications and get approval for CEP. Biem has applied for CEP Submission variation in 03.08.2016 and get approval for variation in 10.10.2016. The applicant, in their response, submitted a revised Certificate of Pharmaceutical Product (CoPP) indicating a label claim of Iohexol 755.0 mg/mL (equivalent to 350 mg of iodine per mL) but did not specify the corresponding filled volume.
2.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.	Firm submitted the specification and analytical procedure of drug substance under the document head of product license holder.
3.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.	Firm submitted the validation report of Bacterial Endotoxin test.

4.	Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.	Not submitted the response of this query
5.	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.	Firm replied that the test methods for Biemexol are adopted as USP monograph. For specifications Related substances, Assay and Density analysis methods are which limits given by In-house methods. The assay release and shelf-life specifications of Biemexol 350 mg I/ml vial containing solution for IA, IV injection are proposed as 90.0% - 110.0% according to the results obtained from analytical results of development batches, validation batches and reference product. Also the stability results of validation batches were used for determination of the specifications. Biem developed Biemexol product in 2013 and received approval in 2015 year. During development of the product USP monograph was not available so Biem have approved limits according development batches, validation batches, reference product and stability results of validation batches. Along with reply firm submitted the COA of finished product manufactured back in year 2018 and 2019 in which limit were kept between 90-110%.
6.	Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.	
7.	Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board. Further, submit the stability data of both 50ml and 200ml volumes in accordance with the given bracketing plan and Justification the bracketing plan in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.	

Decision: The Registration Board decided to reject the instant application for the following reasons:

1. The firm has not submitted the assay verification report of the drug substance performed by the drug product manufacturer.
2. The drug product manufacturer has not provided justification from the drug substance manufacturer for not including the impurities test, sterility test, and bacterial endotoxin test during the stability studies of the drug substance.
3. The drug product manufacturer has applied widened assay limits (90-110%) for the drug product compared to those recommended in the USP monograph for Iohexol Injection (95-105%).
4. The drug product manufacturer has not submitted stability data for both applied volume size i.e. 50ml and 100ml, in accordance with the CTD guidance approved by the Registration Board, nor in accordance with recognized international guidelines (WHO, ICH, etc.).

131.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd 14Km Adyala Road Post office Dahgal Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 04-11-2021 specifying Tablet (general) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 24207 dated 26-08-2022
	Details of fee submitted	PKR 30,000/- Dated 22-08-2022
	The proposed proprietary name / brand name	CABER 0.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Cabergoline...0.5mg
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Dopamine Receptor Agonists
	Reference to Finished product specifications	USP
	Proposed Pack size	8's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dostinex Tablet (USFDA Approved)
	For generic drugs (me-too status)	Not submitted
	Name and address of API manufacturer.	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petach Tikva 4951033, Israel
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Dostinex Tablet Firm has submitted results of CDP studies for their product against Dostinex Tablet
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petach Tikva 4951033, Israel		
API Lot No.	70235000421		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	30-11-2021	30-11-2021	30-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision 335th meeting held on 25th April 2024: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of me-too status since fee of generic application is submitted.	Firm has submitted additional fee of 45000/-
	The claimed source of API is Teva Pharmaceutical Industries Ltd Israel, Justify how API was imported from a country from where imports are not permitted.	Firm has stated that the correspondence address Teva Pharmaceutical Industries Ltd Israel, is Teva Czech industries and manufacturing site is also Teva Czech industries.
2.	Submit complete details of drug substance in section 3.2.S with clarity since various information including specs, analytical method, COA and stability studies is from Teva Czech industries, while the API manufacturer specified throughout the application is Teva Pharmaceutical Industries Ltd. Israel.	Firm has stated that they are using API from Teva Netherlands country of origin Czech republic
3.	Pharmaceutical equivalence and CDP studies are claimed to be performed against Dostinex Tablet while the same have been discontinued in USFDA. Specify the details of the manufacturing site of the product along with pictorial evidence of the innovator's product.	Firm has submitted pictorial evidence and batch details of dostinex tablet
4.	Submit documents confirming import of API	Firm has submitted Form-3, and AD attested invoice
5.	Submit stability studies as per 6 points checklist specified in the CTD guidance document.	Submitted

Decision: Approved.

132.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd Plot No. A-94 , S.I.T.E. Super highway Karachi Pakistan. S6S-4NW-JWDR
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd Plot No. A-94 , S.I.T.E. Super highway Karachi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26036 dated 27-10-2023.

Details of fee submitted	Rs.75,000/- vide slip No. 43571526733 dated 6-10-22
The proposed proprietary name / brand name	Novamet 10% w/w vaginal cream.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm Contains: Metronidazole 1000mg
Pharmacotherapeutic Group of (API)	Nitroimidazoles. J01XD01
Reference to Finished product specifications	Innovator specifications.
The status in reference regulatory authorities	Flagyl 10% vaginal cream, Health Canada.
For generic drugs (me-too status)	New drug
Proposed Pack size	60gm (as per S.R.O)
Proposed unit price	As per S.R.O.

Decision 343 : Registration Board deferred the case for submission of reply to the above cited shortcomings,

Sr. No.	Section	Observation	Reply submitted by the firm.
1	1.6.5	Valid copy of GMP certificate of API manufacturer.	Firm has submitted COPP of Metronidazole bulk drug valid till 23-july-25
2	2.3	Copies of executed BMRs with a copy of blank production document shall be submitted	Firm has submitted copies of executed BMRs with a copy of blank production document
3	3.2.S.4.1	Specification of drug substance from drug substance manufacturer shall be submitted	Firm has submitted Specification of drug substance from drug substance manufacturer
4	3.2.S.4.2	Signed analytical procedures for drug substance from drug product manufacturer shall be submitted.	Firm has submitted Signed analytical procedures for drug substance from drug product manufacturer
5	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted	Submitted
6	3.2.S.4.4	Justification shall be submitted for providing exactly same results for all the test performed as that of the drug substance manufacturer by drug product manufacturer.	Firm has resubmitted COAs of API
7	3.2.P.1	Qualitative composition of the applied formulation (excipients) is different from the innovator product. Clarification shall be submitted	Firm has submitted pharmaceutical equivalence report
8	3.2.P.2.2.1	CDP studies in all three mediums with complete information and different time points along with analytical record shall be submitted	Cream intended for local use with minimal systemic absorption
9	3.2.P.5.1	Official monograph has mentioned content uniformity test while submitted specification has not mentioned the same. Clarification shall be submitted	Revised FPP specification's submitted

10	3.2.P.8	Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted	Submitted
11		Raw data sheets for calculation of assay and dissolution as per calculation formula for each time interval shall be submitted	Submitted
12		Justification shall be submitted for not performing content uniformity in the stability data sheets as recommended by the monograph	Firm has briefed that its part of initial testing and remained same during stability
13		Chromatograms for each time interval for both accelerated and real time shall be submitted	Submitted
14		Justify the standard and sample concentration in the submitted raw data sheets with respect to that concentration submitted in the analytical method, as analytical method has mentioned final concentration of 0.5mg/ml while raw data sheets has 0.1mg/ml	Firm has revised analytical method concentration of 1mg/ml
15		Documents for procurement of API with approval from DRAP shall be submitted	Form-6 and invoice submitted
16		Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	Submitted
17		Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted

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

133.

Name, address of Applicant / Marketing Authorization Holder	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan 1L7-YBL-QQ52
Brand Name + Dosage Form and Strength	Luras 80mg Tablet
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No 7283 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Lurasidone as HCl.....80mg
Pharmacotherapeutic Group of (API)	Anti-psychotic
Reference to Finished product specifications	Manufacturer's specifications
The status in reference regulatory authorities	LATUDA (20mg, 40mg, 60mg, 80mg, 120mg) film

	coated tablets USFDA Approved
For generic drugs (me-too status)	Luda 80mg tablets of Genome pharmaceuticals (Reg#095155)
GMP Status	The firm was inspected on 04-07-2018 and conclusion of inspection was: Based on above observations their current GMP compliance level is rated as GOOD.
Remark of the Evaluator XI	☐ ☐ The firm revised the formulation from uncoated to film coated tablets and submitted revised master formulation. The firm also revised the label claim without considering the salt factor along with submission of Rs. 5000/- on deposit slip No# 2032873 dated 01.02.2021. the revised label claim is as under: Each Film Coated Tablet Contains: Lurasidone HCl.....80mg ☐ ☐ Submit stability studies data as per the guidelines approved in 293rd meeting of Registration Board.
Decision of 307th meeting of RB:	Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.
Decision of 344th meeting:	Deferred for submission of the following: ☐ ☐ Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board, ☐ ☐ Valid GMP certificate of applicant.
Decision of 347th meeting:	Copy of receiving of initial stability data submitted in DRAP, ☐ Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin ☐ Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36 months. ☐ Record of comparative dissolution data.
Proposed Pack size	20's;
Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1		Copy of receiving of initial stability data submitted in DRAP,	Copy of receiving of initial stability data submitted in DRAP dated 23.01.23
2	1.6.5	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
3	3.2. S.7	Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36months	Firm submitted Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36months
4	3.2. P.2 .2.1	Record of comparative dissolution data.	Submitted

Decision: Approved with innovator's specifications. The firm shall submit applicable fee for change of specifications.

134.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22451 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 51563153188 dated 25-07-23.
	The proposed proprietary name / brand name	Estika 10mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Escitalopram as Oxalate(USP) 10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake Inhibitors-Anti Depressants N06AB10
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Escitalopram Oxalate 10mg M/s Brown& Burk UK Ltd MHRA approved
	For generic drugs (me-too status)	Repram 10mg Tablets, M/s Regal Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 081962.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	
2	3.2.P.2.2	In CDP F ₂ Calculations are not submitted. Further only average values are submitted, data of each unit of test product and reference product is require. (12 units of each test and reference product).	
3	3.2.P.5	- Submit data of system suitability run. - As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification. - Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision 343: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	GMP certificate of drug substance manufacturer submitted Valid until:22/06/2021
2	3.2.P.2.2	In CDP F ₂ Calculations are not submitted. Further only average values are submitted, data of each unit of test	Revised CDP submitted

		product and reference product is require. (12 units of each test and reference product).	
3	3.2.P.5	Submit data of system suitability run.	At the time of submission, product is not included in USP
		As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification.	We had run first 2 injections for 15 minutes but no extra peak was observed after 3.5 minutes. So we set the run time for 6 minutes.
		Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	We have loop of 10µl but in system software reading not show less than 20µl, Mistakenly not mentioned.

Decision: Approved. The firm shall submit system suitability studies as per USP before issuance of registration letter.

135.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22449 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 67853187 dated 25-07-23.
	The proposed proprietary name / brand name	Estika 20mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Escitalopram as Oxalate(USP) 20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake Inhibitors-Anti Depressants
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Escitalopram Oxalate 20mg M/s Brown& Burk UK ltd MHRA approved
	For generic drugs (me-too status)	Repram 20mg Tablets, M/s Regal Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 081962.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	
2	3.2.P.2.2	In CDP F ₂ Calculations are not submitted. Further only average values are submitted, data of each unit of test product and reference product is require. (12 units of each test and reference product).	
3	3.2.P.5	Submit data of system suitability run.	

		- As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification. - Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	
Decision 343: Registration Board deferred the case for submission of reply to the above cited shortcomings.			
Evaluation by PEC:			

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	GMP certificate of drug substance manufacturer submitted Valid until:22/06/2021
2	3.2.P.2.2	In CDP F ₂ Calculations are not submitted. Further only average values are submitted, data of each unit of test product and reference product is require. (12 units of each test and reference product).	Revised CDP submitted
3	3.2.P.5	Submit data of system suitability run.	At the time of submission, product is not included in USP
		As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification.	We had run first 2 injections for 15 minutes but no extra peak was observed after 3.5 minutes. So we set the run time for 6 minutes.
		Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	We have loop of 10µl but in system software reading not show less than 20µl, Mistakenly not mentioned.

Decision: Approved

136.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22782 dated 25-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 54666303896 dated 25-07-23.
	The proposed proprietary name / brand name	Dicloz 25mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Diclofenac Sodium(USP) 25mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Diclofenac Sodium 25mg tablets, HPRA Approved.

	For generic drugs (me-too status)	Panslay 25mg Tablets, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 024907.	
	Proposed Pack size	As per S.R.O.	
	Proposed unit price	As per S.R.O.	
Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	
2.		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	
3.	3.S.4	Assay limits in COA of API provided by applicant does not comply with adopted BP Specification's.	
4.	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	
5.	3.2.P.2.2	F ₂ Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	
6.	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	
7.	3.2.P.8	- Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2% - Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	
Decision 343: Registration Board deferred the case for submission of reply to the above cited shortcomings.			

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	Not submitted
2		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	Loan Documents submitted to DRAP on 14th February, 2023. Intimation Receiving Attached.
3	3.S.4	Assay limits in COA of API provided by applicant does not comply with adopted BP Specification's.	Not submitted
4	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	Submitted
5	3.2.P.2.2	F ₂ Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	Submitted
6	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	Submitted
7	3.2.P.8	Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2%	Not submitted
		Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

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

137.	M/s. Wenovo Pharmaceuticals, Plot No. 31 & 32 Punjab Small	Linavo 5 mg Tablets Each film coated tablet contains:-	Form 5 18-02-2014 Dy.No.196 Rs.20,000/-	Tradjenta (Linagliptin) USFDA approved	Me too status cannot be confirmed Product	Decision of 267 th meeting of RB;

	Sundar Industrial Estate Taxila Rawalpindi.	Linagliptin 5mg (Diabetes, dipeptidyl peptidase-4 (DPP-4) inhibitor	18-02-2014 10x10 ⁶ s As per SRO	Not provided Last inspection report 22-01-2016 For GMP certificate for export	deferred for comments of IPO in 253 rd DRB meeting Firm has claimed Mfg Specs and the product is not present in available pharmacopoeias (USP 39& BP2013).	Deferred till the comments of IPO
Drug		Linavo 5 mg Tablets (Linagliptin)				
Manufacturer of API		M/s Anhui Haikang Pharmaceutical Co., Ltd., China				
API Lot No.		21121901				
Description of Pack (Container closure system)		1x10's tablets in Alu-Alu blister pack.				
Stability Storage Condition		Real time: 30 °C ± 2 ° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%				
Time Period		Real time: 06 months Accelerated: 06 months				
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)				
Batch No.		T-01	T-02	T-03		
Batch Size		1200 Tablets	1200 Tablets	1200 Tablets		
Manufacturing Date		04-2022	04-2022	04-2022		
Date of Initiation		04-2022	04-2022	04-2022		
No. of Batches		03				
Date of Submission		Dy. No. 37573 dated 23-12-2022.				
DOCUMENTS / DATA PROVIDED BY THE APPLICANT						
Sr. No.	Documents to Be Provided			Status		
1.	Reference of previous approval of applications with stability study data of the firm.			Not submitted		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.			Copy of COA (Batch#21121901) of API from M/s Anhui Haikang Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals is submitted.		
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer			Method used for analysis of API from Finished Product Manufacturer is provided by the firm.		
4.	Stability study data of API from API manufacturer			Submitted as per zone IV-A		
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Firm has submitted copy of audit evaluation report on GMP certification in Anhui Province of API manufacturer issued by Anqing Biomedical Industry Association valid upto 09-09-2024.		

6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of letter “ issuance of Linagliptin 100gm as loan for CTD Dossier” from M/s Weather Folds Pharmaceuticals in name of Wenovo Pharmaceuticals dated 05-04-2022. Firm has submitted copy of clearance certificate cleared dated 11-03-2022 specifying 05kg Linagliptin. The clearance is cleared by AD (I&E) DRAP.												
7.	Protocols followed for conduction of stability study	Submitted.												
8.	Method used for analysis of FPP	Submitted.												
9.	Drug-excipients compatibility studies (where applicable)	N/A(The firm submitted that formulation of applied drug product is qualitatively similar to that of innovator Brand).												
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch manufacturing record of following 03 Batches:												
		<table> <tr> <th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr> <tr> <td>T-01</td><td>1200 tablets</td><td>04-2022</td></tr> <tr> <td>T-02</td><td>1200 tablets</td><td>04-2022</td></tr> <tr> <td>T-03</td><td>1200 tablets</td><td>04-2022</td></tr> </table>	Batch No.	Batch Size	Mfg. Date	T-01	1200 tablets	04-2022	T-02	1200 tablets	04-2022	T-03	1200 tablets	04-2022
Batch No.	Batch Size	Mfg. Date												
T-01	1200 tablets	04-2022												
T-02	1200 tablets	04-2022												
T-03	1200 tablets	04-2022												
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against brand leader in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.												
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.												
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.												
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.												

Remarks of Evaluator:

Sr. No.	Observations	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm.	
2.	Method used for analysis of API from API Manufacturer shall be submitted	
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
5.	- Justification shall be submitted for selecting different conditions of dissolutions test in finished product specifications (medium; 6.8 phosphate buffer, apparatus 2, rpm 75rpm) than innovator product review document (medium; 0.1N HCl, apparatus 1, rpm 50rpm) - Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per innovator's product review document	

6.	• Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed • Complete record of CDP studies shall be submitted	
7.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	
Decision 344: Registration Board deferred the case for submission of reply to the above cited shortcomings		

Remarks of Evaluator:

Sr. No.	Observations	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm.	Dexxoo 30mg, Dexxoo 60mg
2.	Method used for analysis of API from API Manufacturer shall be submitted	Submitted
3.	Submit valid copy of cGMP certificate / GMP inspection report of applicant conducted within last three years	F.3-15/2018-Add Dir(QA-LT-FO)-17 date of issue 7-feb-25
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Submitted
5.	• Justification shall be submitted for selecting different conditions of dissolutions test in finished product specifications (medium; 6.8 phosphate buffer, apparatus 2, rpm 75rpm) than innovator product review document (medium; 0.1N HCl, apparatus 1, rpm 50rpm)	We have performed CDP in all media and in acid and phosphate release of linagliptin was upto 95% in 30min, so we adopt now in HCl also, RPM mistakenly written 75RPM, it was 50RPM for 30min throughout stability studies.
	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications as per innovator's product review document	Test for uniformity of dosage units was performed but mistakenly not written in finished product specifications. Revised Specification Attached in Annexure-1
6.	• Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed • Complete record of CDP studies shall be submitted	Tradjenta 5mg, B. No: LN0523, Mfg. Date: 04, Exp Date: 03,2 Complete record of CDP studies submitted
7.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted
Decision: Approved and the firm shall submit fee for revision of formulation.		

138.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila
	Brand Name + Dosage Form + Strength	Wencuval 24/26 mg Tablet

Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex...24.3mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...25.7mg		
Diary No. Date of R& I & fee	Dy No. 14098: 07-03-2019 PKR 20,000/-: 06-03-2019		
Pharmacological Group	Angiotensin II receptor blockers, other combinations		
Type of Form	Form 5		
Finished Product Specification	Firm has claimed in house specification		
Pack size & Demanded Price	As per SRO		
Approval status of product in Reference Regulatory Authorities.	USFDA Approved		
Me-too status	Sacuvia Tablet by Highnoon		
GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.		
Remarks of the Evaluator ³ .	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.		
Decision of 323rd meeting of Registration Board: Deferred for following submissions: • Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Stability study data as per the guidelines provided in 293rd meeting of Registration Board.			
STABILITY STUDY DATA			
Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex...24.3mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...25.7mg		
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province,China.		
API Lot No.	RCD-LCZ696-202104211		
Description of Pack (Container closure system)	1X10's in alu-alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	23-12-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 24 months and at Accelerated conditions; $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	NA
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches:
11.	Record of comparative dissolution data (where applicable)	Not submitted
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

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

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Innovator label claim is “Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is required in this regard
3.	Submit reference of previous approval of applications with stability study data of the firm.
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
7.	Submit record of comparative dissolution data.

Decision 344: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- Submit requisite fee required along with stability documents.
- Innovator label claim is “Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength, so clarification is required in this regard.
- Submit reference of previous approval of applications with stability study data of the firm.
- Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation. Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- Submit record of comparative dissolution data.

Remarks of Evaluator:

Sr No	Short comings	Replies
1.	Submit requisite fee required along with stability documents.	Not submitted
2.	Innovator label claim is “Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is required in this regard	Mentioned as per Label Claim adopted in USFDA. Revised Master Formulation has been attached.
3.	Submit reference of previous approval of applications with stability study data of the firm.	Dexxoo 30mg, Dexxoo 60mg
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.	Test was performed according to FDA guidelines, but mistakenly wrong condition of speed and apparatus was written its typo mistake. Revised and correct SAP attached
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Attached

6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
7.	Submit record of comparative dissolution data.	Record of comparative dissolution data submitted.

Decision: Approved and the firm shall submit fee for revision of formulation.

139.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila
	Brand Name +Dosage Form + Strength	Wencuval 49/51 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex...48.6mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...51.4mg
	Diary No. Date of R& I & fee	Dy No. 14099: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator ³ .	- Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. - Latest GMP inspection report conducted within a period of last three years. - Revise your label claim as per the reference product along with submission of requisite fee.
	Decision of 323rd meeting: Deferred for following submissions: - Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. - Stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

STABILITY STUDY DATA

Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex...48.6mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...51.4mg
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province, China.
API Lot No.	RCD-LCZ696-202104211
Description of Pack (Container closure system)	1X10's in alu-alu blister packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)

Batch No.	T-04	T-05	T-06
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	23-12-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.	
7.	Protocols followed for conduction of stability study	Submitted.	
8.	Method used for analysis of FPP	Submitted.	
9.	Drug-excipients compatibility studies (where applicable)	NA	
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches:	
11.	Record of comparative dissolution data (where applicable)	Not submitted	

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Batch No.	Batch Size	Mfg. Date
		T-01	1200 TABLETS	10-2021
		T-02	1200 TABLETS	10-2021
		T-03	1200 TABLETS	10-2021
		Submitted		
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted		
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator:

Sr.no.	Shortcoming/Deficiencies
1.	Submit requisite fee required along with stability documents.
2.	Innovator label claim is “Each film-coated tablet contains 48.6mg sacubitril and 51.4mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is required in this regard
3.	Submit reference of previous approval of applications with stability study data of the firm.
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
7.	Submit record of comparative dissolution data.

Decision 344: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- Submit requisite fee required along with stability documents.
- Innovator label claim is “Each film-coated tablet contains 48.6mg sacubitril and 51.4mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength, so clarification is required in this regard.
- Submit reference of previous approval of applications with stability study data of the firm.
- Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
- Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- Submit record of comparative dissolution data.

Remarks of evaluator

Sr No	Short comings	Replies
1.	Submit requisite fee required along with stability documents.	Not submitted
2.	Innovator label claim is “Each film-coated tablet contains 48.6mg sacubitril and 51.4mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is	Mentioned as per Label Claim adopted in USFDA. Revised Master Formulation has been attached.

	required in this regard	
3.	Submit reference of previous approval of applications with stability study data of the firm.	Dexxoo 30mg, Dexxoo 60mg
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA. Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.	Test was performed according to FDA guidelines, but mistakenly wrong condition of speed and apparatus was written its typo mistake. Revised and correct SAP attached
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Attached
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
7.	Submit record of comparative dissolution data.	Record of comparative dissolution data submitted.
Decision: Approved and the firm shall submit fee for revision of formulation.		
140.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila
	Brand Name +Dosage Form + Strength	Wencuval 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex...97.2mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...102.8mg
	Diary No. Date of R&I & fee	Dy No. 14100: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator ³ .	- Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. - Latest GMP inspection report conducted within a period of last three years. - Revise your label claim as per the reference product along with submission of requisite fee.
Decision of 323rd meeting of Registration Board: Deferred for following submissions: - Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. - Stability study data as per the guidelines provided in 293rd meeting of Registration Board.		
STABILITY STUDY DATA		
Drug	Sacubitril As Sacubitril Valsartan Sodium Salt Complex...97.2 mg Valsartan As Sacubitril Valsartan Sodium Salt Complex...102.8mg	
Manufacturer of API	M/s. Nantong Chanyoo Pharmatech Co., ltd. Jiangsu Province, China.	
API Lot No.	RCD-LCZ696-202104211	

Description of Pack (Container closure system)	1X10's in alu-alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	27-10-2021	27-10-2021
No. of Batches	03		
Date of Submission	23-12-2022		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted	
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5% RH for 6 months.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a Loan letter in which applicant take loan of 1.5kg from M/s. Weather fold Pharmaceuticals. Along with loan letter applicant submitted commercial invoice on which M/s. Weather fold imported 40kg API from China, the invoice no.NT121062A dated 26,May,2021 was bearing the DRAP R&I stamp of dated 01/02/2021.	
7.	Protocols followed for conduction of stability study	Submitted.	
8.	Method used for analysis of FPP	Submitted.	
9.	Drug-excipients compatibility studies (where applicable)	NA	

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches:		
11.	Record of comparative dissolution data (where applicable)	Not submitted		
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Batch No.	Batch Size	Mfg. Date
		T-01	1200 TABLETS	10-2021
		T-02	1200 TABLETS	10-2021
		T-03	1200 TABLETS	10-2021
		Submitted		
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted		
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator:				
Sr.no.	Shortcoming/Deficiencies			
1.	Submit requisite fee required along with stability documents.			
2.	Innovator label claim is “Each film-coated tablet contains 97.2mg sacubitril and 102.8 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength, so clarification is required in this regard.			
3.	Submit reference of previous approval of applications with stability study data of the firm.			
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA.Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.			
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer			
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin			
7.	Submit record of comparative dissolution data.			

Decision 344: Deferred for submission of following shortcomings along with verification of DRAP attested documents related to the procurement of API.

- Submit requisite fee required along with stability documents.
- Innovator label claim is “Each film-coated tablet contains 97.2mg sacubitril and 102.8 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength, so clarification is required in this regard.
- Submit reference of previous approval of applications with stability study data of the firm.
- Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA. Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.
- Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer
- Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- Submit record of comparative dissolution data.

Sr No	Short comings	Replies
1.	Submit requisite fee required along with stability documents.	Not submitted
2.	Innovator label claim is “Each film-coated tablet contains 97.2mg sacubitril and 102.8 mg valsartan (as sacubitril valsartan sodium salt complex)”, while the label claim mentioned by you is “Each film-coated tablet contains 24mg sacubitril and 26mg valsartan”, same difference is observed in other 2 strength,so clarification is required in this regard	Mentioned as per Label Claim adopted in USFDA. Revised Master Formulation has been attached.
3.	Submit reference of previous approval of applications with stability study data of the firm.	Dexxoo 30mg, Dexxoo 60mg
4.	Justify for not adopting the same dissolution acceptance criteria for the applied formulation as recommended by the innovator product approved in USFDA. Since the review literature of innovator brand revealed the dissolution condition and acceptance limit of applied formulation.	Test was performed according to FDA guidelines, but mistakenly wrong condition of speed and apparatus was written its typo mistake. Revised and correct SAP attached
5.	Submit method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Attached
6.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
7.	Submit record of comparative dissolution data.	Record of comparative dissolution data submitted.

Decision: Approved and the firm shall submit fee for revision of formulation.

141.	Name, address of Applicant / Marketing Authorization Holder	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
	Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26286 dated 31-10-2023.

Details of fee submitted	Rs.30,000/- vide slip No. 6899192054 dated 16-10-2023.																		
The proposed proprietary name / brand name	Vosul 25mg Tablet																		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride.....25mg																		
Pharmacotherapeutic Group of (API)	Antipsychotic																		
Reference to Finished product specifications	Innovactor's Specifications.																		
The status in reference regulatory authorities	Livodomed 25mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.																		
For generic drugs (me-too status)	Hi Pride Tablet 25mg Manufactured by M/s. Bloom Pharmaceutical. (077423)																		
Proposed Pack size	As per SRO																		
Evaluation by PEC :																			
<table><tr><td>Sr.</td><td>Shortcomings communicated</td><td>Response by the firm No</td></tr><tr><td>1.</td><td>Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division</td><td></td></tr><tr><td>2.</td><td>Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.</td><td></td></tr><tr><td>3.</td><td>Submit details of reference product against which PE studies are conducted.</td><td></td></tr><tr><td>4.</td><td>Submit evidence of procurement of API.</td><td></td></tr><tr><td>5.</td><td>Submit BMR of stability batches</td><td></td></tr></table>		Sr.	Shortcomings communicated	Response by the firm No	1.	Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division		2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.		3.	Submit details of reference product against which PE studies are conducted.		4.	Submit evidence of procurement of API.		5.	Submit BMR of stability batches	
Sr.	Shortcomings communicated	Response by the firm No																	
1.	Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division																		
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.																		
3.	Submit details of reference product against which PE studies are conducted.																		
4.	Submit evidence of procurement of API.																		
5.	Submit BMR of stability batches																		
Decision 343: Registration Board deferred the case for submission of reply to the above cited shortcomings.																			
Evaluation by PEC :																			
Sr No	Short comings	Replies																	
1	Submit evidence of approval of requisite manufacturing facility / section approval letter from Licensing Division	No. F.1-3/2011-LIC dated 6.02.25																	
2	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted																	
3	Submit details of reference product against which PE studies are conducted	L-Pride 25mg tab B. No: 556 Mfg. Date: 11,2022																	
4	Submit evidence of procurement of API.	Loan from M/s Wnsfield 106/2021 dated 15.01.2021																	
5	Submit BMR of stability batches	Submitted																	
Decision : Approved																			
142.	Name, address of Applicant / Marketing Authorization Holder	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.																	
	Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.																	

Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26287 dated 31-10-2023.	
Details of fee submitted	Rs.30,000/- vide slip No. 125104739719 dated 16-10-2023.	
The proposed proprietary name / brand name	Vosul 50mg Tablet	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride.....50mg	
Pharmacotherapeutic Group of (API)	Antipsychotic	
Reference to Finished product specifications	Innovactor's Specifications.	
The status in reference regulatory authorities	Livodomed 50mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.	
For generic drugs (me-too status)	Hi Pride Tablet 50mg Manufactured by M/s. Bloom Pharmaceutical. (077424)	
Proposed Pack size	As per SRO	

Evaluation by PEC :

Sr.	Shortcomings communicated	Response by the firm No
1.	Submit evidence of approval of requisite manufacturing facility / section approval letter from Licensing Division	
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit details of reference product against which PE studies are conducted.	
4.	Submit evidence of procurement of API.	
5.	Submit BMR of stability batches	

Decision 343 : Registration Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC :

Sr No	Short comings	Replies
1	Submit evidence of approval of requisite manufacturing facility / section approval letter from Licensing Division	No. F.1-3/2011-LIC dated 6.02.25
2	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
3	Submit details of reference product against which PE studies are conducted	L-Pride 25mg tab B. No: 556 Mfg. Date: 11,2022
4	Submit evidence of procurement of API.	Loan from M/s Wnsfield 106/2021 dated 15.01.2021
5	Submit BMR of stability batches	Submitted

Decision : Approved

143.	Name, address of Applicant / Marketing Authorization Holder	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.

Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26288 dated 31-10-2023.
Details of fee submitted	Rs.30,000/- vide slip No. 3649377329 dated 16-10-2023.
The proposed proprietary name / brand name	Vosul 100mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride.....100mg
Pharmacotherapeutic Group of (API)	Antipsychotic
Reference to Finished product specifications	Innovactor's Specifications.
The status in reference regulatory authorities	Livodomed 100mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.
For generic drugs (me-too status)	Hi Pride Tablet 100mg Manufactured by M/s. Bloom Pharmaceutical. (077423)
Proposed Pack size	As per SRO

Evaluation by PEC :

Sr.	Shortcomings communicated	Response by the firm No
1.	Submit evidence of approval of requisite manufacturing facility / section approval letter from Licensing Division	
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit details of reference product against which PE studies are conducted.	
4.	Submit evidence of procurement of API.	
5.	Submit BMR of stability batches	

Decision343: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC :

Sr No	Short comings	Replies
1	Submit evidence of approval of requisite manufacturing facility / section approval letter from Licensing Division	No. F.1-3/2011-LIC dated 6.02.25
2	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
3	Submit details of reference product against which PE studies are conducted	L-Pride 25mg tab B. No: 556 Mfg. Date: 11,2022
4	Submit evidence of procurement of API.	Loan from M/s Wnsfield 106/2021 dated 15.01.2021

5	Submit BMR of stability batches	Submitted	
Decision: Approved			
144.	Name and address of manufacturer / Applicant	M/s.Wenovo Pharmaceuticals. Plot # 31& 32, Punjab Small Industrial Estate, Taxila.	
	Brand Name +Dosage Form + Strength	Dapawen 10mg Tablet	
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate...10mg	
	Diary No. Date of R& I & fee	Form-5 Dy.No 14190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019	
	Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01	
	Type of Form	Form 5-D	
	Finished product Specifications	Innovator's Specifications	
	Pack size & Demanded Price	2x7, MRP as per SRO.	
	Approval status of product in Reference Regulator Authorities	Forxiga 10mg Tablet, Manufactured by AstraZenica Pharmaceuticals. USFDA approved.	
	Me-too status	Dapa 10mg tablet, by Hilton Pharmaceuticals Pvt Ltd.	
	GMP status	Not submitted.	
Remarks of the Evaluator			
STABILITY STUDY DATA			
Drug	Dapawen 10mg Tablet		
Manufacturer of API	M/s. Precise ChemiPharma Pvt Ltd. India.		
API Lot No.	120002012022		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T050	T051	T052
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	30-03.2022	30-03.2022	30-03.2022
No. of Batches	03		
Date of Submission	Dy. No. 38205 dated 28/-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	

1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted						
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Precise ChemiPharma Pvt Ltd. India. Firm has also submitted COA of the drug substance with batch number 120002012022 and manufacturing date Jan-22.						
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.						
4.	Stability study data of API from API manufacturer	Not submitted						
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 28-09- 2022. Issued by Food and Drug Administration Maharashtra. DML Valid til 31-12-2022.						
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached in the name of Welmark Pharmaceuticals. (Not approved from DRAP). Firm not provided the API loan document.						
7.	Protocols followed for conduction of stability study.	Not Submitted.						
8.	Method used for analysis of FPP	Submitted.						
9.	Drug-excipients compatibility studies (where applicable)	Not submitted						
10.	Complete batch manufacturing record of three stability batches.	Not submitted						
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dapawen 10mg tablet (Dapagliflozin) against Dapa 10mg tablet, Batch No. 144526, Mfg. date 02-2022 manufactured by Hilton Pharmaceuticals Pvt Ltd. in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.						
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted						
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted						
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted						
Remarks of Evaluator:								
	<table border="1"> <thead> <tr> <th>Sr. No.</th><th>Observation</th><th>Reply by the firm</th></tr> </thead> <tbody> <tr> <td></td><td></td><td></td></tr> </tbody> </table>	Sr. No.	Observation	Reply by the firm				
Sr. No.	Observation	Reply by the firm						

1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
9.	Your form application shows that you applied for Zenwo 10mg Tablet but all the stability data / documents is with the name of Dapawen 10mg Tablet, Justifications required.	
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	

Decision 344: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Dexxoo 30mg, 60mg Capsules
2.	Stability study data of API from API manufacturer shall be submitted.	Submitted
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Valid till 28-09-22
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	Loan from M/s Well mark Computerized No: E-124968025781 Date of issue: 22-Feb-2022
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	We Followed the Same Excipient as per Innovator, hence Compatibility studies not Applicable
6.	Complete batch manufacturing record of three stability batches shall be submitted..	Complete batch manufacturing record of three stability batches submitted
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Record of HPLC software 21CFR submitted.
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for real time and accelerated submitted
9.	Your form application shows that you applied for Zenwo 10mg Tablet but all the stability data / documents is with the name of Dapawen 10mg Tablet, Justifications required.	AS OUR Brand name is Dapawen tab, mistakenly it was written Zenwo tab. Data attached with correct Brand name
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	Certificate submitted valid 14-06-24

Decision: Approved

145.	Name and address of manufacturer / Applicant	M/s.Wenovo Pharmaceuticals. Plot # 31& 32, Punjab Small Industrial Estate, Taxila.

Brand Name +Dosage Form + Strength	Dapawen 5mg Tablet		
Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate...5mg		
Diary No. Date of R& I & fee	Form-5 Dy.No 14189 dated 07-03-2019 Rs.20,000/- dated 06-03-2019		
Pharmacological Group	Blood glucose Lowering drugs ATC Code: A10BK01		
Type of Form	Form 5-D		
Finished product Specifications	Innovator's Specification		
Pack size & Demanded Price	2x7, MRP as per SRO.		
Approval status of product in Reference Regulator Authorities	Forxiga 5mg Tablet, Manufactured by AstraZenica Pharmaceuticals. USFDA approved.		
Me-too status	Dapa 5mg tablet, by Hilton Pharmaceuticals Pvt Ltd.		
GMP status	Not submitted.		
Remarks of the Evaluator			
STABILITY STUDY DATA			
Drug	Dapawen 5mg Tablet		
Manufacturer of API	M/s. Precise ChemiPharma Pvt Ltd. India.		
API Lot No.	120002012022		
Description of Pack (Container closure system)	Alu-Au Blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, (months)		
Batch No.	T047	T048	T049
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	15-03.2022	15-03.2022	15-03.2022
No. of Batches	03		
Date of Submission	Dy. No. 38205 dated 28/-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted	

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA of the drug substance (Dapagliflozin propandiol monohydrate)) from M/s. Precise ChemiPharma Pvt Ltd. India. Firm has also submitted COA of the drug substance with batch number 120002012022 and manufacturing date Jan-22. (Manufacturer's Specification)
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Not submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has Submitted GMP Certificate Vald till 28-09- 2022. Issued by Food and Drug Administration Maharashtra. DML Valid til 31-12-2022.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	API Procurement In-voice attached in the name of Welmark Pharmaceuticals. (Not approved from DRAP). Firm not provided the API loan document.
7.	Protocols followed for conduction of stability study.	Not Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted
10.	Complete batch manufacturing record of three stability batches.	Not submitted
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dapawen 10mg tablet (Dapagliflozin) against Dapa 10mg tablet, Batch No. 144526, Mfg. date 02-2022 manufactured by Hilton Pharmaceuticals Pvt Ltd. in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Stability study data of API from API manufacturer shall be submitted.	
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by	

	concerned regulatory authority of country of origin shall be submitted..	
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
6.	Complete batch manufacturing record of three stability batches shall be submitted..	
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
9.	Your form application shows that you applied for Zenwo 10mg Tablet but all the stability data / documents is with the name of Dapawen 10mg Tablet, Justifications required.	
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	

Decision 344: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Dexxoo 30mg, 60mg Capsules
2.	Stability study data of API from API manufacturer shall be submitted.	Submitted
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Valid till 28-09-22
4.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	Loan from M/s Well mark Computerized No: E-124968025781 Date of issue: 22-Feb-2022
5.	Drug-excipients compatibility studies (where applicable) shall be submitted.	We Followed the Same Excipient as per Innovator, hence Compatibility studies not Applicable
6.	Complete batch manufacturing record of three stability batches shall be submitted..	Complete batch manufacturing record of three stability batches submitted
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Record of HPLC software 21CFR submitted.
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for real time and accelerated submitted
9.	Your form application shows that you applied for Zenwo 10mg Tablet but all the stability data / documents is with the name of Dapawen 10mg Tablet, Justifications required.	AS OUR Brand name is Dapawen tab, mistakenly it was written Zenwo tab. Data attached with correct Brand name
10.	Submit valid GMP certificate of Wenovo Pharmaceuticals.	Certificate submitted valid 14-06-24

Decision: Approved

146.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals., Plot # 31& 32 Punjab Small Industrial Estate Taxila
	Brand Name + Dosage Form + Strength	Weglor 90mg tablet
	Composition	Each Film Coated Tablet Contains: Ticagrelor 90mg
	Diary No. Date of R & I & fee	Dy No. 14191: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Platelet aggregation inhibitors
	Type of Form	Form 5

Finished product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	USFDA Approved
Me-too status	Hitica Tablet by Highnoon
GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
Remarks of the Evaluator	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293 rd meeting.
Previous Decision (M-323 rd -RB)	Deferred for submission of stability study data as per the guidelines approved in 293 rd meeting of Registration Board.

STABILITY STUDY DATA

Drug	Tacvo 90mg Tablet		
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20210402T		
Description of Pack (Container closure system)	1x10's; Alu-alu blister		
Stability Storage Condition	Real time: 30°C ± 2 °C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablet	1200 tablet	1200 tablet
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		
Date of Submission	Dy No. 37574 Dated; 23-12-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch#20210402T) from M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China and M/s Wenovo Pharmaceuticals., is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted
4.	Stability study data of API from API manufacturer	Not submitted

5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 cleared dated 11- 10-2021 specifying 0.5kg Ticagrelor. The form 6 is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	N/A (The firm submitted that Formulation of applied drug product is qualitatively similar to that of innovator product).
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted complete batch manufacturing record of three stability batches.
11.	Record of comparative dissolution data (where applicable)	Submitted. Results of comparative dissolution performed against brand leader in pH 1.2 HCl Buffer, acetate buffer pH 4.5, phosphate buffer pH 6.8. The values of f2 factor are in acceptable range.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail reports on product testing is submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.

Remarks of Evaluator:

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

9.	Compliance Record of HPLC software 21CFR shall be submitted.	
10.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	
Decision 344: Registration Board deferred the case for submission of reply to the above cited shortcomings		
Remarks of Evaluator:		
Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Vonoprazan 10mg & 20mg Tablet DRB 339 Meeting.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	COA of API and Finished Product manufacturer submitted
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Analytical Method of API submitted
4.	Stability study data of API from both API manufacturer shall be submitted.	submitted
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	submitted
6.	Copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP shall be submitted	submitted
7.	Justification shall be submitted for selecting different chromatographic conditions of assay test of finished product than BP monograph	As our HPLC system is manual with rheodyne it takes only 5 µl volume as a loop of 5 microliter attached . During working due to typo mistake 20µl was written in place of 5µl in software
8.	- Submit details of brand leader including manufacturer name, batch number, manufacturing date and expiry date against which CDP studies were performed - Complete record of CDP studies shall be submitted	Complete record of CDP submitted
9.	Compliance Record of HPLC software 21CFR shall be submitted.	Compliance Record of HPLC software submitted
10.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Record of Digital data logger submitted
Decision: Approved		

Case No.01. Disposal of Cases Conditionally Approved in 344th Meeting of Registration Board.

Registration Board in its 344th meeting (held on 31st Dec- 2nd Jan, 2025) approved the following cases and decided that the registration letters shall be issued after **submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website.**

S/N	Name, address of Applicant.	Product Detail	Decision of M-344 th Meeting of R.B	Type of Form, Diary No. Date of R&I & fee
1.	M/s Amros Pharmaceutical, A/96, S.I.T.E Super highway Karachi.	Amroplus Syrup Each 5ml contains: Iron Polymaltose Complex eq. to elemental Iron...50mg Manufacturer specs	Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.	Form-5 Dy. No 25405 dated 19-10-2023 (Duplicate dossier) verified vide Dy. No 226 dated 27-10-2010 from R&I Rs.8000/- (photo copy) Rs.12000/- 19-07-2017 (photo copy) to be verified
2.	M/s Navegal Laboratories, 41/1 -A2, Phase 1, Industrial Estate, Hattar	Sudofen Forte Tablet Each film coated tablet contains: Ibuprofen... 400mg Pseudoephedrine HCl ...60mg Inhouse specs	Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.	Form-5 Dy. No. 1313 dated 22-01-2024 (Duplicate dossier) Rs.8000/- (Photocopy) Dy. No 704 dated 27-05-2011 to be verified from R&I Rs.12000/- not attached
3.	Maple Pharma Pvt. Ltd. Plot No.147, Sector 23, Korangi	Lumart 80mg /ml IM injection Each ml contains: Artemether 80mg Inhouse specs	Approved. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12,000 within 6 months	Form-5 (Duplicate dossier) Fee 8000/- dated 13-10-2010 (Photocopy)

	Industrial Area, Karachi.		of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •submission of fee Rs. 9000/- for pre-approval variation/revision of FPP Specifications.	Fee 12,000/- dated 16-03-2015 (Photocopy)
4.	Maple Pharma Pvt. Ltd. Plot No.147, Sector 23, Korangi Industrial Area, Karachi. Contract manufactured by: M/n Nexus Pharma Pvt. Ltd., 4/19-4/36 Sector 21 Korangi Industrial Area Karachi.	Levolife injection 500mg/100ml IV Each 100ml contains: Levofloxacin (as hemihydrate) ...500mg Inhouse specs	Approved with innovator's specifications. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •submission of fee Rs. 9000/- for pre-approval variation/revision of FPP Specifications.	Form-5 (Duplicate dossier) Fee 8000/- dated 13-10-2010 (Photocopy) Dy. No. nil. Dated 01-08-2016; Fee 12,000/- (Photocopy)
5.	M/s. MKB Pharmaceuticals, Peshawar	Telsa 40mg Tablets Each tablet contains: Telmisartan 40mg USP	Approved. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs.8000/- (Photocopy) Dy. No. 594 dated 28-06-2012 verified from R&I Rs.12000/- (Photocopy) dated 31-12-2015 to be verified from R&I
6.	M/s. MKB Pharmaceuticals, Peshawar	Amloval Tablets Each film coated tablet contains: Amlodipine besylate eq. to Amlodipine..... 5mg Valsartan	Approved. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website.	Form-5 (Duplicate dossier) Rs.8000/- (Photocopy) Dy. No. 587 dated 28-06-2012 verified from R&I Rs.12000/- (Photocopy) dated

		80mg Inhouse	•verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •fee Rs. 9000/- for pre-approval variation in FPP specifications	31-12-2015 to be verified from R&I
7.	M/s. MKB Pharmaceuticals, Peshawar	Amloval Tablets Each film coated tablet contains: Amlodipine besylate eq. to Amlodipine..... 10mg Valsartan 160mg Inhouse	Approved. Registration Board further decided that Registration letter shall be issued after the following: •Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. •verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. •latest GMP inspection report conducted within period of three years. •fee Rs. 9000/- for pre-approval variation in FPP specifications	Form-5 (Duplicate dossier) Rs.8000/- (Photocopy) Dy. No. 590 dated 28-06-2012 verified from R&I Rs.12000/- (Photocopy) dated 31-12-2015 to be verified from R&I
8.	Masfa industries (pvt).ltd, 17km sheikhupura road ,lahore	Mascon Gel Dicyclomine HCl ... 2.5mg Aluminium Hydroxide ... 200mg Magnesium Oxide ... 100mg Simethicone 20mg	Approved the products at Sr. No. 165-166. Registration Board further decided that Registration letter shall be issued after the following: • Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. • verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. • fee Rs. 9000/- for pre-approval variation in FPP Specifications	Rs.8000/- Dy. No. nil dated 02-04-2011 No evidence of Rs.12000/-
9.	Masfa industries (pvt).ltd, 17km sheikhupura road ,lahore	Laxiron Liquid Sodium Picosulphate monohydrate ... 5mg/5ml	Approved the products at Sr. No. 165-166. Registration Board further decided that Registration letter shall be issued after the following: • Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. • verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Rs.8000/- Dy. No. nil dated 01-06-2011 No evidence of Rs.12000/-

			• fee Rs. 9000/- for pre-approval variation in FPP Specifications	
10.	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhpura Road Lahore	Rajumat 50/500mg XR tablets Composition Each film coated tablet contains: Sitagliptin as phosphate monohydrate...50mg Metformin	Registration Board on the basis of submitted drug product stability data approved the instant application as per following label claim: “Each film coated tablet contains: Sitagliptin as phosphate monohydrate 50mg Metformin hydrochloride.....500mg” Registration Letter shall be issued upon submission of following: ☐ Fee of Rs. /- 37,000 for pre-registration variations of label claim as per SRO1324 (I)/2024 dated 30-08-2024. ☐ Original receipt of submission of fee of Rs. 12,000/- within 6 months of publication of minutes of instant meeting on DRAP website.	30-11-2010 (Duplicate dossier) Rs. 8,000/- (30-11-2010) Rs. 12,000/- (to be verified) Dy No. 18307 dated 23.06.2022 (Stability)
11.	M/s Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhpura Road Lahore	Rajumat 50/1000mg XR tablets Composition Each film coated tablet contains: Sitagliptin as phosphate monohydrate 50mg Metformin hydrochloride (Extended release) 1000mg	Registration Board on the basis of submitted drug product stability data approved the instant application as per following label claim: “Each film coated tablet contains: Sitagliptin as phosphate monohydrate 50mg Metformin hydrochloride 1000mg” Registration Letter shall be issued upon submission of following: ☐ Fee of Rs. /- 37,000 for pre-registration variations of label claim as per SRO1324 (I)/2024 dated 30-08-2024. ☐ Original receipt of submission of fee of Rs. 12,000/- within 6 months of publication of minutes of instant meeting on DRAP website.	30-11-2010 (Duplicate dossier) Rs. 8,000/- (30-11-2010) Rs. 12,000/- (to be verified) Dy No. 18306 dated 23.06.2022 (Stability)
12.	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat,	Rezal S Capsule Composition Each capsule contains: Omeprazole...20mg Sodium bicarbonate...1100 mg	Approved with as per innovator’s specifications. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to

			☐ Verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board ☐ Submission of fee Rs. 9000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications. ☐ Latest GMP inspection report conducted within period of three years.	Pharmaceutical Evaluation Cell. Verified vide Dy. No 6165 dated 05-07-2012 from R&I Rs.8000/- (photo copy) Rs.12000/- (photo copy) verified vide Dy No.32461 -R&I dated 31-01-2020.
13.	M/s Wise Pharmaceuticals Plot No.3-A, Street No.S-1, RCCI Industrial Estate, Rawat,	Itope Tablet Composition Each tablet contains: Itopride HCl...50mg	Approved with as per innovator's specifications and following label claim: Each film coated tablet contains: Itopride HCl...50mg Moreover, Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ Verification of duplicate fee challans of Rs. 8,000 and Rs.12000/- will be done as per decision of 285th meeting of Registration Board ☐ Submission of fee Rs. 9000/- for pre-approval variation/revision of formulation in line with reference product and correction in FPP specifications. ☐ Latest GMP inspection report conducted within period of three years.	Form-5 AD R-II has informed letter vide No.F.1-11/2019-Reg-II dated 27-11-2023 verified Duplicate dossier from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell. Verified vide Dy. No 6166 dated 05-07-2012 from R&I Rs.8000/- (photo copy) Rs.12000/- (photo copy) verified vide Dy No.32461 -R&I dated 31-01-2020.
14.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Zeflam 50mg tablet Composition Each tablet contains: Diclofenac potassium....50mg	Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No. 19443 dated 04-08-2023 (Duplicate dossier) DD R-II has informed vide letter No.F.1-11/2019-Reg-II dated 15-01-2024 that duplicate dossier is verified from diary record of R&I and accordingly forwarded to Pharmaceutical Evaluation Cell.

			☐ submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.	Verified vide Dy. No 5603 dated 18-05-2011 from R&I Rs.8000/- (photo copy) Rs.12000/- (to be verified)
15.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Aproxen 550mg tablet Composition Each tablet contains: Naproxen sodium 550mg eq. to naproxen...500mg	Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ submission of fee Rs. 9000/- for pre-approval variation/revision from uncoated to film coated tablet.	Form-5 Dy. No. 19453 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5601 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)
16.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Bezix 10mg Tablet Composition Each tablet contains: Loratadine....10mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No. 19452 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5610 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)
17.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Begix 10mg tablet Composition Each tablet contains: Cetirizine 2HCl....10mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 Dy. No. 19446 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5608 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)

			☐ latest GMP inspection report conducted within period of three years.	
18.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Belden 20mg tablet Composition Each tablet contains: Piroxicam....20mg	Approved with Innovator's Specifications. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.	Form-5 Dy. No. 19445 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5587 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)
19.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Zadol 500mg tablet Composition Each tablet contains: Paracetamol....500mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No. 19444 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5596 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- to be verified)
20.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Blufen 100mg tablet Composition Each tablet contains: Flurbiprofen...100mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No. 19451 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5578 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)

21.	M/s Basel pharmaceutical, 227-Phase-II, Multan Industrial Estate, Multan.	Befam 40mg tablet Composition Each tablet contains: Famotidine...40mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ submission of fee Rs. 9000/- for pre-approval variation/revision of formulation from uncoated to film coated tablet.	Form-5 Dy. No. 19448 dated 04-08-2023 (Duplicate dossier) Verified vide Dy. No 5597 dated 18-05-2011 from R&I Rs.8000/- dated 18-05-2011 (photo copy) Rs.12000/- (to be verified)
22.	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat	Diacin Capsule 50mg Composition Each capsule contains: Diacerein 50mg As per Innovator's specs	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12,000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No. 1455 dated 29-06-2022 (Duplicate dossier) Fee 8000/- dated 20-12-2010 (Photocopy challan) Fee 12000/- challan and its receiving in DRAP is not attached
23.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Diva Tablets 5mg Composition Each tablet contains: Diazepam...5mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000/- within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challan of Rs.8000/- will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ submission of fee Rs. 9000/- for pre-approval variation/revision of FPP specifications.	Form-5 (Duplicate dossier) Rs. 8000/- (photocopy challan) Dy.No.32398 dated.31-01-2020 Rs.12000/- dated 31-01-2020 (original)

24.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	T-Val tablet 250mg Composition Each tablet contains: Sodium Valproate 250mg	Registration Board approved the formulation as per following label claim: Each enteric coated tablet contains: Divalproex sodium eq. to Sodium Valproate 250mg Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 37000/- for pre-approval variation in label claim.	Form-5 (Duplicate dossier) Dy. No 26844 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
25.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Fiden Tablet 30mg Composition Each tablet contains: Ephedrine HCl...30mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs. 8000/- (photocopy challan) Dy.No.32391 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
26.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Risdone Tablet Composition Each tablet contains: Risperidone...2mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Dy. No 26840 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)

27.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Amdol-P Tablet Composition Each tablet contains: Tramadol HCl ...37.5mg Paracetamol....325mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Dy. No 26841 dated 22-09-2022 Rs. 8000/- (photocopy challan) Rs.12000/- dated 25-06-2018 (photocopy)
28.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Derminone Cream Composition Each gram contains: Hydroquinone.....20mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs. 8000/- (photocopy challan) Dy.No.32393 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
29.	M/s Tagma Pharma (Pvt) Ltd., 12.5 Km Raiwind Road, Lahore.	Felix Ointment Composition Each gram contains: Diflucortolone Valerate.....0.1 %	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs. 8000/- (photocopy challan) Dy.No.32392 dated.31-01-2020 Rs.12000/- dated 30-01-2020 (original)
30.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Erythro tablet 250mg Composition Each film coated tablet contains: Erythromycin as Stearate.....250mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 Dy. No 24859 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 26-05-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)

			☐ latest GMP inspection report conducted within period of three years.	
31.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore	Diclofast -P tablet 50mg Composition Each film coated tablet contains: Diclofenac Potassium ...50mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No 24868 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
32.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Diclofast tablet 50mg Composition Each film coated tablet contains: Diclofenac Sodium ...50mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No 24864 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
33.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Medisulide Tablet 100mg Composition Each tablet contains: Nimesulide....100mg	Keeping in view the approval status of Nimesulide 100mg tablet in EMA, Registration Board approved the applied formulation of Nimesulide tablet 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • Treatment of acute pain • Primary dysmenorrhea Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per	Form-5 Dy. No 24862 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)

			decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP specifications.	
34.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Lomeflo tablet 200mg Composition Each film coated tablet contains: Lomefloxacin Hydrochloride eq. to Lomefloxacin 200mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP specifications.	Form-5 Dy. No 24860 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
35.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore. Contract manufactured by: M/s Dyson Research Laboratories Pvt. Ltd., 28 Km Ferozpur Road Lahore.	Medipram Tablet 10mg Composition Each film coated tablet contains: Escitalopram as Oxalate 10mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of submitted differential fee of contract manufacturing within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs.8000/- dated 18-07-2009 (Photocopy) to be verified form R& I Rs.12,000/- 30-07-2013 (photocopy challan only)
36.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Clomimed tablet 50mg Composition Each tablet contains: Clomiphene Citrate.....50mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 Dy. No 24863 dated 08-09-2021 (Duplicate dossier) Dy. No. 4645 dated 20-04-2011; Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R& I R&I and fee challan of Rs.12,000/- are not attached

			☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP specifications.	
37.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Biovirin capsule 200mg Composition Each capsule contains: Ribavirin 200mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 Dy. No 24867 dated 08-09-2021 (Duplicate dossier) Rs.8000/- dated 20-04-2011 (Photocopy) to be verified form R&I R&I and fee challan of Rs.12,000/- are not attached
38.	M/s Medisearch Pharmacal Private Limited, 5-Km Raiwind Manga Road, Lahore.	Palen 1g cream Each gram contains: Adapalene ...1mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 12000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Rs.8000/- dated 21-05-2011 (Photocopy) to be verified form R&I Rs.12,000/- 30-07-2013 (photocopy challan only)
39.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore,	Foxin 50mg capsule Composition Each capsule contains Etifoxine HCl...50mg	Approved. Registration Board further decided that registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP Specifications.	Form-5 (Duplicate dossier) Dy. No. 28834 dated 01-01-2020; Rs.12000/- dated 01-01-2020, (original) R&I receiving and Rs.8000/- fee challan are not attached

40.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore,	Senox forte tablet Each film coated tablet contains: Secnidazole...1000mg	Approved. Registration Board further decided that registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ Submission of fee Rs. 37,000/- for pre-approval variation in formulation (strength) and FPP Specifications.	Form-5 (Duplicate dossier) Dy. No. 28834 dated 01-01-2020; Rs.12000/- dated 01-01-2020, (original) Rs.8000/- dated 08-11-2010 (photocopy challan only) R&I receiving is not attached
41.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore,	Zopic 1mg tablet Composition Each film coated tablet contains: Eszopiclone...1mg	Approved. Registration Board further decided that registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Dy. No. 30984 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (original) Dy. No. Nil, dated 04-01-2011; Rs.8000/- dated 04-01-2011 (photocopy) to be verified from concerned section
42.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore,	Zopic 2mg tablet Composition Each film coated tablet contains: Eszopiclone...2mg	Approved. Registration Board further decided that registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Dy. No. 30985 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (original) Dy. No. Nil, dated 04-01-2011; Rs.8000/- dated 04-01-2011 (photocopy) to be verified from concerned section
43.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore,	Sabilax Sachet Composition Each Sachet contains: Vigabatrin....500mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website.	Form-5 (Duplicate dossier) Dy. No. 30986 dated 21-01-2020; Rs.12000/- dated 20-01-2020, (original) Rs.8000/- dated 27-11-2010 (photocopy challan only) R&I

			☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP Specifications.	receiving is not attached
44.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Aprazole 40 mg tablets Composition Each enteric coated tablet contains: Pantoprazole (as Sodium Sequihydrate).....40 mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP Specifications.	Form-5 (Duplicate dossier) Dy. No. 14059 dated 30-12-2024 intimation dated 16-11-2020 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified
45.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Mupical cream Composition Each gram contains: Mupirocin as calcium.....20mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years.	Form-5 (Duplicate dossier) Dy. No. 14050 dated 30-12-2024 and intimation dated 16-11-2020 and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan are not attached
46.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Acnetek gel 0.1% w/w Composition Each gram contains: Adapalene 1mg	Approved. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 (Duplicate dossier) Dy. No. 14051 dated 30-12-2024 and intimation dated 16-11-2020 and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified

			☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation in FPP Specifications.	R&I receiving and Rs.8000/- fee challan are not attached
47.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Linopril -10 mg Tablets Composition Each film coated tablet contains: Lisinopril Dihydrate eq. to Lisinopril Anhydrous 10mg	Approved as uncoated tablet. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 (Duplicate dossier) Dy. No. 14061 dated 30-12-2024 and intimation dated 16-11-2020 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan are not attached
48.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Ethylcol 500mcg Tablet Composition Each film coated tablet contains: Mecobalamin 500mcg	Approved as sugar coated tablet. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 9000/- for pre-approval variation of formulation in line with reference product.	Form-5 (Duplicate dossier) Dy. No. 14060 dated 30-12-2024 and intimation dated 16-11-2020 and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan are not attached
49.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Rubonac gel Composition Each gram contains: Diclofenac Diethylamine 10mg	Approved as per following label claim: Each gram contains: Diclofenac Diethylamine eq. to Diclofenac Sodium 1% . Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board.	Form-5 (Duplicate dossier) Dy. No. 14058 dated 30-12-2024 and intimation dated 16-11-2020 and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan are not attached

			☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 37000/- for pre-approval change in label claim.	
50.	M/s Derma Techno Pakistan, 528-Sundar Industrial Estate Riawind Road, Lahore.	Dermolimus 0.1% Ointments Each gram contains: Tacrolimus 0.1%w/w Inhouse specs	Approved as per following label claim: Each gram contains: Tacrolimus as Monohydrate 0.1%w/w. Registration Board further decided that Registration letter shall be issued after the following: ☐ Submission of original receipt of fee of Rs. 8000 within 6 months of publication of minutes of instant meeting on DRAP website. ☐ verification of duplicate fee challans will be done as per decision of 285th meeting of Registration Board. ☐ latest GMP inspection report conducted within period of three years. ☐ fee Rs. 37000/- for pre-approval change in label claim.	Form-5 (Duplicate dossier) Dy. No. 14057 dated 30-12-2024 and intimation dated 16-11-2020 and 08-05-2024 Dy. No. nil dated 13-06-2016; Rs.168000/- (14 x 12,000/-) dated 13-06-2016, (photocopy) to be verified R&I receiving and Rs.8000/- fee challan are not attached

In this context, it is submitted that minutes of 344th meeting were published on 25-02-2025 on the official website of DRAP. However, after the lapse of stipulated time period, above mentioned applicants have not submitted the requisite information/ documents.

Decision: Keeping in view that the applicants have not submitted the requisite document(s) within the stipulated time period, Registration Board rejected the registration applications of products mentioned at S.No. 01-50 of above table. Furthermore, the relevant approvals granted by the Board in its 344th meeting shall stand redundant/ disposed of.

Case No.02. Approval of Cephalosporin Containing Products Issued to M/s Hicon Pharmaceuticals, Peshawar

Registration Board in its 349th meeting 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 of submission	(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 of 297th Meeting of Registration Board (12-15th January, 2026)
	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	
2.	Approved	
	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 of submission	(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 atrihydrate.....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	

While 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 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):

- 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.

Proceedings of 353rd Meeting:

Registration Board was apprised that in compliance with the decision taken by the Board in its 297th (held on 12th -15th January, 2021) meeting, registration of following products were suspended (dated 06.04.2021) on request of M/s Hicon, Peshawar:

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: Cephadrine 125mg
6.	041511	Concef Dry Suspension Each 5ml contains: Cephadrine 250mg
7.	041512	Concef Capsules Each Capsule contains: Cephadrine 250mg
8.	041513	Concef Capsules Each Capsule contains: Cephadrine 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

Decision: 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.

Case No. 03. Requirement of Fee & Source Fixation for Tablets Containing Modified Release Imported Pellets.

Registration Board in its 352nd meeting approved the following product of M/s Hoechst Pakistan Limited, Karachi.

Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
Application Form Dy. No / Tracking ID & date of submission	(LNX-DGN-8YPU, 2025-10-01)
Detail of Fee Submitted	97200.0, 2025-08-12,
The proposed proprietary name / brand name	Xatramax-S 0.4mg/6mg Tablets
Label Claim	Each bilayer modified release tablet contains: Tamsulosin hydrochloride.....0.4mg (Corresponding to 0.37mg of Tamsulosin base) Solifenacin succinate.....6mg (Corresponding to 4.5mg of Solifenacin base)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1x10's-As per SRO, 1x7's-As per SRO, 2x10's-As per SRO, 2x7's-As per SRO, 3x10's-As per SRO, 4x7's-As per SRO
Shelf Life (Unit)	2 Year Store at controlled room temperature 20°C - 25°C.
For generic drugs (me-too Status)	Tamsol-S Tablets by Global Pharmaceuticals Pvt Ltd (Reg. No. 096667)
Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
Name, address of Manufacturing site:	Global Pharmaceutical Pvt. Ltd-Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad-
The status in reference regulatory authorities	Approved by MHRA UK
Detail of previous approval	UFI-S 6mg/0.4 mg Tablet approved in 339th DRB Dated 6-8 Aug 2024
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	

While processing for issuance of registration letter it was noted that both Solifencin Immediate Release Pellets and Tamsulosin Modified Release Pellets are being imported from M/s Alphamed, Formulations Pvt. Ltd., Sy. No. 225, Sampanbole Village, Shamirpet Mandal, Medchal–Malkajigiri District, Telangana–500078 India. However, the applicant has submitted registration fee of Rs.97200/-

In this context, it is informed that Registration Board has already considered registration applications of same formulation with different fees i.e.,

- Rs. 30000/- (Ref. M-336; Case Dy. No. 33021: 17-11-2022),
- Rs.225,000/- (Ref. M-339; Case Dy No. 14530 dated 09-06-2023),
- Rs.75,000/- (Ref. M-339; Case Dy.No 12728 dated 30-11-2022),
- Rs.300000/-(Ref. M-345; Case Dy.No. 4862 dated 06-06-2017),
- Rs.300000/-(Ref. M-345; Case TID: VUL-XPB-SM4L)

Furthermore, source of pellets is not mentioned on registration letters of above referred products. However, modified release behavior of pellets is retained in final finished product.

Accordingly, the case has been placed before the Registration Board for deliberation regarding requirement of fee and fixation of source for all such products of similar nature.

Decision: Registration Board decided that for all those cases where finished pharmaceutical product retains the modified release behavior of pellets, source of pellets shall be fixed. Furthermore, requisite fee for import shall be applicable as prescribed under the prevailing SRO addressing regulatory fee for therapeutic goods.

In this context, registration holders of already registered products shall be directed to get PRV approval for source fixation after submission of requisite documents and fee, if applicable to the relevant section of PE&R Division.

Registration-II Section

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

The Registration Board in its 295th meeting approved following product (containing narcotic / controlled substance) in the name of M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhpura Road, Lahore. However, the firm does not possess the relevant manufacturing facility / section for manufacturing of controlled substances.

S.#	Brand name and composition	Applied pack size and MRP	Decision of RB / Remarks
1.	Egofin Tablet 1mg/100mg Each Tablet Contains: Ergotamine tartarate..... 1mg Caffeine (anhydrous)..... 100mg USP Form-5	Bottle of 100 tablets, price as per SRO	Approved Label claim has been corrected as under: Each film coated tablet Contains: Ergotamine tartarate.....1mg Caffeine (anhydrous).....100mg (USP Specifications) Firm has submitted fee of Rs.9400/- vide challan No. 586537386563 for standardization of label claim. (verified from website)

The case is placed before the Registration Board for cancellation of registration / approval of all approved / registered products including the abovementioned product since the firm doesn't possess the "Tablet Narcotic / Psychotropic Section".

Decision:-

The Registration Board decided to withdraw its earlier decision taken in 295th meeting and rejected the application as the firm does not possess Narcotic/Psychotropic Section.

CASE NO. 02: RESUBMISSION OF CASES CONSIDERED BY THE REGISTRATION BOARD IN ITS 329th MEETING:

Following products were also considered / approved by the Registration Board in its 329th meeting, however, these cases need to be again placed before the Registration Board for the reasons recorded in the last column of the table below:

S. No.	Name of Manufacturer	Brand name with composition and Applied FPP specifications	Decision of 329 th meeting of RB	Remarks / Reason for resubmission before the Board
1.	M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore	Just N 200mg/ml Injection Each ml Contains: Norethisterone Enanthate...200mg Firm has claimed in house specification while monograph is available in international pharmacopoeia	Approved with International Pharmacopoeia specifications. Registration letter will be issued upon submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, along with latest GMP inspection report conducted within last three years.	The firm has withdrawn the “Injectable Hormone Section” The same has been communicated vide licensing division letter IOJ-OP6-X9A1 dated 02-12-2025.
2.	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad	Buprenor Injection 0.3mg Each 1ml Ampoule contains: Buprenorphine (As Hydrochloride)... 0.3mg In-house Specs	Approved. Registration letter shall be issued after confirmation of Section approval and submission of NOC from Ministry of narcotics Control by the firm.	The firm does not possess the required section / manufacturing facility.
3.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dyspro 0.3mg Tablet Each Film Coated Tablet Contains: Conjugated Oestrogen...0.3mg USP		Submitted for decision as no decision is recorded in the minutes.
4.	M/s Pharmawise Labs Pvt Ltd., 25-M. Q.A Industrial Estate, Kot Lakhpat Lahore	Floricort 0.1mg Tablet Each Tablet Contains: Fludrocortisone Acetate.....0.1mg USP		Submitted for decision as no decision is recorded in the minutes.
5.	M/s Aventek Pharmaceuticals Pvt Ltd 44-c, Sunder	Trama Plus Tablet 325/37.5mg Each Film Coated Tablet Contains:	Approved with Innovator’s specifications.	License was declared Invalid in 2025. However, later re-granted. The Approval was granted before the invalid

	Industrial Estate, lahore	Paracetamol...325 mg Tramadol HCl...37.5mg In-House specifications	Registration letter will be issued after submission of updated GMP inspection report by the firm. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	status of the DML. Such cases are yet to be decided.
6.	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad	Tobrin-D Eye Drops Each ml ophthalmic suspension contains: Tobramycin... 3mg Dexamethasone...1 mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	Product is already registered in the name of firm "Tobral-D Eye Drops Reg. No. 107011" Submitted for disposal.
7.	M/s Care Pharmaceuticals 8-Km, Thokar Raiwind Raod, Lahore	Nepcare 1mg Eye Drops Each ml of Suspension Contains: Nepafenac...1mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	Product was approved and letter issued in 327 th meeting. Submitted for disposal.
8.	M/s Davis Pharmaceutical Laboratories (DML # 000432) 121, Industrial Triangle Area, Kahuta Road, Islamabad	Davischoll Cream Each tube contains: Terbinafine (as HCl) 10mg/g (1% w/w) JP Specification	Approved	Product is already registered in the name of firm Davischoll 1% Cream Reg. No. 117488 Submitted for disposal.
9.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Tritop Tablet 25mg Each film-coated tablet contains: Topiramate... 25mg USP Specs	Approved. The firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	Product is already registered in the name of firm Todd 25mg Tablet Reg. No. 103391 Submitted for disposal.
10.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Tritop Tablet 50mg Each film-coated tablet contains: Topiramate... 50mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	Product is already registered in the name of firm Todd 50mg Tablet Reg. No. 103392 Submitted for disposal
11.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-	Teracetam Tablet 250mg Each film-coated tablet contains:	Approved. Firm shall submit latest GMP inspection report conducted within last	Product is already registered with the firm under R.No. 098295.

	Km, Lahore-Sheikhupura Road, Sheikhupura	Levetiracetam 250mg USP	three years before issuance of registration letter.	Submitted for disposal
12.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Teracetam Tablet 500mg Each film-coated tablet contains: Levetiracetam...500 mg USP Specs	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	Product is already registered with the firm under R.No. 098296. Submitted for disposal

Decision:-

S. No.	Name of Manufacturer	Brand name with composition and Applied FPP specifications	Decision of 329 th meeting of RB	Decision of Board in 353 rd meeting with ground
1.	M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore	Just N 200mg/ml Injection Each ml Contains: Norethisterone Enanthate...200mg Firm has claimed in house specification while monograph is available in international pharmacopoeia	Approved with International Pharmacopoeia specifications. Registration letter will be issued upon submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, along with latest GMP inspection report conducted within last three years.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as the firm has withdrawn the “Injectable Hormone Section” and issuance of show cause notice under Section 7(11)(b)&(c) read with Section 42 of the Drugs Act, 1976 for cancellation of registration of already registered products in the Narcotic/Psychotropic Section.
2.	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad	Buprenor Injection 0.3mg Each 1ml Ampoule contains: Buprenorphine (As Hydrochloride)... 0.3mg In-house Specs	Approved. Registration letter shall be issued after confirmation of Section approval and submission of NOC from Ministry of narcotics Control by the firm.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as the firm does not possess Narcotic/Psychotropic Section.
3.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dyspro 0.3mg Tablet Each Film Coated Tablet Contains: Conjugated Oestrogen...0.3mg USP		Approved
4.	M/s Pharma wise Labs Pvt	Floricort 0.1mg Tablet		Approved

	Ltd., 25-M. Q.A Industrial Estate, Kot Lakhat Lahore	Each Tablet Contains: Fludrocortisone Acetate.....0.1mg USP		
5.	M/s Aventek Pharmaceutical s Pvt Ltd 44-c, Sunder Industrial Estate, lahore	Trama Plus Tablet 325/37.5mg Each Film Coated Tablet Contains: Paracetamol...325 mg Tramadol HCl...37.5mg In-House specifications	Approved with Innovator's specifications. Registration letter will be issued after submission of updated GMP inspection report by the firm. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7- 11/2012-B&A/DRAP dated 07-05-2021.	Deferred for decision by the Authority as License was declared Invalid in 2025. However, later re- granted.
6.	M/s. Panacea Pharmaceutical s, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad	Tobrin-D Eye Drops Each ml ophthalmic suspension contains: Tobramycin... 3mg Dexamethasone...1 mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered in the name of firm "Tobral-D Eye Drops Reg. No. 107011"
7.	M/s Care Pharmaceutical s 8-Km, Thokar Raiwind Raod, Lahore	Nepcare 1mg Eye Drops Each ml of Suspension Contains: Nepafenac...1mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered in the name of firm (Reg. No. 117867).
8.	M/s Davis Pharmaceutical Laboratories (DML # 000432) 121, Industrial Triangle Area, Kahuta Road, Islamabad	Davischoll Cream Each tube contains: Terbinafine (as HCl) 10mg/g (1% w/w) JP Specification	Approved	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered in the name of firm Davischoll 1% Cream Reg. No. 117488
9.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20- Km, Lahore- Sheikhupura Road, Sheikhupura	Tritop Tablet 25mg Each film-coated tablet contains: Topiramate... 25mg USP Specs	Approved. The firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered in the name of firm Todd 25mg Tablet Reg. No. 103391
10.	M/s De-Mont Research	Tritop Tablet 50mg	Approved. Firm shall submit latest GMP	The Registration Board decided to withdraw its

	Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Each film-coated tablet contains: Topiramate... 50mg USP	inspection report conducted within last three years before issuance of registration letter.	earlier decision taken in 329th meeting and rejected the application as Product is already registered in the name of firm Todd 50mg Tablet Reg. No. 103392
11.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Teracetam Tablet 250mg Each film-coated tablet contains: Levetiracetam 250mg USP	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered with the firm under R.No. 103389.
12.	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura	Teracetam Tablet 500mg Each film-coated tablet contains: Levetiracetam...500 mg USP Specs	Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	The Registration Board decided to withdraw its earlier decision taken in 329th meeting and rejected the application as Product is already registered with the firm under R.No. 103390.

S. No.	CASE TITLE
1.	Substandard Zayzine Syrup Batch No. 23150, Reg No. 096969 Manufactured By M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar.
2.	Substandard Anarob Infusion, Reg. No. 026985 Batch No # H24219 Manufactured By M/s Vision Pharmaceutical (Pvt) Ltd, Islamabad
3.	Substandard Imcomox For Oral Suspension 60ml, Reg. No. 013756 Batch No # 029 And Imcodal Oral Suspension Reg. No. 013363 Batch No # 013 Manufactured By M/S Imco Pharmaceutical Labs, Industrial Estate Hayatabad, Peshawar
4.	Substandard Zolint Suspension, Reg. No. 016494 Batch No # 25024 Manufactured By M/s Libra (Private) Limited
5.	Availability Of Counterfeit Product Against Our Product Dettol Liquid Registration No. 000150 Along With Illegal Price
6.	Substandard Famila 28f Tablet, Reg. No. 023941 Manufactured By M/S Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Karachi.
7.	Manufacture And Sale Of Sub-Standard Injection Cara-Doba 5ml (Dobutamine 250mg/5ml) Batch No. 24J009 And 25E004 Manufactured By M/s. Caraway Pharmaceuticals Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat, Islamabad DML No. 000629)
8.	Manufacture/Sale of Substandard Drug Namely Famila Injection (Reg. No. 015615) Batch No. 083 Manufactured By M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi

**CASE NO.1: SUBSTANDARD ZAYZINE SYRUP BATCH NO. 23150, REG NO. 096969
MANUFACTURED BY M/S ZAYNOON PHARMACEUTICALS (PVT) LIMITED,
PESHAWAR.**

Federal Inspector, DRAP, Quetta on 08th November, 2023 has inspected the premises of M/s Umar Traders, satellite Town, Quetta and took following sample of drug for the purpose of test/analysis on prescribed Form-3

2. The sealed sample of Zayzine Syrup was sent for testing and analysis to the Federal Government Analyst at the Central Drug Laboratory in Karachi under Section 19(3)(i) dated 10th November, 2023 and additionally sent a portion to the Chairman, Drug Registration Board. DRAP, Islamabad under Section 19(3) (ii).

3. M/s Umar Traders, Satellite Town, Quetta, presented the bill warranty from M/s Shah Traders, Quetta, as proof of purchase. In this regard, M/s Shah Traders, Quetta, was requested to provide a subsequent copy of the bill warranty/invoice. In response, they submitted a bill warranty/commercial invoice issued by M/s Zaynoon Pharmaceutical (Pvt) Limited, Peshawar.

4. A sealed portion of the sample (the manufacturer's portion) was also sent to M/s Zaynoon Pharmaceutical (Pvt) Limited, Peshawar, under Section 19(3)(iii) via office letter No. DK-38-39/2023-FID-QTA-169, dated November 10, 2023. Following a subsequent Reminder-1, M/s Zaynoon Pharmaceutical (Pvt) Limited acknowledged receipt of the sample through their letter Ref. No. ZPPL/QC/024/002, dated January 25, 2024.

5. The Federal Government Analyst, Central Drug Laboratory, Karachi declared the sample of Zayzine Syrup as of "*Adulterated and Sub-Standard (Sub-standard & Falsified)*" quality vide their test report No. KQ-11-23-000152 dated 15th January, 2024. Details of sample as below:

Name of Drug	Manufactured by	Batch No	Mfg. Date	Exp.Date	CDL Report
Zayzine Syrup (60ml) (Cetirizine) Reg No. 096969	M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar	23150	10-2023	09-2025	Containing foreign particles visible to the naked eye. Does not comply " <i>Adulterated and Sub-Standard (Sub-standard & Falsified)</i> "

6. The Federal Inspector of Drugs, Quetta, concluded that "Based on all the facts, M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar, has violated Section 23(1)(a) (iv & v) of the Drugs Act, 1976, along with the rules framed thereunder, which is punishable under the relevant section." He further mentioned that a comprehensive case was being submitted under Section 19(7) of the Drugs Act, 1976, for appropriate action.

7. FID DRAP, Quetta submitted M/s Zaynoon Pharmaceuticals (Pvt) Limited request for appellate testing of their product Zayzine Syrup from the appellate laboratory under Section 22(4) of the Drugs Act, 1976 vide letter No. ZPPL/QC/024/010 dated 26th April, 2024, from the company after receiving the letter from the Federal Inspector of DRAP, Quetta, along with the CDL report (which was FID sent on 30th January, 2024)

8. The request of the company for testing of the sample of the drug lying with the Registration Board from the appellate laboratory specified for the purpose by the Federal Government under Section 22(5) of the Drugs Act 1976 could not be processed as the thirty-day period had elapsed.

9. Under Section 22(4) of The Drugs Act 1976, person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of a copy of the report to notify in writing that he intends to adduce evidence in contravention of the report.

10. Division of QA&LT issued show cause notice vide office F.03-48/2024-AD(QALT-IV)

dated 6th December, 2024 under Section 42 of the Drugs Act 1976.

11. In response to said show cause, M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar. Vide letter ZPPL/QC/2024/029 dated 24th December, 2024 replied as under:

In reply of your letter no. F.03-48/2024-AD(QALT-IV) dated 06/12/2024 and received on 11/12/2024, it stated that have the following findings & reservations regarding our product.

A.) FINDINGS:

- 1.) *The warrantor portion of the said sample when received was found broken and was nothing to observe except broken glass pieces and damaged letter of DRAP Quetta, FID was informed timely regarding the matter and also send a video shoot of the received stuff.*
- 2.) *We immediately Re-call our product through office circular and print media and upon receiving the recall we thoroughly observed our product and found it ok.*
- 3.) *We analyzed our product after the complete recall and found OK as it was comply all the test protocols including Appearance, pH, Assay, weight per ml etc.*

B.) RESERVATIONS:

- 1.) *The above mentioned sample was not fully tested by the CDL, therefore, the report does not reflect the complete assay results. Based on the presence of foreign particles the sample has been declared adulterated and substandard. This decision appears to stem from potential biases within the FID, as the sample was not subjected to thorough testing at the CDL.*
 - 2.) *The Test report is also time barred as the sample was picked by FID on 08.11,2023, whereas test report issued on 15.01.2024 more than 60-days which is mandatory to issue the report within 60- days.*
 - 3.) *We requested for Re-testing at the appellate Labs, which was denied on the grounds that the time period for Re-testing had elapsed. This seems incorrect, as the time frame should begin from the date we received the test report, which was on 24.04.2024, as indicated by the FID Quetta letter dated 16.04.2024. in contrast, the test report itself was received by FID in January 2024.*
12. Accordingly, the firm has been issued notice of personal hearing to appear before the Board, under Section 42 of the Drug Act 1976.

13. Proceedings and Decision of 345th Meeting of Registration Board

In Compliance to personal Hearing letter from Division of QA&LT Mr. Shaukat Ayaz Q.C Manager and Mr. Dawood Kamal, Legal advisor of M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar appeared before the Board. They said that the warrantor portion of the said sample when received was found broken and was nothing to observe except broken glass pieces and accordingly was informed to FID, Quetta regarding the matter. That they said that in retained sample they did not found any visible particles.

The Board after considering the facts of the case and thorough deliberations decided to accede request of firm for appellate testing, under Section 22 (5) of the Drugs Act, 1976, of Zayzine Syrup (096969), Batch No. 23150 Manufactured by M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar.

14. The sample was sent to Appellate Laboratory (NIH) vide No.F.3-9/2025-QALT(345-RB) dated 17th April,2025.

15. Letter from National Institute of Health vide letter No. F.1-20/04-M/2025-DC &TMD dated 29th September, 2025 (Received on 20-11-2025) wherein it was submitted that

- a. *The sample in question pertains to physical description of Zayzine Syrup manufactured by M/S Zaynoon Pharmaceutical (Pvt) Limited, 27-28 13. Industrial Estate Hayatabad Peshawar-Pakistan, which holds registration no. 096969 approved by Drug Regulatory Authority of Pakistan (DRAP).*
- b. *DRAP submitted the said sample for visual inspection on the basis of physical description and the request made by M/S Zaynoon pharmaceutical (Pvt) Limited. 27-28 B, Industrial Estate Hayatabad Peshawar-Pakistan, for appellate testing.*
- c. *It is pertinent to inform that this esteemed laboratory has already clarified as per USP (Copy attached at Annex-A) in another case that it is the decision of regulatory body to consider physical description as test specifications or otherwise.*
- d. *The physical description as requested by you is not mentioned in the individual monograph of United States Pharmacopeia (Copy attached at Annex-B).*

c. It is also significant to mention that DRAP vide letter no. F.13-22/2024-QC dated March 14, 2025 clarified "if monograph (testing specification) of any registered drug product is available in the official pharmacopeia then the same needs to be complied with for the purpose of test/analysis". Keeping in view the clarification provided by the USP Technical Department on specifications, along with its endorsement by DRAP and reply on verification of manufacturer specifications by the DRAP, Islamabad, we kindly request you to withdraw your request as the sample cannot be proceed on the said request. The reason for this request is that the physical description as requested by you is not available in the individual monograph of USP.

16. **Proceedings and Decision of 353rd Meeting of Registration Board**

The Board after considering the facts of the case and thorough deliberations decided as under:

- i. **Submission of RCA and CAPA by the firm.**
- ii. **Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.**
- iii. **Suspension of the Registration of Zayzine Syrup (60ml), Registration No. 096969 manufactured by M/s Zaynoon Pharmaceuticals (Pvt) Limited, Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel constituted by the Director (QA&LT) with satisfactory report.**
- iv. **Firm shall submit complete recall status of aforementioned batch of product "Zayzine" as per Recall Guidelines Doc No. QALT/GL/RA/001 to the QALT Division, DRAP, Islamabad.**

CASE NO.2: SUBSTANDARD ANAROB INFUSION, REG. NO. 026985 BATCH NO # H24219 MANUFACTURED BY M/S VISION PHARMACEUTICAL (PVT) LTD, ISLAMABAD

The Federal Inspector of Drugs, DRAP, Quetta (Mr. Muhammad Yaqoob) visited the premises of M/s Bolan Medical Complex hospital, Barwery Road, Quetta on 2nd July, 2025 and took samples of the Anarob Infusion 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. KQ-7-25-000083 dated 13th august, 2025, declared the batch H24219 of product Anarob Infusion manufactured by M/s Vision Pharmaceutical (Pvt) Ltd, Islamabad as of "Substandard Quality". Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Anarob Infusion (Metronidazole)	M/s Vision Pharmaceutical (Pvt) Ltd, Islamabad	026985	H24219	08-2024	07-2027	Sample has been declared as "Substandard" on the basis of Bacterial Endotoxins Does not comply Not more than 0.35 EU/mg

2. Federal Inspector of Drugs Quetta was directed to investigate the matter and submit a comprehensive report in the matter.

3. Federal Inspector of Drugs, DRAP, Quetta, submitted the company's request of Appellate testing vide letter REF/VP/060/2025 dated 2nd September, 2025, after receiving letter along with CDL report from FID Quetta which was sent on 25th August 2025 Received by firm on 1st September, 2025)

4. 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.”*

5. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. 03-39/2025-DD (QALT) dated 19th September, 2025, requested the Federal Government Analyst CDL Karachi and M/s Vision Pharmaceuticals (Pvt) Ltd, Islamabad for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with USP 2024 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 Vision Pharmaceuticals (Pvt) Ltd, Islamabad

M/s Vision Pharmaceuticals in their reply

Following are the main point of the scientific justification/grounds.

1. Comprehensive investigation on reported batch (H24210) of Anarob Infusion and no loophole in the manufacturing process of Anarob 100ml Infusion Batch No H24219
2. M/s Vision Pharmaceutical (Pvt) Ltd, Islamabad producing Anarob 100ml Infusion in LDPE through BFS technology which sale and automatic process and there is no human contact with the product during filling process.
3. So many steps involved the raw water filtration through multimedia softening of water. Double RO process. D-ionization. Distillation and filtration “Solution of Infusion passing through filters of 1.2 μ (0.66 μ + 0.45 μ) and finally 0.2 μ “before filling process, after filling LDPE Bottles are sterilized through autoclave.
4. BET is verified at all stages, Distillation Process, after collection of bulk water ready for manufacturing process, filling tanks and filling nozzles are also verified for BET before filling process.
5. BET test of bottles also performed at start, mid and end of the filling.
6. After sterilization of filled LDPE bottles, randomly collected Bottles are analyzed for chemical and microbiological analysis including BET
7. It is not possible that after involving so many steps filled LDPE Bottles become contaminated
8. We have rechecked our retained sample of the same batch for Bacterial Endotoxin and no discrepancy found. Bacterial Endotoxin of the retained sample found well with in limit. Also we perform sterility test on same batch and after completion of sterility test no growth observed and sterility test passes.
9. We have reviewed complete Batch Manufacturing Record and Analytical Reports of the above mentioned batches No H24219 no such problem was reported by microbiologist at that time.
10. We have checked warrantor portion for BET testing and results are found well with in limit.

7. Proceedings and Decision of 353rd Meeting of Registration Board

The Board after considering request of the firm, facts of the case and thorough deliberations decided to accede request of firm for appellate testing of product Anarob Infusion (026985), Batch No. H24219 Manufactured by M/s Vision Pharmaceutical (Pvt) Ltd, Islamabad, under Section 22 (5) of the Drugs Act, 1976.

CASE NO.3: SUBSTANDARD IMCOMOX FOR ORAL SUSPENSION 60ML, REG. NO. 013756 BATCH NO # 029 AND IMCODAL ORAL SUSPENSION REG. NO. 013363 BATCH NO # 013 MANUFACTURED BY M/S IMCO PHARMACEUTICAL LABS, INDUSTRIAL ESTATE HAYATABAD, PESHAWAR

The Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar on 07-05-2025 and took samples of the Imcomox for Oral suspension 60ml and Imcodal Oral Suspension 60ml on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

3. Federal Government Analyst, CDL Karachi vide test report No. IP-5-25-000019 and No. IP-5-25-000021 dated 29th July, 2025 declared the batch 029 of product Imcomox for Oral suspension 60ml and batch 013 of product Imcodal Oral Suspension 60ml manufactured by M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar as of “*Substandard Quality*”. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Imcomox for Oral suspension 60ml (Amoxicilline trihydrate 125mg/5ml)	M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar	013756	029	03-2025	03-2027	Sample has been declared as “ Substandard ” on the basis of Assay:52.7% Limit;90-120%
Imcodal Oral Suspension 60ml (Metronidazole benzoate 64mg Furazolidone 25mg/5ml)	M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar	013363	013	05-2024	05-2026	Sample has been declared as “ Substandard ” on the basis of Assay of Furazolidone:45% Limit;90-110%

8. Federal Inspector of Drugs Peshawar was directed to investigate the matter and submit a comprehensive report in the matter.

9. Federal Inspector of Drugs, DRAP, Peshawar, submitted the company's request of Appellate testing vide letter nil dated nil received on 23rd September, 2025, after receiving letter along with CDL report from FID Peshawar which was sent on 9th September, 2025)

10. 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."

11. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. 03-38/2025-DD (QALT) dated 6th October, 2025, requested the Federal Government Analyst CDL Karachi and M/s Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample of Imcomox for Oral suspension 60ml is tested in accordance with USP 2024 and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample of Imcodal Oral Suspension 60ml is tested in accordance with Innovator specifications 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 Imco Pharmaceuticals, Plot No, 73, Industrial Estate, Hayatabad, Peshawar

M/s Imco Pharmaceuticals, Peshawar in their reply has provided OOS investigation of Imcomox for Oral suspension 60ml at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

M/s Imco Pharmaceuticals, Peshawar in their reply has provided OOS investigation Imcodal Oral Suspension 60ml at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

13. Proceedings and Decision of 353rd Meeting of Registration Board

The Board after considering the facts of the case, reports of CDL, Karachi showing assay results as 52.7% and 45%, and after thorough deliberations decided:

- i. *Not to accede the firm's request for retesting of samples from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. *To issue show cause notice to M/s Imco Pharmaceutical Labs, Industrial estate Hayatabad, Peshawar under Section 42 of the Drugs Act, 1976 and*
- iii. *To call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.*

CASE NO.4: SUBSTANDARD ZOLINT SUSPENSION, REG. NO. 016494 BATCH NO # 25024 MANUFACTURED BY M/S LIBRA (PRIVATE) LIMITED

The Federal Inspector of Drugs, DRAP, Quetta (Mr. Muhammad Yaqoob) visited the premises of M/s Nazir & sons H.No.8-20/33-B Balochi street, Quetta on 24th June 2025 and took samples of the Zolint Suspension 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. KQ-6-25-000077 dated 10th October, 2025 declared the batch 25024 of product Zolint Suspension manufactured by M/s Libra (Private) Limited, Peshawar. as of "Substandard Quality". Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
Zolint Suspension Furazolidone 25mg/5ml Metronidazole 75mg/5ml	M/s Libra (Private) Limited, Peshawar.	016494	25024	05-2025	04-2027	Sample has been declared as “ Substandard ” on the basis of Assay Furazolidone: 79% Does not comply Limit: 90 to 110% Metronidazole: 81% Does not comply Limit: 90 to 110%

3. Federal Inspector of Drugs Quetta was directed to investigate the matter and submit a comprehensive report in the matter.

4. Federal Inspector of Drugs, DRAP, Quetta, submitted the company's request of Appellate testing vide letter nil dated 25th October, 2025, after receiving letter along with CDL report from FID Quetta which was sent on 20th October, 2025)

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:

- 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.*
- Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.*
- 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. 03-56/2025-DD (QALT) dated 19th November, 2025, requested the Federal Government Analyst CDL Karachi and M/s Libra (Private) Limited, 77-Industrial Estate, Hayatabad Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with Innovator specification 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 Libra (Private) Limited, 77-Industrial Estate, Hayatabad Peshawar.

M/s Libra (Private) Limited Peshawar in their reply has provided OOS investigation at laboratory and manufacturing level along with relevant evidences and has also ruled out any chance of error in the manufacturing or testing of the product in question.

8. Proceedings and Decision of 353rd Meeting of Registration Board

The Board after considering the facts of the case, reports of CDL, Karachi showing assay results of Furazolidone: 79%, Metronidazole: 81%, and after thorough deliberations decided:

- i. *Not to accede the firm's request for retesting of sample from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.*
- ii. *To issue show cause notice to M/s Libra (Private) Limited, Peshawar under Section 42 of the Drugs Act, 1976 and*
- iii. *To call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.*

CASE NO.5: AVAILABILITY OF COUNTERFEIT PRODUCT AGAINST PRODUCT DETTOL LIQUID REGISTRATION NO. 000150 ALONG WITH ILLEGAL PRICE

M/s Reckitt Benckiser Pakistan Submitted an application dated 13-08-2025 Wherein they stated that that the registered product 'Sevtol 50ml' (Registration No. 006939), manufactured by M/s Sapien Pharma, 123/6, Quaid-e-Azam Industrial Estate, Kot Lakh pat, Lahore, is counterfeit with the resemblance of the artwork of their registered product 'Dettol Antiseptic Liquid' (Registration No. 000150).

2. They further stated that the product is being sold at higher price of Rs.200/50ml. The same has no evidence of pricing issued by DRAP on the Website (evidence of DRAP website screenshot attached). They requested to take action against these spurious drugs.



3. **Proceedings and Decision of 352nd meeting of Registration Board**

Dr. Syed Haider Ali Head Regulatory & Medical Affairs and Mr. Akhtar Hussain Regulatory Manager of M/s Reckitt Benckiser Pakistan appeared before Board. They said that many counterfeit products emerged in market after stop of production of Dettol. Moreover, “Sevtol 50ml’ (Registration No. 006939), manufactured by M/s Sapient Pharma, 123/6, Quaid-e-Azam Industrial Estate, Kot Lakh pat, Lahore is being sold at higher price of Rs.200/50ml.

The Board after considering the facts of the case and after thorough deliberations decided:

- i. *Directed the Area FID to conduct verification of the price of Sevtol 50 ml (Registration No. 006939), manufactured by M/s Sapient Pharma, 123/6, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, and submit its findings accordingly.*
 - ii. *The representatives of M/s Sapient Pharma shall be called for a personal hearing before the Registration Board in its forthcoming meeting to explain and clarify the matter concerning the reported resemblance of their product with Dettol.*
4. In the light of Registration Board decision, Division of QA&LT issued a notice of personal hearing vide letter F.03-02/2026-QALT (353-RB) dated 6th January, 2026.

5. Proceedings and Decision of 353rd Meeting of Registration Board

“In compliance with the personal hearing notice issued by the Division of QA&LT, Mr. Mirza Ali Zahir, Managing Partner of M/s Sapiant Pharma, Lahore, appeared before the Board. He apprised the Board that M/s Sapiant Pharma had submitted an application through the PRVC for approval of change in label design. After deliberation, the Board acknowledged the compliance submitted by M/s Sapiant Pharma, Lahore and directed to Managing Partner of M/s Sapiant Pharma, Lahore for submission of new request in PRV for further change in color of label.”

CASE NO.6: SUBSTANDARD FAMILA 28F TABLET, REG. NO. 023941 MANUFACTURED BY M/S ZAFI PHARMACEUTICALS LABORATORIES (PVT) LTD, KARACHI.

The Federal Inspector of Drugs, DRAP, Karachi (Mr. Hakim Masood) in compliance to the direction contained on M/s Zafi Pharmaceutical Laboratories (Pvt) Ltd., Karachi request letter dated 19th May, 2025 and 4th June, 2025 visited the premises of Directorate of Central Warehouse and Supplies, situated at Plot No. F-508, S.I.T.E, Karachi on 22-05-2025 and 04-06-2025 respectively. Sample were drawn for the purpose of test/analysis on prescribed form-3.

2. The sealed samples of drugs were sent to Federal Government Analyst, Central Drugs Laboratories, Karachi for the test/analysis.

3. Federal Government Analyst, Central Drugs Laboratories, Karachi declared the below mentioned batches of FAMILA 28F TABLET” manufactured by M/s Zafi Pharmaceutical Laboratories (Pvt) Ltd., Karachi as of “Substandard Quality”. Details of CDL test reports are as under.

S.NO	Product Name	Manufactured by	Batch No.	Mfg. Date	Exp. Date	Test Results	CDL Test Report No and Date
1.	Tab. Famila 28F Reg. No 023941	M/s. Zafi Laboratories, A-46, SITE North Karachi	K-217	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6-25-000162 dated 28 th July, 2025,
2.	Tab. Famila 28F Reg. No 023941	M/s. Zafi Laboratories, A-46, SITE North Karachi	K-177	04-2025	04-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply	PWD-5-25-000129 dated 17 th July, 2025

						Limit: meets the requirements Assay (Levonorgestrel):134.8% Does not comply Limit: 90.0% to 110.0%	
3.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-203	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6-25-000148 dated 17 th July, 2025,
4.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-207	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6-25-000152 dated 17 th July, 2025
5.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-184	04-2025	04-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Assay (Levonorgestrel):144.8% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000132 dated 28 th July, 2025,
6.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-190	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements	PWD-5-25-000137 dated 28 th July, 2025

						Assay (Levonorgestrel):26.3% Does not comply Limit: 90.0% to 110.0%	
7.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-191	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Assay (Levonorgestrel):26.3% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000138 dated 28 th July, 2025
8.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-182	04-2025	04-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6-25-000146 dated 28 th July, 2025
9.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-199	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Ethinyl Estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements	PWD-6-25-000147 dated 28 th July, 2025

	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-204	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Ethinyl Estradiol) <i>Does not comply</i> Limit: meets the requirements Weight variation (Ferrous Iron) <i>Does not comply</i> Limit: meets the requirements	PWD-6- 25-000149 dated 28 th July, 2025
11.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-205	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Ethinyl Estradiol) <i>Does not comply</i> Limit: meets the requirements Weight variation (Ferrous Iron) <i>Does not comply</i> Limit: meets the requirements	PWD-6- 25-000150 dated 28 th July, 2025,
12.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-185	04- 2025	04- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements Content Uniformity (Ethinyl estradiol) <i>Does not comply</i> Limit: meets the requirements Assay (Levonorgestrel):134.0% <i>Does not comply</i> Limit: 90.0% to 110.0%	Test report No. PWD- 5-25- 000133 dated 31 st July, 2025,
13.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-189	05- 2025	05- 2028	Sample has been declared as “ <i>Substandard</i> ” on the basis of Content Uniformity (Levonorgestrel) <i>Does not comply</i> Limit: meets the requirements	PWD-5- 25-000136 dated 29 th July, 2025

						Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Assay (Levonorgestrel):144.0% Does not comply Limit: 90.0% to 110.0%	
14.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-187	04-2025	04-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements Assay (Levonorgestrel):132.4% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl estradiol):126.1.0% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000134 dated 18 th July, 2025,
15.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-192	05-2025	05-2028	Sample has been declared as “ Substandard ” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements	PWD-5-25-000139 dated 23 rd July, 2025

						Assay (Levonorgestrel):35.6% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl estradiol):25.5.0% Does not comply Limit: 90.0% to 110.0%	
16.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-194	05-2025	05-2028	Sample has been declared as “Substandard” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Assay (Levonorgestrel):27.0% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000140 dated 23 rd July, 2025,
17.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-195	05-2025	05-2028	Sample has been declared as “Substandard” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements Assay (Levonorgestrel):88.5% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000141 dated 1 st August, 2025
18.	Tab. Famila 28F	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-159	10-2024	10-2027	Sample has been declared as “Substandard” on the basis of	PWD-5-25-000090 dated 12 th

	Reg. No 023941					Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirement	August, 2025,
19.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-198	05-2025	05-2028	Sample has been declared as “Substandard” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements Assay (Levonorgestrel):113.9% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl estradiol):160.4% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000144 dated 13 th August, 2025
20.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-196	05-2025	05-2028	Sample has been declared as “Substandard” on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron)	PWD-5-25-000142 dated 12 th August, 2025

						Does not comply Limit: meets the requirements Assay (Levonorgestrel):117.0% Does not comply Limit: 90.0% to 110.0%	
21.	Tab. Famila 28F Reg. No 023941	M/s. Zafa Laboratories, A-46, SITE North Karachi	K-197	05-2025	05-2028	Sample has been declared as " Substandard " on the basis of Content Uniformity (Levonorgestrel) Does not comply Limit: meets the requirements Content Uniformity (Ethinyl estradiol) Does not comply Limit: meets the requirements Weight variation (Ferrous Iron) Does not comply Limit: meets the requirements Assay (Levonorgestrel):118.8% Does not comply Limit: 90.0% to 110.0% Assay (Ethinyl estradiol):173.2% Does not comply Limit: 90.0% to 110.0%	PWD-5-25-000143 dated 13 th August, 2025

4. Federal Inspector of Drugs Lahore was directed to investigate the matter and submit a comprehensive report in the matter.

5. Federal Inspector of Drugs, DRAP, Karachi, submitted the company's request of Appellate testing vide letter nil dated 30th July, 2025 and 7th August 2025, after receiving letter along with CDL report from FID, Lahore for following batches

S.NO	Product Name	Batch No	CDL Test Report No and Date
	Tab. Famila 28F Reg. No 023941	K-217	PWD-6-25-000162 dated 28 th July, 2025
	Tab. Famila 28F	K-177	PWD-5-25-000129 dated 17 th July, 2025
	Tab. Famila 28F	K-203	PWD-6-25-000148 dated 17 th July, 2025,
	Tab. Famila 28F	K-207	PWD-6-25-000152 dated 17 th July, 2025
	Tab. Famila 28F	K-184	PWD-5-25-000132 dated 28 th July, 2025,
	Tab. Famila 28F	K-190	PWD-5-25-000137 dated 28 th July, 2025
	Tab. Famila 28F	K-191	PWD-5-25-000138 dated 28 th July, 2025
	Tab. Famila 28F	K-182	PWD-6-25-000146 dated 28 th July, 2025
	Tab. Famila 28F	K-199	PWD-6-25-000147 dated 28 th July, 2025
	Tab. Famila 28F	K-204	PWD-6-25-000149 dated 28 th July, 2025
	Tab. Famila 28F	K-205	PWD-6-25-000150 dated 28 th July, 2025,

6. Federal Inspector of Drugs, DRAP, Karachi, submitted the company's request of Appellate testing vide letter nil dated 12th August, 2025 and 25th August, 2025, after receiving letter along with CDL report from FID, Lahore for following batches

S.NO	Product Name	Batch No	CDL Test Report No and Date
	Tab. Famila 28F Reg. No 023941	K-185	PWD-5-25-000133 dated 31 st July, 2025
	Tab. Famila 28F	K-187	PWD-5-25-000134 dated 18 th July, 2025,
	Tab. Famila 28F	K-189	PWD-5-25-000136 dated 29 th July, 2025
	Tab. Famila 28F	K-192	PWD-5-25-000139 dated 23 rd July, 2025
	Tab. Famila 28F	K-194	PWD-5-25-000140 dated 23 rd July, 2025,
	Tab. Famila 28F	K-195	PWD-5-25-000141 dated 1 st August, 2025

7. Federal Inspector of Drugs, DRAP, Karachi, submitted the company's request of Appellate testing vide letter nil dated 25th August, 2025 and 27th August, 2025, after receiving letter along with CDL report from FID, Lahore for following batches

S.NO	Product Name	Batch No	CDL Test Report No and Date
	Tab. Famila 28F Reg. No 023941	K-198	PWD-5-25-000144 dated 13 th August, 2025
	Tab. Famila 28F	K-196	PWD-5-25-000142 dated 12 th August, 2025
	Tab. Famila 28F	K-197	PWD-5-25-000143 dated 13 th August, 2025
	Tab. Famila 28F	K-159	PWD-5-25-000090 dated 12 th August, 2025,

8. 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:

Minutes of 353rd Meeting of Registration Board (14th – 15th January, 2026)

- 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.”

9. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F.03-37/2025-DD(QALT) dated 25th August, 2025, 5th September, 2025 and 20th October 2025 requested the Federal Government Analyst CDL Karachi and M/s. Zafa Laboratories, A-46, SITE North Karachi for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:

Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the test/analysis method provided in the USP 2024 (Levonorgestrel and Ethinyl estradiol) and by BP 2024 (Ferrous Fumarate) 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. Zafa Laboratories, A-46, SITE North Karachi
M/s. Zafa Laboratories, A-46, SITE North Karachi, in their reply has submitted that as per the Zafa Quality control (QC), reports these batches were found to be satisfactory and in compliance with the internal quality specifications at the time of release.

- a. The batches were tested using the USP method on HPLC, while the BP method is used specifically for testing Ferrous Fumarate, which is titration method.
- b. The testing method is verified in accordance with ICH guideline Q2(R1)
- c. Weight variation of Ferrous Fumarate is performed during in-process control as per BP specifications, applying a $\pm 7.5\%$ weight range. The weight variation is also checked during final QC testing and was found to be within acceptable limits.
- d. Weighing scales in both QC and Production are calibrated, with external calibration (contracted) conducted biannually. Daily verification is performed to ensure accuracy and compliance
- e. Content uniformity of Levonorgestrel and Ethinyl Estradiol was performed as per USP specifications, applying the NMT 15% acceptance criterion, and the results were meeting the specification.
- f. No deviations were observed between dispensing, manufacturing, and filling processes for all respective batches.
- g. The complaint batches of Famila 28 F Tablet and combo product Ferrous Iron re- tested in August, September and the results are as per prescribed specifications

Technical Evaluation of OOS Investigation:

- i. Total of twenty-one (21) batches of Famila 28 Tablet were declared by CDL as sub-standard on the basis of Assay, Content Uniformity of Levonorgestrel and Ethinyl Estradiol and weight variation of Ferrous Fumarate
- ii. Multiple batches failed for content uniformity. Content uniformity issues indicate uneven distribution of active pharmaceutical ingredients (APIs).
- iii. Defect of content uniformity may not be equally distributed over the batch that's why it is not necessary for a Board or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.

- iv. Assay values for Levonorgestrel and Ethinyl Estradiol in certain batches were far outside the permissible limit (90–110%), e.g.:

Batch. No	Levonorgestrel	Ethinyl estradiol
K-177	134.8%	
K-184	144.8%	
K-185	134.0%	
K-187	132.4	126.1.0%
K-189	144.0%	
K-190	26.3%	
K-191	26.3%	
K-192	35.6%	25.5.0%
K-194	27.0%	
K-195	88.5%	
K-196	117.0%	
K-197	118.8%	173.2%
K-198	113.9%	160.4%

Such extreme deviations indicate serious formulation or process issues rather than minor analytical variation.

11. **Proceedings and Decision of 352nd meeting of Registration Board**

The Board after reviewing the facts of the case and thorough deliberations decided to call the representatives of the firm for personal hearing to justify their request for retesting of product “Famila 28F Tablet” (023941) from Appellate testing before Registration Board in its forthcoming meeting.

12. In the light of Registration Board decision, Division of QA&LT issued a notice of personal hearing vide letter F.03-02/2026-QALT (353-RB) dated 6th January, 2026.

13. **Proceedings and Decision of 353rd Meeting of Registration Board**

In compliance to the personal hearing letter issued, Mr. Aqeel Ahmed Rizvi Regulatory Affairs, and Mr. Tahir Mirza, Group Director Quality operations of M/s. Zafa Laboratories, A-46, SITE North Karachi appeared before Board. The board raised queries regarding reason for variation in content uniformity, assay and weight variation.

The Board after considering reports of CDL, Karachi showing huge difference in results of content uniformity, weight variation & assay and after thorough deliberations decided as under:

“Product Specific Inspection by panel of inspectors/experts to be nominated by Director QA/LT. After submission of the panel inspection report, the Board will decide the request for appellate testing under Section 22(5) of the Drugs Act, 1976”.

CASE NO.7: MANUFACTURE AND SALE OF SUB-STANDARD INJECTION CARA-DOBA 5ML (DOBUTAMINE 250MG/5ML) BATCH NO. 24J009 AND 25E004 MANUFACTURED BY M/S. CARAWAY PHARMACEUTICALS PLOT NO. 12 STREET NO. N-3 NATIONAL INDUSTRIAL ZONE (RCCI) RAWAT, ISLAMABAD DML NO. 000629)

A Therapeutic Good Related Problem Report No. 2165 dated 02-12-2025, reported by Pharmacovigilance Officer, Services Hospital, Lahore, had been forwarded to Drug Regulatory Authority of Pakistan by the Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, Punjab letter No. PPC/QI-2/2022 (P-III) dated 09-12-2025.

2. The said TGRP pertains to a product quality issue that is dark brown discoloration and crystallization observed in Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch Nos. 25E004 and

24J009 manufactured by M/s Caraway Pharmaceuticals, National Industrial Zone (RCCI), Rawat, Islamabad.

3. Drugs Testing Laboratory of Punjab also declared the above mentioned batches of Inj. Cara-Doba as of “Substandard” Quality details are reproduced below:

Name of Product	Manufactured by	Reg. No.	Batch No.	DTL, Punjab Report
Inj. Cara-Doba (Dobutamine HCl 250mg/5ml)	M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI), Rawat, Islamabad	054987	25E004 and 24J009	Batch 24J009 the sample has been declared Sub-Standard on the basis of Physical description and visible particulates Batch 25E005 The color has been changed to Dark Brown with Crystallization (Sub-Standard on the basis of Physical description and visible particulates)

4. The Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, Punjab had desired that a detailed Product Specific Inspection of the firm M/s Caraway Pharmaceutical, may be conducted.

5. Consequently, DRAP Alert No. N⁰I/S12-25-126 was issued on 30th December 2025. Additionally, as per directions of the Director, QA & LT Division, FID-I, Islamabad on 24-12-2025 and 31-12-2025 conducted the Product Specific Inspection of the firm M/s Caraway Pharmaceuticals, Rawat. The critical and major deficiencies noted during inspection are being reproduced below:

“Critical observations/deficiencies:

1. Brown discoloration was observed in finished batch of Cara-Doba (Dobutamine HCl) injection; however, the firm failed to adequately assess, investigate and control this critical quality defect in a timely manner. This critical quality attribute may adversely affect the quality, safety and efficacy of the product.
2. Discrepancy was observed in the BMR of Inj. Cara-Doba 250mg/5ml, as the autoclaving time for terminal sterilization of filled ampoules was recorded as 02 hours, which differs from the validated and/or recommended sterilization cycle parameters (30 mins at 121 °C). Furthermore, the batch manufacturing records did not contain recorded sterilization temperature. In the absence of complete and accurate sterilization cycle records, the firm is unable to demonstrate that filled ampoules of Dobutamine injection were not exposed to excessive thermal stress, which may have contributed to degradation and discoloration of the product. Moreover, the QA failed to effectively review the BMR, before release of drug product to the market.
3. It was observed that a single batch of Cara-Doba 250mg/5ml injection (24E004) was subjected to terminal sterilization in two separate autoclave loads due to limited autoclave capacity. However, the firm failed to provide adequate documented justification, risk assessment and validated controls to demonstrate that both sterilization cycles were equivalent and performed within validated parameters. The firm was unable to demonstrate uniformity of sterilization conditions and thermal exposure across the entire batch. Variability in thermal exposure may have contributed to degradation and discoloration of the defective product.
4. The investigation (Customer Complaint Report) initiated for brown discoloration of Dobutamine injection was superficial and did not establish a scientifically justified root cause. The investigation failed to consider oxidation, formulation sensitivity and oxygen exposure during manufacturing.

Major Deficiencies/Observations:

1. The firm’s stability studies did not sufficiently evaluate Photo-stability and oxidation-related degradation and stability data did not support the claimed shelf life. The firm failed to provide adequate evidence demonstrating that the container provides protection against light and oxygen ingress for Dobutamine injection throughout its shelf life.
2. It was observed that nitrogen gas used for purging during the manufacture of Dobutamine injection was not adequately controlled. The firm relied solely on the Certificate of Analysis (CoA)

provided by the gas supplier/manufacturer without performing vendor qualification. Furthermore, no in-house testing of nitrogen gas quality was conducted and the firm lacked facilities and procedures for verification of critical quality attributes of nitrogen gas prior to use. Resultantly, Oxygen content, moisture or impurities in nitrogen gas are not verified that may cause ineffective purging that directly increases the risk of oxidation of Dobutamine, leading to discoloration.

3. As per the firm's approved SOP for vendor qualification, qualification of API suppliers/manufacturers is required to be conducted on a documentation basis. However, during the inspection, the firm failed to provide complete vendor qualification data for the supplier/manufacturer of Dobutamine API. The firm was therefore unable to demonstrate that the API supplier had been appropriately evaluated and approved prior to use.
4. It was observed that the firm failed to present vendor qualification records and supporting data for the supplier/manufacturer of the primary packaging material (glass ampoules) used for Dobutamine injection. The firm was therefore unable to demonstrate that the ampoule supplier had been appropriately evaluated, approved and monitored in accordance with established procedures prior to use. Therefore, in the absence of documented qualification of the ampoule supplier, the firm cannot demonstrate that the primary packaging material is suitable for use with an oxidation-sensitive injectable product such as Dobutamine injection, which may have contributed to the observed discoloration.
5. It was observed that a silicone pipe/tubing was used for the transfer of Dobutamine injection solution from the manufacturing vessel to a Pyrex glass flask. However, the firm failed to provide documented evidence of qualification, material compatibility, extractables/leachables studies and cleaning validation for the silicone tubing used as product-contact equipment. The firm was therefore unable to demonstrate that the silicone transfer tubing was suitable for use with an oxidation-sensitive sterile injectable product. In the absence of qualification and compatibility studies for silicone transfer tubing, the firm cannot rule out the possibility of extractables or interaction with the product, which may have contributed to degradation and discoloration of Cara-Doba injection.

Conclusion & Recommendation:

A Product Specific Inspection (PSI) was conducted following receipt of a critical quality complaint regarding brown discoloration in Inj. Cara-Doba (Dobutamine HCl), 250mg/5ml, Batch No. 24E004, a life-saving sterile injectable product. The inspection revealed multiple critical and major GMP deficiencies recorded above, that directly and indirectly impacting product quality, sterility assurance and chemical stability.

Based upon the recorded major and critical GMP deficiencies, it is recommended that the registration of the drug product Inj. Cara-Doba (Dobutamine HCl) 250mg/5ml, Registration No. 054987 of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI), Rawat, Islamabad, be **suspended** with immediate effect due to failure to ensure consistent quality, safety and efficacy of the product. The firm may be directed to conduct a comprehensive, scientifically justified investigation, implement effective CAPAs, reassess formulation, manufacturing controls, container integrity and stability studies."

6. Consequently, A Show Cause and Personal Hearing Notice vide No.F.03-01/2026-DD(QALT)-VI dated 2nd January 2026 was issued to the firm for violating section 23(1)(a)(v) of the Drug Act 1976, read with Schedule-II of the DRAP Act 2012 and the rules made there under as well as the conditions of Registration, which is punishable under section 27 of the Drugs Act, 1976 read with Schedule-III of DRAP Act, 2012.

7. The reply of the firm to the Show Cause Notice vide No. 8333 received in the office of QA&LT on 15-01-2026 wherein the firm stated as following:

2026, "We refer to the show cause notice dated 02 January 2026, received on 06 January
24J009 regarding Injection Cara-Doba 250mg/5ml (Dobutamine HCl 250mg/5ml), Batch No.
declared substandard by DTL Punjab on the basis of physical description and visible
 particulates.

Batch No. 24J009 was manufactured in September 2024 strictly in accordance with approved BMRs, SOPs, and GMP requirements. The batch passes all in-house quality control tests, including physical inspection, sterility, assay, and particulate matter evaluation, prior to release. Samples of the same batch were also tested at multiple independent Drug Testing Laboratories, where compliance with all parameters was confirmed.

A genuine manufacturing defect would have manifested uniformly across the batch, which has not been observed.

Subsequent to manufacture, our facility has undergone systematic GMP upgradation, including installation of continuous water loop, GMP-compliant automatic washing machine, online particle counter, and improved MAL/PAL segregation, all approved and verified by regulatory authorities.

As no written intimation from PQCB has been received, our right to appellate testing remains reserved. We respectfully request deferment of consideration until appellate results are available”

Proceedings and Decision of 353rd Meeting of Registration Board

In compliance to the show cause notice and personal hearing letter issued, Mr. Umer Farooq Managing Director, Mr. Murad Head of Quality Operations and Mr. Noman Masood Incharge of Sterile Manufacturing area of M/s. Caraway Pharmaceuticals, Islamabad appeared before Board. They submitted before the Board that they had voluntarily initiated recall of their product after TGRP reported by Pharmacovigilance Officer, Services Hospital, Lahore on 02-12-2025, except the quantity that was part of Government supply which is being held at the institute from where the report had been initiated as per Punjab Government policy. Furthermore, the firm stated that the problem might have occurred during transportation in hot and humid months as the stock retained at the factory premises did not show discoloration or crystallization. The firm also added that they had taken several GMP upgradation measures and have undertaken CAPA but admitted that they did not arrive at a definitive Root Cause. It is pertinent to mention that the reply of the firm received in QA&LT did not have any supporting evidences but had rather provided only the statement reproduced above:

The Board after considering the facts of the case, to ensure availability of this life saving drug and after thorough deliberations decided as follows:

“i. To conduct PSI of the liquid sterile manufacturing facility of M/s Caraway Pharmaceuticals, Islamabad in light of report of FID-I, Islamabad including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT

ii. The firm shall reduce the batch size, as per available capacity”.

CASE No.8: MANUFACTURE/SALE OF SUBSTANDARD DRUG NAMELY FAMILA INJECTION (REG. NO. 015615) BATCH NO. 083 MANUFACTURED BY M/S. ZAF A PHARMACEUTICAL LABORATORIES (PVT) LTD. KARACHI.

FID Karachi submitted letter No. F.SHM-56-92/2024-FID-IV (K) dated 01st October 2024, wherein he stated that he, in compliance to the directions contained on M/s / Zafa Pharmaceutical Laboratories (Pvt) Ltd., Karachi request letter received vide DRAP Karachi office Dy. No. 559 dated 19/07/2024, inspected the premise of M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., 1-41 A&R Block-21 FB industrial Area, Karachi on 22/07/2024, wherein following samples of drugs were taken along with other drugs for the purpose of test analysis on prescribed Form-3 for PWD Sindh.

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Manufactured by	CDL Report No. & Remarks
Famila Injection (015615)	083	02/24	02/29	M/s Zafa Pharmaceuticals Laboratories (Pvt.) Ltd., Karachi.	Report No.PWD-8-24- 000051 dated 10 th September 2024. Non- Sterile Does Not Comply

2. The Government Analyst Central Drugs Laboratory, Karachi vide test report No.PWD-8-24-000051 dated 10th September, 2024 declared the above batch of Famila Injection as "SUBSTANDARD" quality under the Drugs Act, 1976, which is violation of Section 234(1) (a) (v) of Deng Act 1976 and rules framed there under.

3. M/s. Zafa Pharmaceutical Laboratories (Pvt.) Ltd., L-4/1 A&B Block-21 FB Industrial Area, Karachi vide their letter No. Nil received in area FID's office vide Dy. No. 752 dated 30- 09-2024 submitted as following:

"The sample of Familla Injection, Batch No. 083 was taken for the purpose of test/analysis and sent to Federal Government Analyst, Central Drugs Laboratory, Karachi. The Government Analyst, Central Drugs Laboratory, Karachi vide Test Report No. PWD-8-24-000051 dated 10-09-2024 (received along with your letter) declared the sample as substandard on the basis of Sterility Test whereas the Famila Injection is sterilized by terminal sterilization process. The filled and sealed vials of Famila Injection, Batch No. 083 were sterilized by heating in an autoclave at 121°C and 15 lb pressure for 30 minutes. The batch was released for packing by Quality Control after compliance of physical, chemical and microbiological tests including Sterility Test which was performed as per USP by Microbiologist. Therefore, in the light of our Quality Control Test Results you are requested to send the sample of Famila Injection, Batch No. 083 to the Federal Appellate Drug Laboratory for retesting under Section 22 (5) of the Drugs Act 1976".

4. Firm submitted their reply (OOS Investigation) vide their letter no. Nil dated 07-11-2024. They stated as following:

The drug product was continuously manufactured from about last 20 years with name of Famila Injection. We have an established manufacturing method. As per our manufacturing method Famila Injection is sterilized by terminal sterilization process. The filled and sealed vials of Famila Injection, Batch No. 083 were sterilized by heating in an autoclave at 121°C and 15 lb pressure for 30 minutes. The batch was released for packing by Quality Control after compliance of physical, chemical and microbiological tests including Sterility Test which was performed as per USP by Microbiologist. The Government Analyst, Central Drugs Laboratory, Karachi vide Test Report No. PWD-8-24-000051 dated 10-09-2024 (received along with your letter) declared the sample as substandard on the basis of Sterility Test. Please note that Test Report No. PWD-8-24-000051 contains only single test that is Sterility Test whereas other tests including Appearance of Suspension, Identification of API, pH of Suspension, Assay of API and Bacterial Endotoxin Test are essential tests (copy of batch analysis enclosed) These tests were not performed by Government Analyst. Therefore, according to the Section 22 (5) of the Drug Act 1976, request submitted to Federal Inspector of Drugs-IV, Karachi for retesting the sample of Famila Injection, Batch No. 083 at the Federal Appellate Drug Laboratory and stop the sale till the re-testing report (Copy of Letter to Distributor enclosed). We have no doubt on the terminal sterilization process and sterility testing results. After receiving Government Analyst Test Report, Quality Control Microbiologist re-performed Sterility Test of Keeping Samples and found the results as per USP Specification (copy of re-testing of sterility enclosed). According to the Sterility Testing Results, batch of Famila Injection was sterile and complies with drug product specification. Therefore, there is no Out of Specification (OOS) Investigation required as per GMP.

5. Director, CDL, Karachi submitted, on 25-11-2024, OOS investigations of Drug Famila Injection (150mg/ml) Batch No. 083. According to OOS Investigation, OOS is valid with remarks as the sample is not complying with respect to Sterility Testing.

6. Request of the firm for the appellate testing under section 22 (5) was submitted before the Board.

7. Proceeding and Decision of 343rd Meeting of Registration Board

QA & LT Division presented the case before the Registration Board. The Board considered the request of firm and after threadbare deliberation decided to accede request of firm for appellate testing, under Section 22 (5) of the Drugs Act, 1976, of Famila Injection (015615), Batch No. 083 for sterility testing only.

8. Accordingly, Board portion of the Drug sample Famila Injection (150mg/ml) Batch No. 083 was sent to NIH for Appellate Testing vide memo No.F.3-2/2025-QALT(343-RB) dated 13-01-2025 by the Division of QA&LT.

9. Report of the Board Portion sent for Appellate Testing was received from NIH vide No.F.1-20/01-M/2025-DC&TMD details are mentioned below:

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Manufactured by	NIH Report No. & Remarks
Famila Injection (015615)	083	02/24	02/29	M/s Zafa Pharmaceuticals Laboratories (Pvt.) Ltd., Karachi.	Report No.01-M/2025 dated 11 th November 2025. Sterility Test: Sterile Sample is of Standard Quality on the basis of Test performed.

Proceedings and Decision of 353rd Meeting of Registration Board

“The Board, after considering facts of the case and keeping in view the report of Appellate Lab, NIH, Islamabad vide letter No. F.1-20/01-M/2025-DC&TMD dated 11th November, 2025, wherein the Lab has declared the sample of “Famila Injection, Batch No 083” as of “Standard Quality” has decided to dispose of the case. The Board also directed the Division of QALT to share report with FID and firm M/s Zafa Pharmaceuticals Laboratories (Pvt.) Ltd., Karachi.”

Item No. IV Division of Biological Evaluation & Research

Case No. 1: Virtual Inspection of Manufacturer Abroad for Sinvac IBD Vaccine applied by M/s Hivet Animal Health Business, Lahore approved in 339th meeting of Registration Board.

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

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 339 th Meeting
M/s. Beijing Sinder-Vet Technology Co., Ltd. Address: Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Shunyu Road No.118, Shunyi District, Beijing, China.	Sinvac IBD Each dose contains: Infectious Bursal Disease Antigen (B87 strain).....≥10(3.0) ELD50/dose before freeze drying (0.0012ml/dose)	1000 doses 18 months (2°C -8°C)	On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

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

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

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

Following are the observations & conclusion of Panel:

Observations:

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

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

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

Conclusion

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

Sinvac IBD

Each dose contains:

Infectious Bursal Disease Antigen (B87 strain)..... $\geq 10(3.0)ELD_{50}/dose$ before freeze drying (0.0012ml/dose)

Decision:

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.

Case No. 2: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Agriprom Pakistan (Pvt.) Ltd., Lahore approved in 347th meeting of Registration Board.

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

Name of Manufacturer	Brand Name & Composition	Pack Size & Shelf Life	Decision of RB in 347th Meeting
M/s. Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China.	CENTRE-NDFLU H9 Each dose (0.5 ml) contains: Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... $10^{8.175} EID_{50}$ Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... $10^{7.175} EID_{50}$	250ml/500 doses 18 months (2°C -8°C)	Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.
	CENTRE-NIEA H9 Each dose (0.5 ml) of vaccine contains: Newcastle Disease	250ml/500 doses 18 months (2°C -8°C)	Keeping in view the legalized GMP & FSC indicating product availability in the

	Virus, Strain La Sota $\geq 10^{8.5}$ EID50 Infectious Bronchitis Virus, Strain M41 $\geq 10^{6.5}$ EID50 Egg Drop Syndrome Virus, Strain HSH23 ≥ 1000 HA units Avian Influenza (subtype H9) Virus, Strain WD $\geq 10^{7.5}$ EID50		country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.

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

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

Following are the observations & conclusion of Panel:

1. Observations

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

Observation	Impact on quality and GMP compliance
The firm had provided a common production area for the manufacture of inactivated virus and bacterial vaccines. Antigen production activities were carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing were performed within the same area.	The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.

2. Conclusion

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

i) **CENTRE-NDFLU H9**

Each dose (0.5 ml) contains:

Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... $10^{8.175}$ EID50

Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... $10^{7.175}$ EID50

ii) **CENTRE-NIEA H9**

Each dose (0.5 ml) of vaccine contains:

Newcastle Disease Virus, Strain La Sota $\geq 10^{8.5}$ EID50

Infectious Bronchitis Virus, Strain M41 $\geq 10^{6.5}$ EID50

Egg Drop Syndrome Virus, Strain HSH23 ≥ 1000 HA units

Avian Influenza (subtype H9) Virus, Strain WD $\geq 10^{7.5}$ EID50

Decision:

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.

Case No. 3: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore approved in 347th meeting of Registration Board.

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

Minutes of 353rd Meeting of Registration Board (14th – 15th January, 2026)

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

One dose (0.5 ml) contains;

Inactivated antigens in the titer before inactivation:

Salmonella enteritidis strain SE-15 at least 10^8 CFU

Salmonella typhimurium strain ST-15 at least 10^8 CFU

Salmonella gallinarum strain SG-15 at least 10^8 CFU

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

Each dose contains:

Newcastle disease, strain Hitchner B1 $\geq 10^6$ EID50

Avian Infectious Bronchitis, strain H-120 $\geq 10^{3.5}$ EID50

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter $\geq 10^{2.8}$ TCID50

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

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

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

One dose of the vaccine contains;

Newcastle disease virus, strain "La-Sota" DK-124 $\geq 10^{6.0}$ EID50

Avian infectious bronchitis virus, strain H-120 $\geq 10^{3.5}$ EID50.

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

Each dose (0.1 ml) contains:

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

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

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

2- Mr. Nafees ur Rehman, Deputy Director (H&OTC), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

Observation

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

Observations	Impact on quality and GMP compliance
The firm has provided a common production area for the manufacture of inactivated viral and bacterial vaccines. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing are performed within the same area.	The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products.
The firm has one live bacterial vaccine among its registered products. Upon inquiry, the firm stated that this product is manufactured once per year and that no segregated area is available for live bacterial vaccine production. Instead, mixing of the live bacterial vaccine is carried out in the Antigen Preparation Room (1-2107). For filling operations, a semi-automatic filling machine installed in the live virus vaccine mixing room (1-2133) is used, and the lyophilizer is shared for the manufacture of both live virus and live bacterial vaccines.	Live viral and live bacterial products present a high risk of biological cross-contamination , particularly when mixing, filling, and lyophilization activities are performed in non-segregated areas .

During a virtual inspection, it was observed that inoculation and harvesting were carried out in a laminar flow cabinet without side curtains . Eggs were manually disinfected, inoculated, and subsequently harvested. The firm stated that the area under the laminar flow cabinet was classified as Grade A, with the surrounding environment classified as Grade B. However, without side curtains, maintaining Grade A conditions during manufacturing is challenging.	Without side curtains, Grade A air cannot be reliably maintained over the critical zone. Risk of particulate and microbial contamination increases during inoculation and harvesting. Proper segregation and enclosure of critical activities are recommended to maintain aseptic conditions.

Conclusion

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

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

One dose (0.5 ml) contains;

Inactivated antigens in the titer before inactivation:

Salmonella enteritidis strain SE-15 at least 10^8 CFU

Salmonella typhimurium strain ST-15 at least 10^8 CFU

Salmonella gallinarum strain SG-15 at least 10^8 CFU

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

Each dose contains:

Newcastle disease, strain Hitchner B1 $\geq 10^6$ EID50

Avian Infectious Bronchitis, strain H-120 $\geq 10^{3.5}$ EID50

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

Each dose (1ml) contains:

Fowl pox virus, strain Cutter $\geq 10^{2.8}$ TCID50

Solvent contains:

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

Brilliant blue dye E 133 - 0.5 g

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

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

Each one dose contains:

Virus of Newcastle disease, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID50 per dose, obtained on SPF chicken embryos.

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

One dose of the vaccine contains;

Newcastle disease virus, strain “La-Sota” DK-124 $\geq 10^{6.0}$ EID50

Avian infectious bronchitis virus, strain H-120 $\geq 10^{3.5}$ EID50.

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

Each dose (0.1 ml) contains:

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

Decision:

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.

Case No. 4: Product Specific Inspection of M/s Macter International Limited, Karachi.

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

1. Zepatide Single Dose Vial 2.5mg

Minutes of 353rd Meeting of Registration Board (14th – 15th January, 2026)

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

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

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

Following are the observations and conclusion of Panel:

Observations/ Remarks:

- i. With reference to submitted documents in registration application, regarding procurement of API Tirzepatide, firm has imported 21.25gm of API. During inspection, calculations were performed which transpired that total quantity of API used in manufacturing was 72.82gm. Then the firm has also intimated and provided invoice of 55gm API for which no DRAP clearance and intimation was presented at the time of inspection. Firm stated that this API was imported through DHL. Any import document e.g. DRAP Clearance / Bill of Landing / Custom Clearance / LC / Custom Invoice, etc. confirming import of API was presented neither at the time of inspection nor later on even after specific query. However, the firm has submitted a precedence of Registration Board wherein only DHL invoice was considered by the Board.
- ii. Remaining stability batches of both Zepatide Single Dose Vials and Multi Dose Pen were placed in stability chamber without any primary labelling in secondary packing of another product namely Epo. Label was only pasted on outer carton.
- iii. Firm has not provided record of Zepatide production and testing in any of the log books except Microbial Limit Testing.
- iv. **During the physical audit of the HPLC system for Tirzepatide Single Dose Injection,** significant discrepancies / variations were observed between the chromatographic data provided in the CTD dossier submitted to DRAP and the data available at the firm's premises. The processing and acquisition date, time, retention times and area values of the chromatograms had significant differences at various time points. Few of the examples are as under:
 - a. In the case of Zepatide 2.5mg single dose injection at the initial time point, the firm recorded an area of 80477 with retention time of 29.581 whereas the data submitted to DRAP reported 19471427 with retention time of 26.309.
 - b. In the case of Zepatide 5mg single dose injection at the 06th month time point, the firm recorded an area of 51886304 with retention time of 26.001 along with two impurities whereas the data submitted to DRAP reported 20303400 with retention time of 26.283 along with one impurity. Moreover, acquisition and processing times are also different.
 - c. In the case of Zepatide 7.5mg single dose injection at the 06th month time point, the firm recorded an area of 53269392 with retention time of 25.960 along with two impurities whereas the data submitted to DRAP reported 20051135 with retention time of 26.534 along with one impurity. Moreover, acquisition and processing times are also different.
 - d. In the case of Zepatide 12.5mg single dose injection at the 06th month time point, the firm recorded an area of 46919906 with retention time of 25.791 along with two impurities whereas the data submitted to DRAP reported area of 19931812 with

retention time of 26.582 along with one impurity. Moreover, acquisition and processing times are also different.

- e. In the case of Zepatide 15mg single dose injection at the 09th month time point, the firm recorded an area of 42287211 with retention time of 20.983 along with three impurities whereas the data submitted to DRAP reported area of 51129566 with retention time of 20.953 along with two impurities. Moreover, acquisition and processing times are same.
- f. The firm has submitted CoA of API indicating Polymer testing while they have not used the method for Polymer testing of API manufacturer as they don't have requisite impurity standard i.e. G27-IM122. Furthermore, the firm has also performed Polymer testing of finished products during stability studies although they don't have requisite impurity standard i.e. G27-IM122.
- v. The firm informed that the requisite reference standard is required for performance of system suitability but on the other hand system suitability of Polymer testing was not performed.

It is pertinent to mention that USP monograph of Chromatography <621> states the following:

"The system suitability tests represent an integral part of the analytical procedure and are used to ensure adequate performance of the chromatographic system."

"Compliance with the system suitability criteria is required throughout the chromatographic procedure."

It is evident from above statement of USP that as the firm has not performed system suitability, hence, their method is not ensuring the adequate performance of the chromatographic system in quantifying the amount of High Molecular Weight Proteins (HMWPs) which are directly related to immunogenicity of product.

Conclusion:

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

- i. Discrepancies between the quantity of procured documented API and API used in manufacturing of the stability batches were observed. Firm has imported 21.25gm of API for which DRAP clearance was available. During inspection, calculations were performed which revealed that total quantity of API used in manufacturing of APIs was 72.82gm. Then the firm has also intimated and provided invoice of 55gm API for which no DRAP clearance and intimation was presented at the time of inspection. Firm stated that this API was imported through DHL. Neither any import document e.g. DRAP Clearance / Bill of Landing / Custom Clearance / LC / Custom Invoice, etc. confirming import of API was presented neither at the time of inspection nor later on even after specific query. However, the firm has submitted a precedence of Registration Board wherein only DHL invoice was considered by the Board.
- ii. For Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg), keeping in view previous practice, the panel recommended the firm to procure Impurity standard of Polymer from the API manufacturer, to conduct complete polymer testing of the drug products using this standard at the next stability study time point and submit a comprehensive report along with chromatograms, raw data sheets, and procurement documents for the standard. The firm then submitted procurement documents including DRAP clearance certificate along with Import License, invoice and Airway bill vide tracking ID: 952-N94-M1QT. The firm also submitted chromatograms of polymer testing for Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg) vide tracking ID: QLD-UQ7-PSY1 and the results were found to be within limits of specifications. Moreover, the Assay and Impurity data of Zepatide Multi Dose Pen (Tirzepatide 20mg, 40mg and 60mg) was satisfactorily verified on-site.
- iii. For Zepatide Single Dose Vial range (Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg), discrepancies were observed between the chromatogram area values, retention times, processing and acquisition times available onsite and those submitted to DRAP in

the CTD dossiers. These differences, observed in multiple chromatograms across all strengths and multiple time points, including initial, 3rd month, 6th month and 9th month stability studies. These discrepancies raised concerns about the authenticity and reliability of the submitted data. Hence, these observations of the panel regarding Zepatide Single Dose Vial range may be placed before Registration Board.

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

Decision:

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

Case No. 5: Registration application of M/s Himmel Pharmaceuticals (Pvt.) Ltd, Lahore.

Below mentioned product applied by M/s Himmel Pharmaceuticals (Pvt.) Ltd, Lahore. was considered by Registration Board in its 350th meeting held on 29-30th July 2025. The details of the product along with the decision of Board is as under:

Applied Product Brand Name & Composition	Manufacturer	Registration Board Decision
Cerebrolysin Solution for Injection/Concentrate for Solution for Infusion, 10ml One ml contains 215.2 mg of porcine brain-derived peptide preparation (Cerebrolysin concentrate) in aqueous solution.	Marketing Authorization Holder & Batch Release: M/s EVER Neuro Pharma GmbH Oberburgau 3 4866 Unterach am Attersee Austria. Compounding, Filling & Packing: M/s EVER Pharma Jena GmbH (Compounding, Filling & Packing) Germany	The Board decided to seek input of Heads of the Department of Neurological Sciences at PIMS Islamabad and Shifa International Hospital Islamabad regarding the current treatment options available for the following conditions/ailments: i) Organic, metabolic and neurodegenerative disorders of the brain, especially senile dementia of Alzheimer's type ii) Post-apoplectic complications iii) Craniocerebral trauma; post-operative trauma, cerebral contusion or concussion.

Accordingly, above experts were requested the to tender their opinion vide DRAP letter 30th September, 2025 and 14th November 2025. The seponses submitted are reproduced as under:

Opinion of Dr. Mansoor Iqbal, Head of Neurology Department, Pakistan Institute of Medical Sciences (PIMS) Islamabad.

As mentioned in your letter dated 30 Sep 2025, DRAP has received the application for registration of Cerebrolysin for following indications and sought opinion of treatment options of these conditions.

- 1. Senile dementia of Alzheimer's type. Currently many options are available including*
- 2. cholinesterase inhibitors (Donepezil, Rivastigmine), NMDA Antagonist(Memantine), Anti amyloid monoclonal antibodies (Lecanemab, Donanemab)*
- 3. Post stroke complications... post stroke complication include spasticity, infections, bed sores all of which are prevented by good Physiotherapy, posture changes, provision of Ripple mattress and if these occur they are treated by muscle relaxants for pasticity (Baclofen), Antibiotics for infections and plastic surgical treatments for bed sores.*
- 4. Craniocerebral injuries. These are mostly managed by neurosurgical techniques along with monitoring and management of complications.*

Regarding Cerebrolysin, I have not received any convincing clinical evidence of benefit or use from any colleague in developed countries. On literature review, it was found that clinical studies on the efficacy of CBL have revealed inconsistent results. Current data demonstrates significant heterogeneity in duration of therapy, initial and sustained dosage, combination therapeutics and time frame of treatment initiation. Major neurological societies (AAN, ESO, WFN) have not included Cerebrolysin in standard treatment guidelines as its clinical significance is debatable.

Opinion of Dr. Muhammad Amjad, MBBS, MCPS, FCPS, (Neurology) Consultant Neurologist and Chief of Neurology Shifa International Hospital, Islamabad dated:

First of all, I am extremely sorry for the delayed response as it required some research of literature before submitting my response. As mentioned in your letter dated 14th November 2025. DRAP has received the application for registration of Cerebrolysin for senile dementia of Alzheimer type, post stroke complications and Craniocerebral injuries.

At shifa International Hospital, we have summed up some DATA regarding Cerebrolysin and is attached with this letter.

Regarding the second question of existing treatment options for the above mentioned conditions this is a vast topic:

- 1). For senile dementia of Alzheimer type, the treatment options include:
Cholinesterase inhibitors (Grade 2A) The choice among donepezil, galantamine, and rivastigmine can be based upon ease of use, individual patient tolerance, cost, and clinician and patient preference. Memantine alone in patients who do not tolerate or benefit from a cholinesterase inhibitor (Grade 2B). Amyloid-targeted therapies like Lecanemab and Donanemab for patients with AD who have mild dementia or mild cognitive impairment and who meet selection criteria and have no contraindications.
- 2). Post stroke complications like dysphagia, infections, bed sores residual hemiparesis all of these complications are treated with multidisciplinary approach including, physio and speech therapy.
- 3). Craniocerebral injuries are managed by Neurosurgeons and again multidisciplinary approach

To conclude I have not found convincing data regarding clinical benefits of Cerebrolysin. It is still not FDA approved.

Decision:

Keeping in view the opinions of Dr. Mansoor Iqbal, Head of Neurology Department, Pakistan Institute of Medical Sciences (PIMS) Islamabad and Dr. Muhammad Amjad, MBBS, MCPS, FCPS, (Neurology) Consultant Neurologist and Chief of Neurology Shifa International Hospital, Islamabad; Registration Board did not accede to request of firm for grant of registration of Cerebrolysin Solution for Injection/Concentrate for Solution for Infusion 10ml.

Case#06: Registration of imported biological product deferred in 350th meeting imported by M/s Amgommed Islamabad:

Sr. No. 01		
	Name, address of Applicant / Importer	M/s AMGOMED, Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Pakistan
	Details of Drug Sale License of importer	License No: DSL-002-ICT/2013 Address: Amgommed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. Validity: 30-01-2024 Status: Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Gennova Biopharmaceuticals Limited, Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.

Name, address of manufacturer(s)	M/s Gennova Biopharmaceuticals Limited , Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original CoPP certificate (CoPP/CERT/PD/110860/2022/11/39406/191298) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. <u>The CoPP is valid till 14-07-2022.</u>
Details of letter of authorization / sole agency agreement	The firm submitted notarized letter of authorization whereby M/s Gennova Biopharmaceuticals Limited, India authorized M/s Amgomed to apply for registration, for marketing, distribution and sale of below mentioned product; Hamsyl 3750 IU / 5ml Injection Each 5 ml vial contains: Pegaspargase (Pegylated L- Asparaginase) HIS 3750 IU The authorization letter is valid till 06-05-2022. Manufacturer ☒ Importer Is involved in none of the above (contract giver) New Drug Product (NDP) ☒ Generic Drug Product (GDP) ☒ Domestic sale Export sale Domestic and Export sales ☒ Finished Pharmaceutical product import Bulk import and local repackaging Bulk import and local repackaging for export purpose only
Status of the applicant	
Status of application	
Intended use of pharmaceutical product	
For imported products, specify one the these	
Dy. No. and date of submission	
Dy. No. and date of submission	Dy. No. 26085 Dated: 30-07-2018
Details of fee submitted	PKR 100,000 (Slip number : 0778294)
Proposed proprietary name / brand name	Hamsyl 3750 IU / 5ml Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Pegaspargase (Pegylated L-Asparaginase) 3750 IU
Pharmaceutical form of applied drug	Solution for IV / IM Administration
Pharmacotherapeutic Group of (API)	Antineoplastic agents ATC- code: 01XX24
Finished product specifications	In-house
Proposed Pack size	1's vial

	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 2 °C to 8 °C
	The status in reference regulatory authorities	Oncaspar Injection 3,750 IU / 5ml vial of M/s Sigma Tau (USFDA approved).
	For generic drugs (me-too status)	Pegaspargase (Peg-L-Asparaginase of LDS (Reg#105067)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	DMF Holder Address: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China. Name and Address of the manufacturer: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Gennova Biopharmaceuticals limited do not intend to store the API manufactured. It is immediately transfer for fill finish activities. Hence formal stability study for Pegaspargase Bulk is not intended as there is no change in the composition of Bulk and Finished product. Its only containerization process. Hence, we have carried out hold time study for bulk and finished product stability study is reflective for API stability as well.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of Pharmaceutical Equivalence: Hamsyl 3750 IU /5ml Injection and reference product Oncaspar by Sigma Tau Corporation, USA.

Analytical method validation / verification of product		The firm has submitted relevant data including analytical method validation for the drug product including the impurities.
Container closure system of the drug product		Pegaspargase Injection is filled in USP Type I Glass vial. One such labelled vial is placed in Plastic Tray and which is packed in Monocarton along with leaflet. Primary packaging materials conform to specifications.
	Stability study data of drug product, shelf life and storage conditions	Real time stability (Long term) studies have been conducted at 5°C ± 3°C for 24 months of 3 batches. Accelerated stability studies is conducted at 25 °C ± 2 °C / 60% ± 5% RH for 6 months of 3 batches. 431401H01 431402H02 431403H03
	Non-Clinical (Module IV)	Single dose toxicity Acute Intravenous toxicity study in Swiss Albino mice Acute Intravenous toxicity study in Sprague Dawley rat Multiple Dose Subchronic intravenous toxicity study in the Swiss Albino Mouse Subchronic intra venous toxicity study in the Sprague Dawley Rat
	Module V	A prospective, open label, randomized, active control, parallel design, comparative pharmacokinetics study of intramuscular pegaspargase (Hamsyl) of M/s Gennova Biopharmaceuticals Ltd versus intramuscular Oncaspar in pediatric patients with relapsed cases of Acute Lymphoblastic Leukemia (ALL). Twenty-four (24) Pediatric patients diagnosed with Acute Lymphoblastic Leukemia (ALL) in relapsed stage enrolled in 1:1 ratio in two arms randomly. To demonstrate the pharmacokinetic comparability of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase) given intramuscularly during induction in patients with ALL therapy. To compare the immunogenicity and toxicity of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase).
Remarks of Evaluator: The submitted original CoPP is not legalized however, the firm has submitted undertaking that we will submit legalized original copy of CoPP after attestation. Meanwhile, we request you to please include our product in DRB meeting.		
Evaluation by BE&R:		
Sr.No.	Decision of 324th meeting	Response by the firm

1.	Submission of Phase I, II, III clinical study data for the proposed indication since already submitted study is a pharmacokinetic comparison of applied product with reference product.	Hamsyl is a pegylated version of native- asparaginase. Hamsyl was approved as an 'Orphan drug' in India in the second line of treatment of relapsed Acute Lymphoblastic Leukemia (ALL). This approval was based on a bioequivalency study (PK) against the reference product (Oncaspar) in patients with ALL in India. The serum asparaginase activity (> 100 IU/L) has been considered as a surrogate marker for efficacy¹ and has been used for the approval of asparaginase formulations worldwide. For instance, <i>Erwinia asparaginase</i> US-FDA approval was based on the nadir serum asparaginase activity >100 IU/L. Hamsyl was found to be 'Bioequivalent' to Oncaspar. Importantly, both drugs maintained a nadir serum L-asparaginase activity > 100 IU/L. The secondary endpoints of the study included comparison of the L-asparaginase antibodies response profile and changes in L-asparagine and glutamine amino acids levels. No statistically significant differences were observed in the secondary endpoints. Based on these results, Hamsyl was approved and Phase III study was waived off. Hamsyl has been available in India for therapeutic use since 2014. Various independent investigators have published their experience of treatment with Hamsyl as retrospective studies with no new significant concerns.
2.	Details of pharmaceutical comparison with reference product Oncaspar Injection 3750 IU / 5ml.	The firm has submitted comparability evaluation report of Oncaspar (ON3066X2) and Hamsyl injection (3750 IU/vial) for the identified critical quality attributes.
3.	Legalization of CoPP	CoPP: Firm has submitted original Legalized CoPP certificate CoPP/CERT/PD/1108776/2022/11/41643/204858) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. <u>The CoPP is valid till 09-07-2025.</u>
Decision: Registration Board decided to refer the case to Pharmacy Services Division for opinion on firm's justification for exemption of Phase III clinical study data. The subject matter was placed before Clinical Studies Committee (CSC) in its 50th meeting held on 11th July 2024. The Committee decided the case as follows: <i>The CSC after detailed deliberation and discussion advised to forward following decision to the BE&R Division:</i> <i>The CSC notified and work under the Bio-Study Rules, 2017 for Clinical Trial Oversight in the country and instant application is not for the conduct of any clinical trial / study hence its not the mandate of CSC.</i>		

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

Previous Decision M-339:

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

Decision of 347th meeting of Registration Board:

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

Evaluation by BE&R:

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

Remarks by BE&R:

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

“This Periodic Safety Update Report (PSUR) presents data on safety and adverse events reported for Pegaspargase injection. There were two spontaneous reports to manufacturer. In the first case, abnormality in liver function tests (LFTs) were demonstrated but later the patient’s LFTs normalized and he received further recommended therapy. In the second case, the patient experienced hepatic encephalopathy and septicemia and died on 10/Feb/2015, the cause of which was unassessable. There were no serious unexpected adverse events neither published for pegaspargase injection in Springer’s Pharmacovigilance Insight Database or in the published literature nor reported to the manufacturer. Safety and tolerability of concomitant use of pegaspargase injection for the treatment of acute lymphoblastic leukemia is well established. After an analysis of available information from various sources, it is concluded that Pegaspargase injection has an acceptable benefit: risk ratio in the treatment of ALL.”

However, Complete clinical studies data is still not provided.

Decision of 350th meeting of RB:

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

Remarks of evaluator:

The firm has submitted a reply as under;

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

Following parameters are tested;

- open-label, parallel-group, comparative pharmacokinetic study in paediatric patients with relapsed ALL (Acute lymphoblastic leukemia). (Report is attached)
 - Immunogenicity (Report is attached).
 - Pharmacodynamics i.e. L-asparaginase activity, Plasma anti-L asparaginase antibodies, Plasma anti- L asparaginase amino acid estimation, L- glutamine amino acid estimation in all patients (Report is attached).
- Asparaginase has been used the treatment of ALL for decades. Based on the abundance of clinical data, pharmacokinetic (PK) and pharmacodynamic (PD) markers have been established for asparaginase. This is advantageous in clinical development because using established PK and PD markers as a surrogate for efficacy simplify clinical trials (more sensitive) and obviate the need to assess long and costly endpoints.

Following documents are attached in response to the query;

Justification letter.

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

Decision:

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

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

Case#07: Imported human biological applied by M/s OBS AGP Limited deferred in 351st meeting

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., K
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP Private Limited Address of Godown: PLOT NO. B-2 KARACHI. Status: License to sell, stock & exhibi Upto: 27-03-2028
Name and address of marketing authorization holder (abroad)	M/s Bharat Serums and Vaccines Li Plot No. K-27, K-27 Part and K-27/1, Village, Additional MIDC, Ambernath (East), Thane 4215
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Li Plot No. K-27, K-27 Part and K-27/1, Village, Additional MIDC, Ambernath (East), Thane 4215
Name of exporting country	INDIA
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, l (No. COPP/CERT/KD/120672/2022/ 400 051 The CoPP confirms free sal periodic inspection once a year. <u>The name of importing country on</u> <u>Republic of Pakistan. Furthermore</u>

		GMP: Firm has submitted original, 12-06-2022 issued by Food & Drug Administration, Maharashtra, Bandra (E) Mumbai-400 051Maharashtra.
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legal Authorization certificate from M/s BL to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (c
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product in ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging
	Dy. No. and date of submission	Dy. No. 15845, 22-06-2023
	Details of fee submitted	PKR 150,000/-: 14-06-2023
	The proposed proprietary name / brand name	Foligraph 75I.U. [Recombinant-Human Follicle Stimu
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Recombinant- Follitropin Concentrate (Freeze Dried) <u>Diluent for Reconstitution</u> One ampoule of sterile water for injecti
	Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
	Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	Each pack of Foligraph 75I.U. contain
		1 vial of Recombinant- Human Follicle Injection (Freeze Dried) 1 ampoule of Sterile Water for Injecti
	Proposed unit price	-
	The status in reference regulatory authorities	Gonal-f (Follitropin alpha) developed
	For generic drugs (me-too status)	Gonadopin 75 I.U. Injection by M/s M
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO properties, solubilities, physical form, procedures and its validation, batch an of drug substance.
	Name, address of drug substance manufacturer	M/s Bharat Serums and Vaccines L Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Maharashtra, India.
	Module-III Drug Substance:	Firm has submitted detailed drug sub form, manufacturers, description of r batch analysis and justification of spe

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data at $\pm 3^{\circ}\text{C}$ RH for 6 months as well as real time stability.
	Module-III Drug Product:	Firm has submitted data of drug product development, process and process control, process validation of analytical procedures, bioequivalence and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bioequivalence study data (formerly, Ares-Serono SA)
	Analytical method validation/verification of product	Firm has submitted analytical method validation data
	Container closure system of the drug product	One tray contains one vial (2 ml USP Class II) One carton contains one tray with one vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%\text{RH}$ for 6 months
Decision of 344th meeting: <i>Deferred for the submission of following along with comparative clinical data with reference to the following:</i> <i>Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies;</i> <i>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;</i> <i>Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product;</i> <i>Post-marketing surveillance (Pharmacovigilance) study reports.</i>		
Evaluation by BE&R:		
Sr.No.	Shortcomings	Response of the firm
1	Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local tolerance and other toxicological studies:	The requested points are already provided in Module 4 clinical data. Enclosing the data in USB again for your reference.
2	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:	All our clinical trial data provided are for the claimed indication; Anovulation and Stimulated Ovarian development in patients undergoing assisted reproductive technologies (ART) are already provided in Module 4. Enclosing the data in USB again for your reference.
3	Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:	Pre-clinical study report and Clinical trial reports (I and IV) is provided in module 4. Enclosing the data in USB for your reference.
4	Post-marketing surveillance (Pharmacovigilance) study reports.	Safety study has been provided in Phase IV. Enclosing the data in USB for your reference.
Concluding remarks: - The innovator product Gonal-f is available in pack size 75IU vial + 1 ml solvent in pre-filled syringe. However, the applied price is not justified. - Module 5 (Clinical data) is not provided. Only literature references attached.		
Decision of 351st meeting: <i>Registration Board deferred the case for submission of following documents/ clarifications:</i>		

i. *Module 5 (Clinical/efficacy data) of applied product.*

ii. *The innovator product Gonal-f is available in pack size 75IU vial + 1ml solvent in pre-filled syringe while the applied product is 75IU vial + 0.5ml solvent ampoule.*

Remarks of evaluator:

Sr.No.	Query	Response	Remarks	
1	<i>Module 5 (Clinical/efficacy data) of applied product.</i>	We have submitted Phase I, Phase III, and Phase IV studies in our dossier to assess the bioequivalence, pharmacokinetic (PK), safety, and efficacy profiles of the BSV test product compared with the reference product. These studies demonstrate that the 75 IU test product is comparable to the reference product. All clinical studies submitted in the dossier pertain specifically to the Foligraf 75 IU strength.	Provided.	
2	<i>The innovator product Gonal-f is available in pack size 75IU vial + 1ml solvent in pre-filled syringe while the applied product is 75IU vial + 0.5ml solvent ampoule.</i>	The innovator product, Gonal-f, is presented as a 75 IU vial with a 1 mL solvent in a pre-filled syringe. In contrast, the applied product, Foligraf 75 IU, is supplied as developed based on Innovator and as market requirement.	Reference product Gonal-f is available in in pack size 75IU vial + 1ml solvent in pre-filled syringe while the applied product is 75IU vial + 0.5ml solvent ampoule.	

Decision:

Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case# 08: Imported human biological applied by M/s OBS AGP Limited deferred in 351 st meeting	
Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP PRIVATE LIMITED Address of Godown: PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter Valid Upto: 27-03-2028
Name and address of marketing authorization holder (abroad)	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
Name of exporting country	INDIA
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.COPP/CERT/KD/120672/2022/11/42600/208254) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. <u>The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29-March,2025</u> GMP: Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 Maharashtra state.India.
Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited to register their products in Pakistan.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 15846, 22-06-2023
Details of fee submitted	PKR 150,000/-: 14-06-2023
The proposed proprietary name / brand name	Foligraph 150IU [Recombinant-Human Follicle Stimulating Hormone for Injection (Freeze Dried)]
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Recombinant- Follitropin Concentrated Solution 150.IU. (Freeze Dried) <u>Diluent for Reconstitution</u> One ampoule of sterile water for injection 0.5ml
Pharmaceutical form of applied drug	Freeze Dried Powder for Injection.
Pharmacotherapeutic Group of (API)	Human Follicle Stimulating Hormone
Reference to Finished product specifications	Innovators specs
Proposed Pack size	Each pack of Foligraph 150.IU. contains: 1 vial of Recombinant- Human Follicle Stimulating Hormone for Injection (Freeze Dried) 1 ampoule of Sterile Water for Injection 0.5ml
Proposed unit price	-
The status in reference regulatory authorities	Gonal-f (Follitropin alpha) developed by Serono International, SA
For generic drugs (me-too status)	Follitrope 150 I.U. Injection by M/s Galaxy Pharmaceuticals (Pvt.) Ltd.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane-421506, Maharashtra, India.
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

	reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (BB1116002, BB1116006, BB1117001) conducted at accelerated conditions $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ RH for 6 months as well as real time conditions. The real time stability data is conducted at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bioequivalence studies against reference product Gonal-f (Follitropin alpha) developed by Serono International, SA (formerly, Ares-Serono SA)
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	One tray contains one vial (2 ml USP Type I) with one ampoule of sterile water for injection 0.5ml. One carton contains one tray with one insert.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (B08717002, B08717004, B08718002) The accelerated stability study data is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%\text{RH}$ for 6 months. The real time stability data is conducted at $2-8^{\circ}\text{C}$ for 24 months.
Decision of 344th meeting: Deferred for the submission of following along with comparative clinical data with reference product: i. Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, 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: ii. Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product: v. Post-marketing surveillance (Pharmacovigilance) study reports.	

Evaluation by BE&R:

Sr.No.	Shortcomings	Response of the firm	Remarks
1	Documented study reports and non-clinical data of pharmacological, pharmacokinetics, toxicology including single-dose and repeat dose toxicity studies, genotoxicity, carcinogenicity, reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations), local	The requested points are already provided in Module 4 Non-clinical data. Enclosing the data in USB again for your reference.	Firm has submitted following; i) "Single dose pharmacokinetic study of r-hFSH in comparison with Gonal-f in wistar rats by subcutaneous route." The study was conducted to evaluate the pharmacokinetic profile of Recombinant Human Follicle

	tolerance and other toxicological studies:		Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal –f. Test product is r-hFSH 75 IU /150 IU Lyophilized Powder for Injection.
2	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:	All our clinical trial data provided are pertaining to claimed indication; Anovulation and Stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologies (ART). The requested points are already provided in Module 5 Non-clinical data. Enclosing the data in USB again for your reference.	ii) “Acute toxicity study of r-hFSH in comparison with Gonal-f in Swiss albino mice by subcutaneous route.” The study was conducted to evaluate the safety and toxicity profile of Recombinant Human Follicle Stimulating Hormone (r-hFSH) product developed by Bharat Serums and Vaccines Ltd in comparison with Gonal –f. Test product is r-FSH 75IU/150IU Lyophilized Powder for Injection.
3	Documented and published study reports of pre-clinical, Clinical trial reports establishing the safety and efficacy of the product:	Pre-clinical study report and Clinical trial data (Phase I, II and IV) is provided in module 4 and 5 respectively. Enclosing the data in USB for your reference.	iii) “Repeat dose toxicity and local tolerance study of FOLIGRAF in comparison with reference product in Wistar rats by subcutaneous route”. The study was conducted to assess the toxicity profile of FOLIGRAF and reference product (Gonal F) in Wistar Rats at dose levels of 9 and 90 IU/kg body weight thrice in a week over a period of 90 day by subcutaneous route. Repeat dose administration did not show any clinical signs and mortality at any of the treated dose groups. Animals injected thrice a week over a 90 days did not show any gross pathological abnormalities as well as histopathological change at injection site. The test product is Foligraf 75IU (Lyophilized powder for Injection).
4	Post-marketing surveillance (Pharmacovigilance) study reports.	Safety study has been provided in Phase IV study in Module 05.	Firm has submitted Literature references in clinical part (Module 5).

Concluding Remarks:

- Evidence of approval of applied product (150IU) in vial container closure system in any reference country as approved by Registration Board.
- Repeat dose toxicity studies and Module 5 (clinical data) of applied product is not provided. Only literature references attached.

Decision of 351st meeting:

Registration Board deferred the case for submission of following documents/ clarifications;

- Evidence of approval of applied product (150IU) in vial container closure system in any reference country as approved by Registration Board.
- Repeat dose toxicity studies and Module 5 (clinical data) of applied product.

Evaluation by BE&R:

Sr.No.	Query	Response	Remarks

1	Evidence of approval of applied product (150IU) in vial container closure system in any reference country as approved by Registration Board.	BSV response- We acknowledge Ministry's remarks; we would like to inform DRAP that BSV is currently not authorized in any of the reference countries approved by the Registration Board. However, the product is registered in several other countries, including India, Cuba, Tanzania, Uzbekistan, Sri Lanka, Ghana, Myanmar, Nigeria, Chad, Kazakhstan, Uganda, and Cambodia, and has been commercialized for the past 15 years.	Evidence submitted.
2	Repeat dose toxicity studies and Module 5 (clinical data) of applied product.	BSV response- We acknowledge Ministry's remarks and would like to submit our response as <u>Module-5 (Clinical data) of applied product</u> We have submitted a Phase-I, Phase III and Phase IV studies in our dossier to assess the bioequivalence and pharmacokinetic (PK), Safety and Efficacy profiles of our BSV test product compared with the reference product. The study demonstrates that the test product is comparable with reference product. Our two strengths (75 IU and 150 IU) are dose-proportionate, hence No separate CT was performed for 150 IU against Innovator for the additional strength, in accordance with EMA's guidance on dose proportionality. Specifically, the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) states that a waiver of bioequivalence studies is acceptable if the following conditions are met: • the qualitative composition of the different strengths is the same, and We have provided a justification for dose-proportionality based on these criteria, highlighted in Annexure-1 (see page 12). <u>Non Clinical data) of applied product</u> The non-clinical data with Repeat dose toxicity studies are already provided under Module-4, section 4.2 Reports of researches of registration dossier. Two studies were performed as a) Sub acute Toxicity Study of r-hFSH in comparison with Gonal-f® in swiss albino mice by subcutaneous route ACT/r-hFSH/05. b) Sub acute toxicity study of r-hFSH in comparison with Gonal-f® in New Zealand White rabbits by intramuscular route ACT/r-hFSH/06 Study report for ACT/r-hFSH/05 is provided on Pg. no 208 of 631 and, Study report for ACT/r-hFSH/06 is provided on Pg. no 304 of 631. Resubmitting the Module-4 for ready reference as Annexure-2	Clinical trial data of 75IU submitted.

Decision:

Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case#09: Imported human biological applied by M/s OBS AGP Limited deferred in 351st meeting:

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi
Details of Drug Sale License of importer	License No:024 Plot No. B-23-C, 2 nd Floor, S.I.T.E, Karachi
	Godown: Muller and Phipps Pakistan Pvt., Ltd., Plot No 32-12 Sector 19, K.I.A, Karachi Validity : 27-03-2028
Name and address of marketing authorization holder (abroad)	M/s Bharat Serums and Vaccines Limited K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane- 421506, Maharashtra, India.
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Limited K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane- 421506, Maharashtra, India.
Name of exporting country	India
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	<u>Original, Legalized and valid CoPP</u> Certificate Number: COPP/CERT/KD/120551/2022/11/42570/208009 Certifying Authority: Joint Commissioner (HQ) and Controlling Authority Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India Validity: 29, March 2025
Details of letter of authorization / sole agency agreement	<u>Original, Legalized and Valid Letter of Authorization</u> M/s BSV hereby appoint M/s OBS AGP Pvt. ,Ltd., will be responsible for the registration /marketing/sales/tender business of BSV Humog 150 HP Validity: 23-08-2028
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 1743 Dated 18, December 2023.
Details of fee submitted	Deposit Slip no. 2918568857 , PKR 150,000/- Dated: 20-07-2023
The proposed proprietary name / brand name	BSV Humog 150 HP

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Menotropin equivalent to activity of Follicle stimulating hormone 150 IU Luteinizing hormone 150 IU Diluent for reconstitution: Each ampoule contains: Sodium Chloride...0.9%
Dosage form of applied drug	Freeze Dried Powder
	Route of Adm SC/IM
Pharmacotherapeutic Group of (API) and Indication	Human Menopausal Gonadotropin ATC Code: G03GA02
Reference to Finished product specifications	BP Specifications
Proposed pack size	1's vial, 1's ampoule.
Proposed unit price	As per SRO
Shelf life	36 months Diluent 60months
Storage conditions	2°C - 8°C
The status in reference regulatory authorities	Approved in Germany.
For generic drugs (me-too status)	N/A
Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
Name, address of drug substance manufacturer	Manufacturing, Testing, Labeling, Packaging, Storage BSV Bioscience GmbH Max Planck-Strasse 12, 52499 Baesweiler, Germany
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The submitted stability data is of 24 months.
Menotrophin	

Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Bharat Serums and Vaccines Limited has developed In-house analytical procedures for BSVHUMOG- 150 HP [Menotrophin for Injection BP (Highly Purified) (Freeze Dried)] and these methods have been suitably validated as per the ICH requirements.
Container closure system of the drug product	2 ml Clear, Colourless glass, USP-Type 1 Vial ,13 mm slotted rubber bung, Aluminium Flip off Seal,13 mm Transparent Pink
Stability study data of drug product, shelf life and storage conditions	Based on available stability data of 6 Months at accelerated condition ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%\text{RH}$) and 36 Months at long term condition (2°C - 8°C), Bharat Serums proposes shelf life of 36 Months when stored at 2°C - 8°C . Diluent Shelf life of 60 Months when stored at 2°C - 8°C .
Diluent (0.9%w/v NaCl)	
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Pharmacopeial analytical procedures method has been verified.
Container closure system of the drug product	2 ml amber coloured neutral borosilicate glass U.S.P. Type I ampoule with concave bottom, snap off ampoule with score on the constriction.
Stability study data of drug product, shelf life and storage conditions	Shelf life of 60 Months when stored at 2°C - 8°C .
Module IV Non-Clinical	No Pharmacology and Pharmacokinetics studies have been conducted. Only Toxicology have been performed. Bharat Serums & Vaccines Limited (BSV) has performed preclinical toxicology evaluation of Human menopausal gonadotrophins (Humog®). The repeat toxicity dose toxicology in rats and rabbits was thoroughly investigated. Studies a) Repeat dose toxicity and local tolerance study of Humog® in New Zealand White rabbits by subcutaneous route (Study No: BSV/PC/11/11) b) Repeat dose toxicity and local tolerance study of Humog® in Wister rats by subcutaneous route (Study No: BSV/PC/11/10)

Module V Clinical Studies	5.2.1 Tabular listing of all clinical studies <table><tr><th>Type of Study</th><th>Study identifier</th><th>Location of Study Report</th><th>Objectives of the study</th><th>Study design and Type of control</th><th>Test products; dosage Regimen; Route of Administration</th><th>Number of Subjects</th><th>Healthy Subjects or Diagnosis of Patients</th><th>Duration of Treatment</th></tr><tr><td>BE</td><td>Project No. 613-14</td><td>Part IV-E</td><td>To compare the rate and extent of absorption of sponsor's test product (lpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy, adult, human female subjects</td><td>open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy, adult, human female subjects.</td><td>lpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH</td><td>24 subject</td><td>non-smokers, premenopausal female subjects</td><td>Single dose One each in Part I and Part II</td></tr></table>	Type of Study	Study identifier	Location of Study Report	Objectives of the study	Study design and Type of control	Test products; dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration of Treatment	BE	Project No. 613-14	Part IV-E	To compare the rate and extent of absorption of sponsor's test product (lpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy, adult, human female subjects	open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy, adult, human female subjects.	lpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH	24 subject	non-smokers, premenopausal female subjects	Single dose One each in Part I and Part II
	Type of Study	Study identifier	Location of Study Report	Objectives of the study	Study design and Type of control	Test products; dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration of Treatment										
BE	Project No. 613-14	Part IV-E	To compare the rate and extent of absorption of sponsor's test product (lpHMG-BSV) versus reference product (Menopur) in pituitary down-regulated healthy, adult, human female subjects	open label, balanced, randomized, two-treatment, two-sequence, two-period, single subcutaneous dose, crossover, bioequivalence study in pituitary down-regulated healthy, adult, human female subjects.	lpHMG-BSV (Humog) 75 IU Manufactured by BSVL Mumbai. Menopur 75 IU Manufactured by: Ferring GmbH	24 subject	non-smokers, premenopausal female subjects	Single dose One each in Part I and Part II											
	Reports of Biopharmaceutic Studies. BA And BE Comparability Report The two preparations were bioequivalent with respect to FSH and HCG immunoreactivity. Bioequivalence could not be proven for LH activity because of the small number of subjects. No invitro and invivo studies performed. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials																		
Remarks of the Evaluator	Observations ☐ ☐ Section 1.4.2 mentions both Domestic and Export sales. Clarification is required. ☐ ☐ Submit bio similarity studies with innovator product as per WHO template. ☐ ☐ Submit GMP of drug substance manufacturing site. ☐ ☐ In section 3.2.S.3.1 characterization drug substance has been compared with innovator product Menopur. Clarification/justification is required. ☐ ☐ The stability data of API is of 24 months, whereas, claimed shelf life is of 36 months. ☐ ☐ There is a significant difference in results of potency and specific activity for FSH and LH in section 3.2.S.7.3 when compared with section 3.2.S.4.4. The potency of FSH and LH is greater than 700IU/mg whereas, in stability summary sheets is greater than 300IU/mg. Same is the case with specific activity. Justification is required. ☐ ☐ Justification is required for not performing forced degradation studies for drug substance. ☐ ☐ Submit section 3.2.R, providing comparability exercise. ☐ ☐ The available monograph is menotrophin in water whereas, the applied formulation is menotrophin in sodium chloride. Clarification is required. ☐ ☐ The section 3.2.5.1 of menotrophin drug product mentions reference of specs BP whereas, section 3.2.P.5.3 mentions inhouse analytical procedures. ☐ ☐ The section 3.2.R.3 includes the data of Menotrophin 75 IU whereas, the applied strength is 150IU. ☐ ☐ The non-clinical studies in white rabbits states that dose level till 100IU is safe whereas, applied strength is 150 IU. Clarification is required. ☐ ☐ The toxicology studies have been done only for SC route whereas, safety studies for IM route not established. ☐ ☐ Justification is required for not performing all the non-clinical																		

		studies. ☐ ☐ Evidence of availability of strength in Germany.	
Decision of M-340 <i>The Registration Board deferred the case for the submission of above cited documents.</i>			
Evaluation by BE&R:			
Sr.No	Remarks of the Evaluator	Firms Response	Remarks
1.	Section 1.4.2 mentions both Domestic and Export sales. Clarification is required.	There is a typographic error in Form 5F. Whereas in Section 1.4.2 of Module 01, Correct option of Domestic sale was selected in a dossier.	-
2.	Submit bio similarity studies with innovator product as per WHO template	The study has been conducted according to EMA guidelines for biosimilars and guidelines for rFSH containing products. The WHO guidelines for BE has similar requirements enclosed as Annexure 1 . Hence the submitted study covers the requirements of WHO.	The product is not manufactured by rDNA technology rather prepared by Extraction of Active Substance from Natural Sources.
3.	Submit GMP of drug substance manufacturing site.	Please find valid GMP certificate of API manufacturer BSV BioScience enclosed as Annexure 2 .	Submitted
4.	In section 3.2.S.3.1 characterization drug substance has been compared with innovator product Menopur. Clarification/justification is required.	3.2.S.3.1 characterization drug substance is attached as Annexure 3 .	Firm has given statement that "In order to determine the structure and characteristics of the constituents, three lab scale batches (1HMG230502, 1HMG230717, 1HMG221114) were manufactured and sent to an external lab for characterization." Detail about the lab where characterization was performed is not mentioned.
5.	The stability data of API is of 24 months, whereas, claimed shelf life is of 36 months.	Please find complete 36 Months stability data of API from API manufacturer BSV BioScience enclosed as Annexure 4 .	Submitted
6.	There is a significant difference in results of potency and specific activity for FSH and LH in section 3.2.S.7.3 when compared with section 3.2.S.4.4. The potency of FSH and LH is greater than 700IU/mg whereas, in stability summary sheets is greater than 300IU/mg. Same is the case with specific activity. Justification is required.	Response from API manufacturer: The minimum required potency is > 40 IU/mg for both FSH and LH according to EP. BSV's internal specification is >100IU/mg and the results are within the compliance limits. The stability data is from batches of 2020; currently our batches are in the range of 500 to 700IU/mg. This does not lead to an impact on the quality of the product, in fact a higher potency is better. For the DP, the drug substance is later dissolved and diluted to the required activity of the finished formulation.	-

		Similarly, the specific activity is adjusted later on as well.	
7.	Justification is required for not performing forced degradation studies for drug substance.	A stress study at +40 °C was performed for one HMG batch. Please find attached data as Annexure 5 .	Submitted
8.	Submit section 3.2.R, providing comparability exercise.	BSV has conducted BE study (Phase I - Project No. 613-14) to compare the rate and extent of absorption of sponsor's test product (BSV Humog versus reference product (Menopur). Attaching the report as Annexure 6 .	Firm has submitted single study of "hpHMG-BSV 75 IU vial" which is not the applied product.
9.	The available monograph is menotrophin in water whereas, the applied formulation is menotrophin in sodium chloride. Clarification is required	In BSV Humog 150 IU, Water for injection is used as a solvent in the formulation (Please refer section 3.2.P.3.2 Batch formula) which is not present in finished product as the product is Lyophilized powder for injection. However, diluent 0.9% Sodium chloride' is used for reconstitution before administration.	-
10.	The section 3.2.5.1 of menotrophin drug product mentions reference of specs BP whereas, section 3.2.P.5.3 mentions in-house analytical procedures.	The section 3.2.P.5.3 claiming IH standard was erroneously mentioned, and the validation of analytical procedures is done as per BP monograph. Please find revised section 3.2.P.5.3 mentioning AMV done as per BP monograph as Annexure 7 .	Finished product specifications is BP.
11.	The section 3.2.R.3 includes the data of Menotrophin 75 IU whereas, the applied strength is 150IU	The dose of Menotrophin: The starting dose is normally 75-150 IU daily. This dose may be increased according to your response to the treatment up to a maximum of 225 IU per day. The dose should be increased by 37.5 IU per adjustment (and not more than 75 IU). Menotrophin administered depends on the dose required for patient as per the Investigator's assessment. Hence the different strength 75 IU or 150 IU or other strength would not affect the dose administration.	The data of 150IU strength is not provided.
12.	The non-clinical studies in white rabbits' states that dose level till 100IU is safe whereas, applied strength is 150 IU. Clarification is required.	Strength BSV HUMOG 150 IU i.e., per 60 kg of human, which is 40 folds higher when compared to 100 IU/kg of rabbit. The dose used for the toxicity study is 100 IU/kg in rabbits, equivalent to 2.5 IU/kg/day of human dose	-

13.	The toxicology studies have been done only for SC route whereas, safety studies for IM route not established	Both the Subcutaneous and Intramuscular routes are clinically intended uses for HUMOG 150 IU due to dose volume restriction in animals' the subcutaneous route is used in toxicology studies. The only difference is the delayed absorption in subcutaneous route, when compared to the intramuscular route, and both are clinically compared in terms of efficacy.	-
14.	Justification is required for not performing all the non-clinical studies	HUMOG 150 IU is a Generic Product. Hence, for Generic drugs it is not recommended to perform all non-clinical studies. Please refer to the EMA guideline for generic filing (Page no 13) enclosed as Annexure 8..	Not performed.
15.	Evidence of availability of strength in Germany.	Menopur 150 IU Powder and Solvent for Solution for Injection <u>Marketing Authorisation Holder:</u> Ferring Pharmaceuticals Ltd. Drayton Hall, Church Road, West Drayton, UB7 7PS, UK PL 03194/0109 <u>Manufacturer:</u> Ferring GmbH Wittland 11, D-24109 Kiel, Germany Reference attached as Annexure 9.	Submitted
<u>Concluding remarks:</u> - Complete clinical and non-clinical data is required as the applied product is a biological and prepared by Extraction of Active Substance from Natural Source. - In-use stability data is required. - Detail of the laboratory where characterization was performed and results of characterization is required.			
<u>Decision of 351st meeting:</u> Registration Board deferred the case for submission of following documents/ clarifications; - Complete clinical and non-clinical data is required as the applied product is a biological and prepared by Extraction of Active Substance from Natural Source. - In-use stability data is required. - Detail of the laboratory where characterization was performed and results of characterization is required.			
<u>Evaluation by BE&R:</u> The response of the firm is as under; BSV response, We acknowledge Ministry's remarks and would like to submit our response as; Clinical: We have submitted a Phase-I (bioequivalence) study in our dossier to assess the bioequivalence and pharmacokinetic (PK) profiles of our BSV test product compared with the reference product. The study demonstrates that the test product meets the bioequivalence criteria relative to the reference. Our two strengths (75 IU and 150 IU) are dose-proportionate, a bioequivalence (BE) waiver for the additional strength, in accordance with EMA's guidance on dose proportionality. Specifically, the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) states that a waiver of bioequivalence studies is acceptable if the following conditions are met: - the qualitative composition of the different strengths is the same, and We have provided a justification for dose-proportionality based on these criteria, highlighted in Annexure-1 (see page 12). Justification for absence of Phase III data: - Humog is not a new molecule; it is a well-established biological product with the same active substance as the reference product.			

- Humog has been marketed for over 12 years with a strong record of safe and effective use, and no reported safety concerns during this period, which proves its safety and efficacy.
- The product is approved in PIC/S member countries, including Philippines and Ukraine, which follow stringent international regulatory standards.
- The API is sourced from Germany, a country recognized for its rigorous quality systems and compliance with EU GMP standards and is listed in the Japanese Pharmacopoeia (JP), further confirming its quality.

Non-clinical data:

BSV response-We acknowledge Ministry's remarks,

We have conducted the following acute toxicity and repeated-dose toxicity studies to comprehensively evaluate the safety profile of the product:

- Acute Toxicity Studies: Designed to assess the potential adverse effects following a single administration of the product at varying dose levels.
- Repeated-Dose Toxicity Studies: Conducted to evaluate the effects of multiple administrations over a defined period.

The results from these studies demonstrate that the product is well-tolerated and safe under the tested conditions. Furthermore, the product has been successfully commercialized since 2014, with no reported safety concerns, supporting its established safety profile.

2) In-Use stability data is required

BSV response-We acknowledge Ministry's remarks and would like to submit our response as;

In-use stability study data was already submitted in initial dossier in section P.8.3 which is provided as Annexure-3

Study concludes that, concluded that all the above mention tests are well within the limits for the period of 4 hours of reconstitution and therefore the stability of the reconstituted solution (in sodium chloride injection) is found satisfactory upto 4 hours of reconstitution study at temperature 2°C - 8°C, however it is recommended to use reconstituted solution immediately.

3) Detail of laboratory where characterization was performed and results of characterization is required

BSV response-We acknowledge Ministry's remarks and would like to submit our response as;

We have provided Section 3.2.S.3.1: Elucidation of Structure and Characteristics, along with the laboratory report, which is included as Annexure 4.

Concluding remarks:

- In clinical part, the firm has submitted following study;

“AN OPEN LABEL, BALANCED, RANDOMIZED, TWO-TREATMENT, TWOSEQUENCE, TWO-PERIOD, SINGLE DOSE, CROSSOVER, STUDY TO ASSESS BIOEQUIVALENCE AND PHARMACOKINETIC PROFILES OF TWO DIFFERENT FORMULATIONS OF HUMAN MENOPAUSAL GONADOTROPIN 300 IU SUBCUTANEOUS INJECTION IN PITUITARY DOWN-REGULATED HEALTHY, ADULT, HUMAN FEMALE SUBJECTS.”

Test product is “hpHMG-BSV 75 IU vial”.

- Phase III clinical trial is not performed.
- In characterization report, only study objective and sample receipt information attached. Complete report including final conclusion is also required.

Decision:

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

- **Phase-III Safety and Efficacy data.**
- **Complete characterization report as only study objective and sample receipt information are submitted.**

Case#10: Imported human biological applied by M/s OBS AGP Limited deferred in 351st meeting:

Name, address of Applicant / Importer	M/s OBS AGP (Private) Limited. Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi-75700, Pakistan.
Details of Drug Sale License of importer	License No: 024 Address: OBS AGP PRIVATE LIMITED Address of Godown: PLOT NO. B-23-C, 2nd FLOOR S.I.T.E KARACHI. Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter Valid Upto: 27-03-2028
Name and address of marketing authorization holder (abroad)	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
Name, address of manufacturer(s)	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India
Name of exporting country	INDIA
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.COPP/CERT/KD/120672/2022/11/42600/208257) dated 18-10-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. <u>The name of importing country on CoPP is mentioned as Islamic Republic of Pakistan. Furthermore, the CoPP is valid till 29march,2025</u> GMP: Firm has submitted original, legalized copy of GMP certificate (NEW-WHO GMP/CERT/KD/107921/2022/11/39826) dated 04-July-2022 issued by Food & Drug Administration, MS. Bandra (E) Mumbai-400 051 Maharashtra stat, India, valid till 29March,2025
Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized copy of letter of Authorization certificate from M/s Bharat Serums and Vaccines Limited. The letter species that the manufacturer appoints M/s AGP Limited to register their products in Pakistan.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No. 17734: 14-07-2023 (Slip # 181426809656)
Details of fee submitted	PKR 150,000/-: 21-06-2023
The proposed proprietary name / brand name	U-Tryp 100,000 IU (Ulinastatin for injection)

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ulinastatin 100,000.IU. (Liquid Injection)
Pharmaceutical form of applied drug	Liquid Injection.
Pharmacotherapeutic Group of (API)	Urinary Trypsin Inhibitor
Reference to Finished product specifications	BSV specs
Proposed Pack size	1's x 5ml Vial (4ml deliverable volume)
Proposed unit price	-
The status in reference regulatory authorities	MIRACLID by Mochida, Japan
For generic drugs (me-too status)	Roan 100,000 IU by M/s Techpool Bio Pharma Co, Ltd.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	M/s Bharat Serums and Vaccines Limited Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East) Thane-421506, Maharashtra, India.
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API (UTIV110314, UTIV110518, UTI120109) conducted at accelerated conditions 5°C ± 3°C RH for 6 months as well as real time conditions. The real time stability data is conducted at -20°C ± 5°C for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bioequivalence studies against reference product MIRACLID developed by Mochida, Japan.
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	U-TRYP 100,000 IU [Ulinastatin for Injection 100,000 IU (Liquid)] is packaged in Clear, Colourless, USP, Type I tubular flint glass vial of 5 ml capacity	
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (A13317002, A13317003, A13317004) The accelerated stability study data is conducted at 25°C ± 2°C / 60% ± 5%RH for 6 months. The real time stability data is conducted at 2-8°C for 36 months.	
	Module IV	Following is submitted by firm: • Single dose toxicity studies • Repeat dose toxicity studies	
	Module V	A Prospective, Multicenter, Double-Blind, Randomized, Phase III Clinical Study to Compare the Efficacy and Safety of Intravenous Ulinastatin Versus Placebo Along with Standard Supportive Care in Subjects with Mild or Severe Acute Pancreatitis. A Prospective, Multicentric, Double-Blind, Randomised, Phase III Clinical Study To Compare The Efficacy and Safety of Intravenous Ulinastatin Versus Placebo Along with Standard Supportive Care in Subjects of Severe Sepsis. Prospective, single center, open label, balanced, randomized, multiple dose strengths, parallel group safety study to evaluate safety of Ulinastatin in healthy, adult, human subjects A phase IV, prospective, multi-centric, double-blind, comparative, clinical study to compare the efficacy and safety of intravenous ulinastatin versus placebo along with standard supportive care in subjects with severe sepsis. At the time of this PSUR, the sponsor has recruited 7 subjects in this study. No major safety concern has been encountered till date.	
Decision of 340th meeting: <i>Registration Board deferred the case for submission of comparative clinical trial data.</i>			
Evaluation by BE&R: Firm has submitted following; “Prospective, single center, Open Label, Balanced, Randomized, Multiple Dose strengths, Parallel group Safety Study to evaluate Safety of Ulinastatin in Healthy, Adult Human Subjects.” • The reference product Miraclid Injection 100,000Units is available as 2ml ampoule in Japan while the applied product is 5ml vial. The reference product is verified from the following link: https://www.pmda.go.jp/PmdaSearch/iyakuSearch • Comparative clinical trial data is not provided by the manufacturer.			
Decision of 351st meeting: <i>Registration Board decided to defer the case and grant final opportunity to the applicant for submission of following documents/ clarifications;</i> i. <i>The reference product Miraclid Injection 100,000Units is available as 2ml ampoule in Japan while the applied product is 5ml vial.</i> ii. <i>Comparative clinical trial data of applied product with innovator.</i>			
Evaluation by BE&R:			
Sr.No.	Query	Response	Remarks
	The reference product Miraclid Injection 100,000 Units is available as 2ml ampoule in Japan while the applied product is 5ml vial.	The detailed response is uploaded as received from our principal manufacturer. Please find below the conclusions: The fill volume of U-Tryp is 4 mL, whereas the reference product Miraclid is 2 mL. This difference is primarily due to the choice of container closure system.	• For Miraclid (reference product), the concentration per mL is 50,000 IU, which translates to 100,000 IU in 2 mL in ampoule container closure system. • For U-Tryp (applied product), the concentration per mL is 25,000 IU, which translates to 100,000 IU in 4

		Despite the difference in fill volume, the total potency remains the same in both products—100,000 IU. Miraclid: $50,000 \text{ IU/mL} \times 2 \text{ mL} = 100,000 \text{ IU}$ U-Tryp: $25,000 \text{ IU/mL} \times 4 \text{ mL} = 100,000 \text{ IU}$ Therefore, the difference in container type and fill volume does not impact product quality or safety, and the applied product delivers the same therapeutic dose as the reference product. • For Miraclid, the concentration per mL is 50,000 IU, which translates to 100,000 IU in 2 mL. • For U-Tryp, the concentration per mL is 25,000 IU, which translates to 100,000 IU in 4 mL	mL in vial container closure system.
	Comparative clinical trial data of applied product with innovator.	<u>The detailed response, as received from our principal manufacturer, has been submitted on the USB (R & I Uploaded) as the data consists of multiple large files that cannot be uploaded on the E-Portal.</u> Please find below the conclusions: A comparative clinical trial was conducted using placebo, due to the unavailability of an innovator product in India. Phase-III and Phase-IV studies were performed to ensure comprehensive clinical evaluation. (Detailed studies provided in USB – Annexure 1, as multiple files could not be uploaded on E-Portal.) The justification for using placebo as choice of comparator is enclosed as as Annexure 2. (Uploaded) <u>The Active Pharmaceutical Ingredient (API) is sourced from Germany, a country recognized for its stringent quality standards and full compliance with EU GMP guidelines.</u> <u>U-Tryp has already been approved in PIC/S member countries, including Ukraine (approval letter uploaded as Annexure 3)</u> These factors collectively confirm that the applied product adheres to high standards of quality, safety, and regulatory compliance, providing assurance regarding its therapeutic efficacy and continued use, even with the use of a placebo as a clinical comparator.	

Decision:

Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Case No. 11: MINUTES OF 8TH MEETING OF EXPERT WORKING GROUP ON VETERINARY DRUGS (HARD CASES)

Sr. No.	Name of Importer & Manufacturer	Brand Name & Composition	Pack Size, Shelf Life & Storage Conditions	Recommendations of EWG in its 8 th Meeting	Decision
1.	Applicant: Name: M/s Lucky Core Industries Limited, 5 West Wharf, Karachi Manufacturer: M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, the Netherlands.	Bovilis Lumpyvax-E Lyophilisate and Solvent for Suspension for Injection for Cattle Each 1ml dose of reconstituted vaccine contains; Live attenuated lumpy skin disease virus (Neethling)... $\geq 1 \times 10^4$ and $\leq 5.0 \times 10^5$ TCID ₅₀ Solvent: Disodium phosphate dihydrate....1.4mg Potassium dihydrogen phosphate...0.2mg Sodium chloride.....8mg Potassium chloride....0.2mg Water for Injection.....Upto 1m	20 doses 100 doses 24 months	The Committee recommended the product for grant of registration.	Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of following by the firm: i. Valid GMP certificate of manufacturer abroad. ii. Proposed pack size along with its stability study data for 3 commercial scale batches. iii. Revised label specimen with name of importer.
2.	Applicant: M/s Hi-Tech Pharmaceuticals (Pvt) Ltd 1-C, Shadman Chowk, Jail Road, Lahore Manufacturer: ZOETIS Inc. 601 West Cornhusker Highway, Lincoln, NE 68521-3577, USA.	Inforce™ 3 Freeze Dried Vaccine with sterile diluent Each dose of 2ml contains; Bovine Rhinotracheitis Virus..... $>10^{6.0}$ TCID ₅₀ at release Strain RLB 106..... $>10^{5.5}$ TCID ₅₀ at expiration Bovine Parainfluenza 3 Virus..... $>10^{5.5}$ TCID ₅₀ at release Strain RLB 103..... $>10^{5.0}$ TCID ₅₀ at expiration Bovine Respiratory Syncytial Virus... $>10^{5.3}$ TCID ₅₀ at release Strain BRSV/375... $>10^{4.8}$ TCID ₅₀ at expiration	18 Months (2 – 8 oC) 1 x 10 doses vial with 20 ml diluent	The Committee deliberated that the combination is required for Exotic Animals. Hence, recommended the product for grant of registration.	Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of following by the firm: i. Valid GMP certificate of manufacturer abroad. ii. Details of diluent along with its application.

3. STATUS OF FOOT AND MOUTH VACCINES FROM CHINA

Cavtovax Foot & Mouth Disease Vaccine applied by M/s Dairy Heed Pakistan (Pvt.) Ltd. The product was approved in 351st meeting of Registration Board as follows:

“Keeping in view FSC 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 Immunological relevance of applied strain & their need for Pakistan and recommendations of Sub-Committee on Veterinary Drugs on provided relevance and need.”

The immunological relevance was provided by the firm and reference was sent to Ministry of National Food Security on the recommendations of Expert Working Group. The following is the response from Ministry of National Food Security which shall be placed in forth coming meeting of Registration Board:

“Pakistan is classified under **Pool 3 of the FMD Virus Ecosystem**, whereas China belongs to **Pool 1**. The vaccine seed strains **O/MYA98/BY/2010**, **Asia1/JSL/ZK/06**, and **Re-A/WH/09** are not characterized within **Pool 3**, and the circulating lineages in the two pools are **antigenically and genetically different**.

FMD vaccine effectiveness is highly dependent on **antigenic matching** between vaccine strains and the **local field virus lineages**. Since Pakistan and China have **different dominant serotype-lineage combinations**, a vaccine formulated for China is **unlikely to provide adequate protection** in Pakistan unless supported by **cross-protection data** demonstrating its efficacy against field strains circulating domestically. Absence of cross-protection evidence, use of that vaccine in Pakistan could produce sub-optimal protection and create a false sense of herd immunity. The vaccine may not be recommended for import and commercial use in Pakistan.”

It is further submitted that following statement is available at official website of Ministry of Agriculture and Rural Affairs of the People's Republic of China:

“Starting from July 1, 2018, immunization against Asian type I foot-and-mouth disease will be suspended nationwide, and the production and sale of vaccines containing Asian type I foot-and-mouth disease virus components will be stopped.”

The website is as follows:

https://www.moa.gov.cn/govpublic/SYJ/201801/t20180102_6133588.html”

Following is the status of other FMD vaccines from China.

Sr. No.	Reg. No.	Brand Name & Composition	Importer & Manufacturer	Status
1.	101725	Foot and Mouth Disease Trivalent Vaccine, Inactivated (Type O, Type A and Asia 1) Each ml contains: FMD virus O/HB/HK/99 strain..... $\geq 10^{7.0}$ TCID ₅₀ before inactivation AF/72 strain..... $\geq 10^{7.0}$ TCID ₅₀ before inactivation Asia-1/XJ/KLMY/04 strain..... $10^{7.0}$ TCID ₅₀ before inactivation	M/s Vet Line International, Plot No. 939-A, Block-J, Phase-I, LDA Avenue-1, Lahore. M/s Lanzhou Bio-Pharmaceutical Factory of China Animal Husbandry Industry Co., Ltd., No. 2, Yanchang Road, Lanzhou City, Gansu Province, China	The firm has applied for Post Registration Variation regarding brand name, composition & address of manufacturer. The firm has been asked for clarification of free sale status as Chinese Government has issued advisory to stop production of Asia 1 containing vaccines.
2.	120537	Foot and Mouth Disease Trivalent Vaccine, Inactivated (Strain O + Strain Asia 1 + Strain A) Inactivated FMD virus Type A antigen..... ≥ 6 PD ₅₀ . Inactivated FMD virus type O antigen..... ≥ 6 PD ₅₀ , Inactivated FMD virus Type Asia 1 antigen..... ≥ 6 PD ₅₀	M/s Pharmakon International Enterprises, Islamabad M/s Jinyubaoling Bio-pharmaceutical Co Ltd No 1 Jinyu street, Hohhot Inner Mongolia, China	Registered
3.	N/A	RINVAC FMD Each dose contains: Inactivated FMD virus Type O (strain OHM/02)..... ≥ 6 PD ₅₀ Inactivated FMD virus Type A (strain AKT-III) ≥ 6 PD ₅₀ Inactivated FMD virus Type Asia 1 (strain Asia 1 KZ/03)..... ≥ 6 PD ₅₀	M/s Ghazi Brothers. D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan Inner Mongolia Bigvet Biotech Co., Ltd. East Side of Culina, Shida East Road, Shengle Economic Park, Helinger County, Hohhot Inner Mongolia Autonomous Region, People's Republic of China.	The product was approved in 345 th meeting of Registration Board, however, the registration letter was not issued due to non-clarity of free sale status in submitted Free Sale Certificate.

Decision of Expert Working Group:

The working group deliberated that the matter of FMD vaccines of different pools is a technical matter and requires extensive discussion with experts of this field. Hence, following are the recommendations:

1. The above mentioned vaccines in table may be referred to M/o National Food Security for their comments regarding relevance and need of strains in Pakistan.
2. Chairman Expert Working Group shall arrange a consultative meeting with relevant Experts and recommendations of Experts shall be placed in next meeting of Registration Board for Policy decision.
3. The registration application of Cavtovax Foot & Mouth Disease Vaccine applied by M/s Dairy Heed Pakistan (Pvt.) Ltd. may be deferred till Policy decision.

Decision:

Keeping in view the recommendations of the Expert Working Group; Registration Board decided as follows:

- The above mentioned vaccines in table are referred to M/o National Food Security for their comments regarding relevance and need of strains in Pakistan.
- Following Sub-Committee is constituted for consultative discussion on Foot and Mouth Disease Vaccines imported from different Pools than Pakistan. The final recommendations of Sub-Committee shall be placed before Registration Board for decision on FMD vaccines.

Sr. No.	Name & Designation	Status
1.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar	Chairman
2.	Dr. Ghazanfar Ali Khan, Director Biological Drugs DRAP	Co-Chairman
3.	Mr. Muhammad Sarfraz Nawaz, Deputy Director PE&R, DRAP	Secretary/ Convener
4.	Dr. Qurban Ali, Ex-DG NVL, Islamabad	Member
5.	Dr. Sayyad Murtaza Hussain Andrabi, Animal Husbandry Commissioner, Ministry of National Food Security & Research, Islamabad.	Member
6.	Technical Expert from each Province	Member
7.	Deputy Director, Biological Drugs DRAP	Member
8.	Any Expert Co-opted by Chairman Sub-Committee from relevant field.	

- The registration application of Cavtovax Foot & Mouth Disease Vaccine applied by M/s Dairy Heed Pakistan (Pvt.) Ltd. is deferred till final decision.



Drug Regulatory Authority of Pakistan
(Pharmaceutical Evaluation & Registration Division)



Item No. V Applications received on e-app.

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Title	Description
1	Case Category	New License (Abdul Mughees)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghouri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(L1P-EG4-MWJ9, 2025-03-04)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	Baknal injection
	Label Claim	Each 5ml ampoule contains: NaCl.....0.9% w/v
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	Nisale injection
	Pharmacotherapeutic Group of (API)	Electrolyte
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rasino Herbs Pvt. Ltd, N-2, MIDC, Chemical Zone, Kupwad, Sangli-416436, Maharashtra, 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	Nasline Injection: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Real time stability study is not provided
	The status in reference regulatory authorities	FDA Approved
	GMP status of the firm	28-04-2022: New DML
	Evidence of approval of manufacturing facility	29-04-2022: New DML issuance letter specifies Injectable ampoule section (General)
	Evaluation Remarks	
	M-351: The Registration Board deferred the case for verification of applicant's provided API loan issuance letter from M/s Global Pharmaceuticals (Pvt) Ltd. The firm has submitted loan letter from M/s Global Pharmaceuticals, Islamabad. The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	

2	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	OBS AGP (Private) Limited Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi (024)
	Application Form Dy. No / Tracking ID & date of submission	(THY-RWH-GM9G, 2025-09-18)
	Detail of Fee Submitted	300000.0, 2024-02-22,
	The proposed proprietary name / brand name	Amphonex 50mg
	Label Claim	Each vial contains: Liposomal Amphotericin B.....50mg.
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 x 20ml-As per SRO
	Shelf Life (Unit)	24 Month(s) 2 C to 8 C
	For generic drugs (me-too Status)	Anfogen Ferozsans Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	M/S. Bharat Serums and Vaccines Limited-Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India.- India
	Name & address of API manufacturer	M/S. Bharat Serums and Vaccines Limited
	Detail of stability batches of drug product	Provided
	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)	Provided
	The status in reference regulatory authorities	USFDA Approved (AMBISOME ASTELLAS PHARMA US INC)
	GMP status of the firm	Provided valid upto 29 March 2025
	Evidence of approval of manufacturing facility	Provided
	Evaluation Remarks	
	Decision of M-351: "Deferred to explain the scientific basis for adopting the particle size specification of NLT 75 nm and NMT 150 nm, whereas the innovator has stated that AmBisome contains liposomes of less than 100 nm. As the batch results of the particle size test are all above 100 nm, and considering that liposome size is a critical determinant of pharmacokinetic performance, the applicant is required to justify the proposed limit." Reply of the firm on January 06th, 2026: Please find acceptance criteria for particle size is as below, Acceptance Criterion: Mean: 50% of particles between 80-150 nm, High: 95% of particles NMT 300 nm BSV Liposomal Amphotericin B for injection is small unilamellar vesicles having average particle size below 150nm. Particle size measurement and its distribution is important to not only characterize the liposome at the time of manufacture, but also to measure its physical stability over the shelf life of the product. Typically, particle size of liposomes is reported as the mean, which defines the average particle size of the product. However, this does not provide a measurement of the distribution. Since physical instability is characterized by formation of particle aggregation, it is considered important to define and monitor the size of particles at the higher end of the distribution. The determination of particle size distribution by photon correlation spectrophotometer is obtained by measuring the mean effective diameter and polydispersity of the liposomal product. With these two parameters, distribution of the population is projected assuming monodispersion (Gaussian	

distribution). This is representative of (equal to) 100% of cumulative particle size distribution, of which every percentile of the Gaussian distribution has some degree of uncertainty. The log normal summary table (generated by the instrument's software) reports cumulative distribution up to 95% of the distribution. Therefore, the maximum size of particles covered within 95% of the distribution is also reported. The manufacturing process of BSV Liposomal Amphotericin B for injection is manipulated to give a product with an average particle size 80 to 150nm. Analysis of batches of the innovator product was also performed to set appropriate specifications for particle size distribution. Based on the outcome of the formulation development studies, the above limits were set. All batches of BSV Liposomal Amphotericin B for injection product were consistently produced within the above specification limits and found to be comparable to the innovator product. Summary of Accelerated stability studies report during Product developmental stage and Summary of Accelerated and Real time studies reports of Test are enclosed as Annexure-1.

Decision

Deferred

The Registration Board deferred the case for clarification from the applicant on the registration status of Amphonex 50 mg in DRAP's Reference Regulatory before proceeding on the case.

3	Case Category	Routine (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	(S1R-LH8-4DM4, 2024-03-26)
	Detail of Fee Submitted	75000.0, 2023-11-14,
	The proposed proprietary name / brand name	Thiorelax
	Label Claim	Each gram contains: Thiocolchicoside.....2.5mg
	Reference to Finished product specifications	As per Innovators Specificatio
	Proposed Pack Size	40g-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool and dry place below 30°C.
	For generic drugs (me-too Status)	Nil
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	India Glycol Limited Plot No. 2, 3, 4&5, Pharmacy, Selaqui Industrial Area, Dehradun, Uttarakhand, and Pin Code – 248197. (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	European Medicine Agency (Relief Gel 0.25%)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks		
Decision of M-348: "Firm to submit approval status in Reference Regulatory Authorities as approved in 275th meeting of the Registration Board." Reply of the firm: The applicant has provided Machine Translated by Google version of EMA list of nationally authorized medicinal products EMA/135315/2022 on January 7th, 2026, which contains MUSCO-RIL 0.25% gel by SANOFI-AVENTIS AEBE in Greece with national MAH number 10560/29-06-1993. Submitted for consideration by the Registration Board.		
Decision		
Deferred		
The Registration Board deferred the product for provision of Assessment Summary of the product by the approving Reference Regulatory Authority.		
4	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	Aptcure (PVT.) Ltd 8th Pharma city , 30-km, multan road lahore (000648)
	Application Form Dy. No / Tracking ID & date of submission	(6QR-MNT-3ZVB, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-04-16,
	The proposed proprietary name / brand name	EMLOZIN
	Label Claim	Each film coated tablet contains Empagliflozin 10mg (as per innovators specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14-As per SRO
	Shelf Life (Unit)	24 Year(s)At room temperature below 25 degree centigrade
	For generic drugs (me-too Status)	JARDY 10 mg tab by CCL Registration Number 094004
	Pharmacotherapeutic Group of (API)	Anti-diabetic: sodium-glucose co-transporter 2 (SGLT2) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited Pakistan
	Detail of stability batches of drug product	3 batches at accelerated and long term conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Invoice from Pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	JARDY manufactured by CCL
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches of 10 Kg at accelerated and long term conditions
	The status in reference regulatory authorities	Jardiance Tablets 10 mg by Boehringer Ingelheim International GmbH MHRA Approved
	GMP status of the firm	For DS manufacturer: Pharmagen For DP manufacturer: Aptcure (to be provided)
	Evidence of approval of manufacturing facility	DML attached
Evaluation Remarks		
The firm was asked to clarify following: Provide latest GMP report/ Certificate of the applicant Provide analytical method validation for assay of raw material Empagliflozin COA of Empagliflozin Reference standard provided by you declares that "use before 24 March 2022". However, you performed analytical validation (in 3.2.P.5.3) where system suitability (not dated) and Linearity was performed on 27.08.2022. Similarly, you have provided COA for empa raw material with testing date 25-07-2022.		

Please justify these anomalies and provide signed and stamped COAs and analytical method validation reports along with supporting data. Provide DML/ GMP for DS manufacturer along with API procurement documents Now, the application is complete as per codal formalities for consideration by the Registration Board.

Decision

Approved

The Registration Board decided to conduct Product Specific Inspection (PSI) by a panel constituted by the Chairman, Registration Board.

5	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(1S8-B91-Z374, 2024-05-14)
	Detail of Fee Submitted	75000.0, 2024-05-09,
	The proposed proprietary name / brand name	Mgab Tablet 2.5mg
	Label Claim	Each film-coated tablet contains Mirogabalin besylate eq. Mirogabalin ----- 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N02BF : Gabapentinoids
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering., Co., Ltd, No.5329, Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice., China
	Detail of stability batches of drug product	3 batches at long term and short term stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided for 400 gm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 2.5 mg tablet by Daiichi Sankoyo Batch # 043085
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long term and short term stability conditions
	The status in reference regulatory authorities	Tarlige Tablet 2.5mg by Daiichi Sankyo Company, limited. (Japan)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML of both contract giver and acceptor
Evaluation Remarks		
The application is complete as per codal formalities for consideration by the Registration Board.		
Decision		

	Approved	
6	Case Category	Routine (Abdul Mughees)
	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	(2V6-R2L-VXJN, 2024-06-06)
	Detail of Fee Submitted	30000.0, 2023-09-25,
	The proposed proprietary name / brand name	Glifmet 12.5/850mg
	Label Claim	Each film coated tablet contains: Empagliflozin.....12.5mg Metformin HCl..... 850mg (As per Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Controlled room temperature
	For generic drugs (me-too Status)	Diampa-M 12.5/850 mg
	Pharmaceutical Group of (API)	Antidiabetics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	empagliflozin, Metformin HCl
	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Diampa M Tablets Batch 261FC2 by Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	Australian GOVT
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML
Evaluation Remarks		
The applicant was initially asked to clarify: Please clearly state from which manufacturers you had procured Empagliflozin and Metformin? Provide License, GMP and clearance document for those sources only. In the last response you have attached documentation and clearance for more than two DS manufacturers for each API which is confusing. Please clarify. The firm attached invoices in which Metformin was cleared in 2023 whereas stability was performed in 2022. Again, it was asked to clarify the following: The provided Clearance for Metformin is from WANBURY LIMITED and is dated 04.05.2023 whereas you have submitted data of stability batches with manufacturing date 05-2022. In the last response you submitted GMP and license of IOL Pharmaceuticals and Chemicals. Please provide signed and stamped execution BMRS for all stability batches. Signed and stamped CDP and method validation report with clear indication to date of manufacture, dispensing dates and other documents proving that batches were manufactured in 05-2022. Submit Drug Substance part in Module 3 as per DRAP Guidelines along with traceable signed and stamped COAs of both APIs (by DS as well as DP manufacturer) for the batches which were used in manufacturing of stability batches. The firm has provided reply to abovementioned. However, the metformin DS manufacturer is still to be confirmed through verification.		
Decision		

Rejected

The Registration Board rejected on the ground that applicant has changed the import and procurement documents of Metformin from two different source. The import was made in 04-05-2023 whereas manufacturing of stability batches was done on 05-2022.

7	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle, Kahuta road, Islamabad. (000569)
	Application Form Dy. No / Tracking ID & date of submission	(3TE-9SJ-A842, 2024-02-26)
	Detail of Fee Submitted	75000.0, 2023-11-08,
	The proposed proprietary name / brand name	Dancef Injection 500 mg IV
	Label Claim	Each Vial Contains: Ceftriaxone Sodium Equivalent to ceftriaxone.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year(s) Ceftriaxone for injection sterile powder should be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] and protected from light. After reconstitution, protection from normal ligh
	For generic drugs (me-too Status)	Oxidil
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.) Ltd-Plot #: 25 & 26, Street #: S-3 RCCI, National Industrial Zone Rawat, Islamabad - Pakistan -
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	16500 vials: 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section
	Evaluation Remarks	
	The applicant was asked to clarify the following on 12.03.2025: 1) Submit specifications of API from drug product manufacturer in section 3.2.S.4.2 2) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist in peak areas of same concentration solution. 3) Justify the precision studies of the drug substance in which results are mentioned in % instead of peak areas. 4) Justify the specificity test in the light of ICH / WHO guidelines. 5) The acceptance criteria for assay specified by	

API manufacturer is >84%, while the drug product manufacturer has used assay limit as NLT795ug/ml. Justify how drug product manufacturer can adopt difference assay limits. 6) Justify how your drug substance qualifies USP specs while the assay limit adopted by API manufacturer is different than USP. 7) Specify the fill weight of API per vial in 3.2.P.1 8) Submt compatibility studies of the drug product with diluent in section 3.2.P.2.6 9) USP monograph for "ceftriaxone for injection" specifies two different assay tests while you have mentioned only 1 test in your specifications. Clarification is required in this regard. 10) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. 11) Submit summary of stability study data in section 3.2.P.8.1 12) Submit stability study data sheets of all batches as per the template given in CTD guidance document in section 3.2.P.8.3 so that assessment of results of stability studies can be made. The raw data of stability studies shall be provided in the Point No. 4 of the 6-points checklist of stability study data. 13) Submit complete 6 months stability study data. 14) Submit COA of API along with its clearance certificate which is used in the manufacturing of batches for which stability study data has been submitted, since you have provided clearance certificate of 2023 while batches were manufactured in 2022. The applicant submitted incomplete response on 24.04.2025 and was asked to submit complete response on the same date. On 30.04.2025 the applicant submitted complete response which was evaluated and still found deficient of the following which was communicated to applicant in July, 2025: 1) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability and precision is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist in peak areas of same concentration solution. Reconduct the analytical verification studies with correct injection volume and submit detailed report (including raw data sheet and chromatograms) accordingly Furthermore values of Peak areas in chromatograms of intermediate precision do not correspond to raw data. 2) Specify the fill weight (600mg) as provided is not justifiable w.r.t salt factor since there is no excipient has been added in finished product formulation. 3) Submit compatibility studies of the drug product with diluent in section 3.2.P.2.6 4) USP monograph for "ceftriaxone for injection" specifies two different sample solutions (A and B or C). Perform analysis of finished product as per USP monograph and submit report accordingly. 5) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. Otherwise re conduct the product verification studies and submit the report accordingly. 6) Re conduct stability studies using sample volume/injection volume as per USP i.e 20 ul. On 21.08.2025, the applicant was sent a reminder to submit replies. The applicant submitted following on 19.09.2025: Subject: Clarification on Our Submission for Ceftriaxone Sodium Injection Respected Concerns, This letter is to clarify a possible confusion in our application for Ceftriaxone Sodium Injection. 1. The Mistake in Our First Submission: We imported two different medicines in one shipment: Ceftriaxone Sodium and Cefotaxime Sodium. In our first documents, we accidentally sent the quality certificate (COA) for a different Ceftriaxone batch and also included the certificate for Cefotaxime (Batch S012102005). This was our error. We are sorry for the confusion. 2. The Correct Information: The correct batches of Ceftriaxone Sodium we used are: Batch Q012105066 Batch Q012105067 We are now attaching the official quality certificates (COAs) for these exact batches. The product meets all USP quality standards. 3. Stability Study Batches: Our stability studies were done using the correct batches of Ceftriaxone Sodium listed above (Q012105066 and Q012105067). The Cefotaxime batch (S012102005) was never used for any Ceftriaxone stability studies. We hope this clear explanation resolves any questions. Please let us know if you need more information. Sincerely, Danas Pharmaceutical Pvt Ltd

Decision

Deferred

The Registration Board deferred the case for verification of submitted data by a panel constituted by the Chairman, Registration Board.

8	Case Category	Routine (Abdul Mughees)

Name, address of Applicant.	Aptcure (PVT.) Ltd 8th Pharma city , 30-km, multan road lahore (000648)	
Application Form Dy. No / Tracking ID & date of submission	(565-8P6-YSE3, 2024-06-27)	
Detail of Fee Submitted	30000.0, 2024-04-16,	
The proposed proprietary name / brand name	EMLOZIN 25MG TABLET	
Label Claim	Each Film coated tablet contains empagliflozin = 25 mg	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	14-As per SRO	
Shelf Life (Unit)	24 Year(s)At room temperature below 25 degree centigrade	
For generic drugs (me-too Status)	JARDY 25 mg tab, BY CCL Reg istration Number 094003	
Pharmaceutical Group of (API)	Antidiabetic	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	PHARMAGEN LIMITED, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore	
Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions	
Documents for the procurement of API with approval from DRAP (in case of Import)	Pharmagen	
Pharmaceutical Equivalence and Comparative Dissolution Profile	JARDY 25mg Tab (CCL) B# RK65	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions	
The status in reference regulatory authorities	Jardiance Tablets 25 mg, BY Boehringer Ingelheim International GmbH, MHRA Approved	
GMP status of the firm		
Evidence of approval of manufacturing facility	DML	
Evaluation Remarks		
The firm was asked to provide following clarifications after which the application is complete as per codal formalities and submitted for consideraiton of the Registration Board:		
No.	Shortcoming/ Observation	Reply of the firm
1	Provide latest GMP report/ Certificate of the applicant	Atached
2	Provide analytical method validation for assay of raw material Empagliflozin	Assay method specifications for the raw material EMPagliflozin are based on the manufacturer testing method. In Annexure-2 Analytical method validation protocol, validation report and related HPLC chromatograms of assay method performed by Aptcure are provided.
3	COA of Empagliflozin Reference standard provided by you declares that “use before 24 March 2022”. However, you performed analytical validation (in 3.2.P.5.3) where system	At the time of dossier submission, the valid COA of Empagliflozin Reference Standard (not expired) was available and was the one actually used during all analytica testing and method validation activities. however, due to a documentation mix up during dossier compilation, an

	suitability (not dated) and Linearity was performed on 27.08.2022. Similarly, you have provided COA for empa raw material with testing date 25-07-2022. Please justify these anomalies and provide signed and stamped COAs and analytical method validation reports along with supporting data.	incorrect/expired version of the COA was inadvertently attached in module 3.2.P.5.3.
4	Provide DML/ GMP for DS manufacturer along with API procurement documents	Copy of DML of Pharmagen

Decision

Deferred

The applicant is directed to provide justification for point No. 3 above.

9	Case Category	Contract Manufacturing (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	(797-B8M-ZZ6J, 2024-05-09)
	Detail of Fee Submitted	75000.0, 2024-03-27,
	The proposed proprietary name / brand name	Miroblin 2.5mg
	Label Claim	Each Film coated tablet contains: 4.39mg Mirogabalin Besylate equivalent to Mirogabalin...2.5mg (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)	24 MonthStore below 30 °C in cool & dry places
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd.-Plot # 33, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	Approved Drug by PMDA OF Japan Tarlige Tablets 2.5 mg Tarlige (Mirogabalin Besylate) Tablets (Daiichi Sankyo Company, Limited)
	Detail of previous approval	

Evaluation Remarks

The applicaiton was considered on its turn and the firm was asked to calrify if the product of the contract manufacturer has been approved by the Registraiton Board on Form 5F in any of its meeting. The applicant replied that product of M/s Horizon was approved in 348th meeting of the Registration Board and submitted documents for cross-referencing. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and

fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

10	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle, Kahuta road, Islamabad. (000569)
	Application Form Dy. No / Tracking ID & date of submission	(BDW-VVU-E5TQ, 2024-02-26)
	Detail of Fee Submitted	75000.0, 75000.0 2023-11-08, 2023-11-08
	The proposed proprietary name / brand name	Dancef Injection 1g
	Label Claim	Each Vial contains ceftriaxone (as sodium).....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1,s-As per SRO
	Shelf Life (Unit)	2 Year(s) Ceftriaxone for injection sterile powder should be
	For generic drugs (me-too Status)	Rocephin Injection 1g I.V Martin Dow Limited Plot No.37, Sector 19, Korangi Industrial Area, Karach
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.)Ltd-Plot #: 25 & 26, Street #: S-3 RCCI, National Industrial Zone Rawat, Islamabad - Pakistan -
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	16500 vials: 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	Rocephin Injection 1g I.V, Hoffmann-La Roche, Ltd.; Basel, Switzerland:
	GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section

Evaluation Remarks

The applicant was asked to clarify the following on 12.03.2025: 1) Submit specifications of API from drug product manufacturer in section 3.2.S.4.2 2) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist in peak areas of same concentration solution. 3) Justify the precision studies of the drug substance in which results are mentioned in % instead of peak areas. 4) Justify the specificity test in the light of ICH / WHO guidelines. 5) The acceptance criteria for assay specified by API manufacturer is >84%, while the drug product manufacturer has used assay limit as NLT795ug/ml. Justify how drug product manufacturer can adopt difference assay limits. 6) Justify how your drug

substance qualifies USP specs while the assay limit adopted by API manufacturer is different than USP. 7) Specify the fill weight of API per vial in 3.2.P.1 8) Submit compatibility studies of the drug product with diluent in section 3.2.P.2.6 9) USP monograph for "ceftriaxone for injection" specifies two different assay tests while you have mentioned only 1 test in your specifications. Clarification is required in this regard. 10) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. 11) Submit summary of stability study data in section 3.2.P.8.1 12) Submit stability study data sheets of all batches as per the template given in CTD guidance document in section 3.2.P.8.3 so that assessment of results of stability studies can be made. The raw data of stability studies shall be provided in the Point No. 4 of the 6-points checklist of stability study data. 13) Submit complete 6 months stability study data. 14) Submit COA of API along with its clearance certificate which is used in the manufacturing of batches for which stability study data has been submitted, since you have provided clearance certificate of 2023 while batches were manufactured in 2022. The applicant submitted incomplete response on 24.04.2025 and was asked to submit complete response on the same date. On 30.04.2025 the applicant submitted complete response which was evaluated and still found deficient of the following which was communicated to applicant in July, 2025: 1) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability and precision is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist in peak areas of same concentration solution. Reconduct the analytical verification studies with correct injection volume and submit detailed report (including raw data sheet and chromatograms) accordingly Furthermore values of Peak areas in chromatograms of intermediate precision do not correspond to raw data. 2) Specify the fill weight (600mg) as provided is not justifiable w.r.t salt factor since there is no excipient has been added in finished product formulation. 3) Submit compatibility studies of the drug product with diluent in section 3.2.P.2.6 4) USP monograph for "ceftriaxone for injection" specifies two different sample solutions (A and B or C). Perform analysis of finished product as per USP monograph and submit report accordingly. 5) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. Otherwise re conduct the product verification studies and submit the report accordingly. 6) Re conduct stability studies using sample volume/injection volume as per USP i.e 20 ul. On 21.08.2025, the applicant was sent a reminder to submit replies. The applicant submitted following on 19.09.2025: Subject: Clarification on Our Submission for Ceftriaxone Sodium Injection Respected Concerns, This letter is to clarify a possible confusion in our application for Ceftriaxone Sodium Injection. 1. The Mistake in Our First Submission: We imported two different medicines in one shipment: Ceftriaxone Sodium and Cefotaxime Sodium. In our first documents, we accidentally sent the quality certificate (COA) for a different Ceftriaxone batch and also included the certificate for Cefotaxime (Batch S012102005). This was our error. We are sorry for the confusion. 2. The Correct Information: The correct batches of Ceftriaxone Sodium we used are: Batch Q012105066 Batch Q012105067 We are now attaching the official quality certificates (COAs) for these exact batches. The product meets all USP quality standards. 3. Stability Study Batches: Our stability studies were done using the correct batches of Ceftriaxone Sodium listed above (Q012105066 and Q012105067). The Cefotaxime batch (S012102005) was never used for any Ceftriaxone stability studies. We hope this clear explanation resolves any questions. Please let us know if you need more information. Sincerely, Danas Pharmaceutical Pvt Ltd

Decision

Deferred

The Registration Board deferred the case for verification of submitted data by a panel constituted by the Chairman, Registration Board.

11	Case Category	Routine (Abdul Mughees)
	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	(D81-YZM-HEP8, 2024-05-30)	
Detail of Fee Submitted	30000.0, 2024-05-29,	
The proposed proprietary name / brand name	LIMPACAL 10MG/5MG TABLET	
Label Claim	Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....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)25°C	
For generic drugs (me-too Status)	Diampa LT Tablet M/s Getz Pharma	
Pharmacotherapeutic Group of (API)	Antidiabetic	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions	
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan form Wimits (Lina) and Seraph (Empa)	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Glyxambi 10mg/5mg by Boehringer Ingelheim (Gulf pack) Batch number 8083FGTLMC Mfg 08.22	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions	
The status in reference regulatory authorities	Glyxambi 10 mg/5 mg film coated tablets M/s Boehringer Ingelheim International GmbH Binger Str. 173 55216 Ingelheim am Rhein, Germany	
GMP status of the firm		
Evidence of approval of manufacturing facility	DML 13.08.2022	
Evaluation Remarks		
The firm was asked to clarify the following after which the application completes all codal formalities and is submitted for consideration of the Registration Board:		
No.	Shortcoming/ Observation	Reply of the firm
1	DML / Renewal of the applicant and latest GMP report/ certificate	Submitted
2	License/ GMP for DS manufacturer (for Empagliflozin) form the Authority of the country of origin	Submitted
3	Signed and stamped CDP protocol and data along with pictures of references product showing batch number and manufacturing dates and relevant chromatograms.	Submitted
4	Submit signed and stamped stability testing summary sheets for DP up to 06-month time point. Also provide details for batch sizes of stability batches along with executed BMRs.	Six month stability data submitted.
5	R&I stamped Intimation of loan letter to DRAP from Seraph and Wimits Pharma	Loan letter is attached in Annexure V. Due to unawareness we were unable to intimate to

		DRAP about the loan. However we commit to intimate DRAP in future if loan taken.
6	COAs of raw material (drug substance) Empagliflozin and Linagliptin by DP manufacturer	Submitted
7	Signed and stamped method validation/verification report by DP manufacturer	Signed and stamped method validation report submitted.
8	Rationale (supported by studies) for specifying Dissolution Acceptance criteria of NLT 80.00% (Q) in 30 minutes for intermediate release dosage form	As per review of the innovator product Glyxambi (empagliflozin and linagliptin) tablets, the innovator does not reveal dissolution specifications. However, we used the same dissolution parameters as mentioned in FDA dissolution database.

Decision

Approved

Approved subject to verification of the API loan letters.

12	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(LV6-UU1-QJTV, 2024-05-29)
	Detail of Fee Submitted	75000.0, 2024-05-14,
	The proposed proprietary name / brand name	Mgab Tablet 15mg
	Label Claim	Each film-coated tablet contains Mirogabalin besylate eq. Mirogabalin ----- 15mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	Not Applicable
	Pharmaceutical Group of (API)	N02BF : Gabapentinoids
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering., Co., Ltd, No.5329, Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice., China
	Detail of stability batches of drug product	3 batches at long term and short term stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided for 400 gm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige 2.5 mg tablet by Daiichi Sankoyo Batch # 043085

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long term and short term stability conditions
	The status in reference regulatory authorities	Tarlige Tablet 15mg by Daiichi Sankyo Company, limited. (Japan)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML of both contract giver and acceptor
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved	
13	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(QUL-QDA-3TBR, 2024-05-23)
	Detail of Fee Submitted	75000.0, 2024-05-09,
	The proposed proprietary name / brand name	Mgab Tablet 10mg
	Label Claim	Each film-coated tablet contains Mirogabalin besylate eq. Mirogabalin ----- 10mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N02BF : Gabapentinoids
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering., Co., Ltd, No.5329, Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice., China
	Detail of stability batches of drug product	3 batches at long term and short term stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided for 400 gm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige tablet by Daiichi Sankoyo
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long term and short term stability conditions
	The status in reference regulatory authorities	Tarlige Tablet 10mg by Daiichi Sankyo Company, limited. (Japan)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML of both contract giver and acceptor
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	

	Decision	
	Approved	
14	Case Category	Routine (Abdul Mughees)
	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	(RJ1-S1J-2242, 2024-06-12)
	Detail of Fee Submitted	30000.0, 2024-05-29,
	The proposed proprietary name / brand name	LIMPACAL 25MG/5MG TABLET
	Label Claim	Each film coated tablet contains: Empagliflozin.....25mg Linagliptin.....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)25°C
	For generic drugs (me-too Status)	Diampa LT Tablet M/s Getz Pharma
	Pharmaceutical Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan form Wimits (Lina) and Seraph (Empa)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Glyxambi by Boehringer Ingelheim (Gulf pack)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	Glyxambi 25mg/5 mg film coated tablets M/s Boehringer Ingelheim International GmbH Binger Str. 173 55216 Ingelheim am Rhein, Germany
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML 13.08.2022
	Evaluation Remarks	
	The firm was asked to clarify the following after which the application completes all codal formalities and is submitted for consideration of the Registration Board:	
	No.	Shortcoming/ Observation
		Reply of the firm
	1	DML / Renewal of the applicant and latest GMP report/ certificate
	2	Submitted
	2	License/ GMP for DS manufacturer (for Empagliflozin) form the Authority of the country of origin
	3	Submitted
	3	Signed and stamped CDP protocol and data along with pictures of references product showing batch number and manufacturing dates and relevant chromatograms.
		Submitted

4	Submit signed and stamped stability testing summary sheets for DP up to 06-month time point. Also provide details for batch sizes of stability batches along with executed BMRs.	Six month stability data submitted.
5	R&I stamped Intimation of loan letter to DRAP from Seraph and Wimits Pharma	Loan letter is attached in Annexure V. Due to unawareness we were unable to intimate to DRAP about the loan. However we commit to intimate DRAP in future if loan taken.
6	COAs of raw material (drug substance) Empagliflozin and Linagliptin by DP manufacturer	Submitted
7	Signed and stamped method validation/verification report by DP manufacturer	Signed and stamped method validation report submitted.
8	Rationale (supported by studies) for specifying Dissolution Acceptance criteria of NLT 80.00% (Q) in 30 minutes for intermediate release dosage form	As per review of the innovator product Glyxambi (empagliflozin and linagliptin) tablets, the innovator does not reveal dissolution specifications. However, we used the same dissolution parameters as mentioned in FDA dissolution database.

Decision

Approved

Approved subject to verification of the API loan letters.

15	Case Category	Contract Manufacturing (Abdul Mughees)
	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	(TAV-WE6-3U6G, 2024-05-24)
	Detail of Fee Submitted	75000.0, 2024-05-09,
	The proposed proprietary name / brand name	Mgab Tablet 5mg
	Label Claim	Each film-coated tablet contains Mirogabalin besylate eq. Mirogabalin ----- 5mg
	Reference to Finished product specifications	As per Innovators Specification
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	N02BF : Gabapentinoids
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi -
	Name & address of API manufacturer	Henan Jin Huaitang Biological Engineering., Co., Ltd, No.5329, Hesuodadao Road Street Avenue, Wuzhi Country, Jiaozuo City, Henan Provice., China
	Detail of stability batches of drug product	3 batches at long term and short term stability conditions

	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided for 400 gm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tarlige tablet by Daiichi Sankoyo
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches at long term and short term stability conditions
	The status in reference regulatory authorities	Tarlige Tablet 5mg by Daiichi Sankyo Company, limited. (Japan)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML of both contract giver and acceptor
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved	
16	Case Category	Routine (Abdul Mughees)
	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	(ZV6-N56-VMNL, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	MELGU XR 50/500MG TABLET
	Label Claim	Each extended release film coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin.....50mg Metformin hydrochloride 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	2 Year(s)30C
	For generic drugs (me-too Status)	Sitaglu- Met XR 50/500mg Tablet(Hilton Pharma (PVT) LTD)098817
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sitaglu Met XR by Hilton Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	Janumet XR 50/500mg Tablet(Merck & Co INC, White house Station, NJ 08889 , USA)USFDA Approved Drug
	GMP status of the firm	

Evidence of approval of manufacturing facility		DML
Evaluation Remarks		
The firm was asked to clarify following after completion of which the application is complete as per codal formalities and submitted for consideration of Registration Board:		
No.	Shortcoming/ Observation	Reply of the firm
1	The SAP document submitted by you bears the name of Siam Pharmaceuticals. Please clarify	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.
2	DML of the applicant as well as GMP report (latest)	Submitted
3	COA under 3.2.S.4.4 is from Siam Pharmaceuticals. Please clarify.	
4	Evidence of procurement of Impurity F and A of metformin as the submitted COA by applicant mentions performance of these tests	Submitted an unattested invoice
5	Signed and stamped CDP by the applicant along with pictures of reference products with clear batch number, manufacturing date and manufacturer details in focus	Provided: From the above results it is concluded that the developed formulation of Melgu XR 50/500mgTablet have comparable drug release and performance profile with that of the comparator product. Based on these results the developed formulation may be considered aspharmaceutically equivalent to the comparator product.
6	Your submitted manufacturing method shows that you mix sitagliptin and metformin in the beginning, add excipients and then do the coating. Please explain this method with reference to innovator's method where core tablet is manufactured first.	Metformin and sitagliptin have different physicochemical properties; therefore, theirgranulation/wetting was performed separately to ensure optimal flow, compressibility, anduniformity. After achieving suitable granules for each component, both masses were blended together to obtain a uniform mixture prior to compression of the extended-release tablets. Sir In future, we undertake that we shall separately mix the both APIs that is Sitagliptin and metformin.
7	The claimed manufacturer for sitagliptin is ANUHI HAIKANG whereas you have submitted invoice and clearance document mentioning ANQING WORLD CHEMICAL CO. Please clarify.	Clarification: Anhui Haikang Pharmaceutical co ltd is a Manufacturer whereas, Anqing WorldChemical Co.Ltd is a Beneficiary/ Exporter.
Decision		
Deferred		
The Registration Board deferred the case for adoption of innovator's manufacturing method.		
17	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(QRT-5P7-GH35, 2025-10-21)

	Detail of Fee Submitted	75000, 2025-09-09,
	The proposed proprietary name / brand name	AVANAFIL 100 mg tablet
	Label Claim	Each tablet contains Avanafil 100 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 × 10's-As per SRO, 1 × 14's-As per SRO, 1 × 4's-As per SRO, 2 × 14's-As per SRO, 2 × 7's -As per SRO, 2 × 10's-As per SRO, 2 × 4's-As per SRO, 3 × 10's-As per SRO, 4 × 7's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited
	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Spedra 100 mg by Berlin Chemie Menarini
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	HPRA (IRELAND)
	GMP status of the firm	Valid (attached)
	Evidence of approval of manufacturing facility	Valid (attached)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board.	
	Decision	
	Approved	
18	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20, North Western Industrial Zone Bin Qasim, Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(V95-N4B-81QJ, 2025-10-27)
	Detail of Fee Submitted	75000, 2025-09-09,
	The proposed proprietary name / brand name	AVANAFIL 50 mg tablet
	Label Claim	Each tablet contains Avanafil 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 × 10's-As per SRO, 1 × 14's-As per SRO, 1 × 4's-As per SRO, 2 × 10's-As per SRO, 2 × 14's-As per SRO, 2 × 4's-As per SRO, 2 × 7's-As per SRO, 3 × 10's-As per SRO, 4 × 7's-As per SRO

	Shelf Life (Unit)	2 Year(s)Store below 30°C in a dry place, protect from light
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited
	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Spedra 100 mg by Berlin Chemie Menarini
	Pharmaceutical Equivalence and Comparative Dissolution Profile	attached
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	HPRA (IRELAND)
	GMP status of the firm	Valid (attached)
	Evidence of approval of manufacturing facility	Valid (attached)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
19	Decision	
	Approved	
	The Registration Board approved the product subject to verification of submitted data by a panel constituted by the Chairman, Registration Board.	
	Case Category	Any Other (Abdul Mughees)
	Name, address of Applicant.	Platinum Pharmaceuticals A-20,North Western Industrial Zone Bin Qasim,Karachi (000415)
	Application Form Dy. No / Tracking ID & date of submission	(XUL-1P8-MSQR, 2025-10-24)
	Detail of Fee Submitted	75000, 2025-09-09,
	The proposed proprietary name / brand name	AVANAFIL 200 mg tablet
	Label Claim	Each tablet contains Avanafil 200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 × 10's-As per SRO,1 × 14's-As per SRO,1 × 4's -As per SRO,2 × 14's-As per SRO,2 × 4's -As per SRO,2 × 7's -As per SRO,2× 10's-As per SRO,3 × 10's-As per SRO,4 × 7's -As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C in a dry place, protect from light.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit pharmaceutical limited

	Detail of stability batches of drug product	03 batches at long term and accelerated stability conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Spedra 100 mg by Berlin Chemie Menarini
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	03 batches at long term and accelerated stability conditions
	The status in reference regulatory authorities	HPRA (IRELAND)
	GMP status of the firm	Valid (attached)
	Evidence of approval of manufacturing facility	Valid (attached)
	Evaluation Remarks	
	The application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
	The Registration Board approved the product subject to verification of submitted data by a panel constituted by the Chairman, Registration Board.	
20	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
	Application Form Dy. No / Tracking ID & date of submission	(MBP-J7W-BP31, 2024-06-14)
	Detail of Fee Submitted	75000.0, 2024-05-16,
	The proposed proprietary name / brand name	SURLIN 300mg Capsule
	Label Claim	Each capsule contains Pregabalin 300 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's, 14's, 20's, 28-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Gabica capsule 300mg by Getz pharma
	Pharmacotherapeutic Group of (API)	N02BF02 Gabapentinoids
	Name, address of Manufacturing site:	Nabiqasim Industries Private Limited-PLOT # 17 SECTOR # 24 KORANGI INDUSTRIAL AREA-
	Name & address of API manufacturer	Atlas Life Sciences Private Limited [C-1/360-361, G.I.D.C. Estate, Ahmedabad-382415, Gujrat.]
	Detail of stability batches of drug product	3 batches, 2000 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Gabica 300mg Capsule B. No. 350C27 Mfg M/s Getz
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per Zone IVa
	The status in reference regulatory authorities	FDA Approved - Lyrica 300mg capsule - Pfizer Inc, USA

	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 22.05.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 27.04.2020 is submitted
	Evaluation Remarks	
	Firm has submitted data as per CTD guidance document. Recommended for consideration of board.	
	Decision	
	Approved	
21	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(351-HSX-VHG4, 2025-07-22)
	Detail of Fee Submitted	75000.0, 2025-04-25,
	The proposed proprietary name / brand name	Viglo 25mg Sublingual Tablet
	Label Claim	Each Sublingual Tablet Contains: Sildenafil as Citrate (USP).....25MG (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches having batch size of 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	-----
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-----
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	TGA Australia
	GMP status of the firm	Renewal in 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 11.06.2024 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority.	
	Observations; In TGA Australia, reference product is a sublingual wafer, not tablet, while you have applied for sublingual tablet. Please clarify. 2.3.R.1.1 Copies of executed BMRs of trial batches are required. 3.2.P.2 Details of reference product used in pharmaceutical equivalence, like its name manufacturer and batch number are required, also submit pictorial evidence. 3.2.P.7 Details of container closure/ primary packing is required.	
	Response: Firm has requested to withdraw their application.	
	Decision	
	Rejected	

	The application is disposed off on withdrawal request of the firm.	
22	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	Rite Bio Sciences (Pvt) Ltd. Plot No. 9-A, Street No. N-5, RCCI Rawat (000871)
	Application Form Dy. No / Tracking ID & date of submission	(71A-ZQL-QHZZ, 2025-01-06)
	Detail of Fee Submitted	37000.0, 2024-11-29,
	The proposed proprietary name / brand name	DOLXTIME 20MG CAPSULE
	Label Claim	Each capsule contains: Duloxetine (HCl) 17% Enteric Coated Pellets eq. to Duloxetine (HCl) 20MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	28's/14's,-As per SRO
	Shelf Life (Unit)	3 Year(s)Room Temperature
	For generic drugs (me-too Status)	Brand Name:Zenbar 20mg Capsule Registration holder: The Searle Company Limited Registration Number: 055608
	Pharmacotherapeutic Group of (API)	N06AX21:Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Vision Pharmaceuticals Plot No 22, 23, Industrial triangle, Kahuta road, Islamabad-Pakistan
	Detail of stability batches of drug product	3 batches, batch size: 1500 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local import hence N/A
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP performed against Dulcan capsule by M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone Iva
	The status in reference regulatory authorities	Cymbalta (duloxetine hydrochloride) Delayed-Release Capsules for Oral Use. Initial U.S. Approval: 2004
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Capsule (general) section
	Evidence of approval of manufacturing facility	GMP certificate issued on the basis of inspection conducted on 22-08-2023 specifies Capsule (general) section
	Evaluation Remarks	
	The application fulfils codal formalities.	
	Decision	
	Approved	
23	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Sante (Private) Limited A-97, SITE Superhighway, Karachi. (000702)

	Application Form Dy. No / Tracking ID & date of submission	(7JU-TES-9RHA, 2025-09-30)
	Detail of Fee Submitted	38700.0, 2025-08-26,
	The proposed proprietary name / brand name	SILDORA 50MG TABLET
	Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-De-Controlled,1x14's-De-Controlled,1x2's-De-Controlled,1x20's-De-Controlled,1x30's-De-Controlled,1x4's-De-Controlled,1x6's-De-Controlled,1x8's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at (20°C-25°C). Excursion permitted between 15°C-30°C.
	For generic drugs (me-too Status)	Hilagra Tablets 50mg, Hilton Pharma (Pvt.) Ltd.
	Pharmaceutical Group of (API)	G04BE03 Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	3 batches, 3333 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Module 3; Pg # 539 Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hilagra 50mg Tablet B. No. 159630 M/s Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 50mg tablet, PFIZER LABORATORIES, USFDA Approved
	GMP status of the firm	GMP Certificate No. 17/2024-DRAP(K) Valid till 24th Jan 2027
	Evidence of approval of manufacturing facility	Approved Section Letter No. F.2-12/2006-Lic (Vol-III) Dated 20th Sep 2021 is attached
	Evaluation Remarks	
	Priority as per decision of 214th meeting of authority. Application fulfils required codal formalities.	
	Decision	
	Approved	
24	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(9TB-Q8G-E5WU, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2024-11-26,
	The proposed proprietary name / brand name	Monti-R 5mg Tablet
	Label Claim	Each chewable tablet contains: Montelukast sodium eq. to Montelukast 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO.-As per SRO

Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
For generic drugs (me-too Status)	Montiget Chewable Tablet 5mg BY Getz Pharma (Pvt) Limited
Pharmacotherapeutic Group of (API)	R03DC03 Leukotriene receptor antagonists
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	METROCHEM API PRIVATE LIMITED Flat no 302,Bhanu Enclave,Sunder Nagar,Erragada Hyderabad-500 038 A.P.India
Detail of stability batches of drug product	3 batches, 1500 Tablets
Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted. Taken loan from M/s Fahmir
Pharmaceutical Equivalence and Comparative Dissolution Profile	Montiget chewable 5mg tablet, B. No. 334T17
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
The status in reference regulatory authorities	Singulair 5mg chewable Tablets, Manufacturer: MERCK & CO., INC. (Registered in USA).
GMP status of the firm	New License
Evidence of approval of manufacturing facility	Copy of section approval letter dated 17.02.2023
Evaluation Remarks	
Query	Response
3.2.P.2 In CDP it appears that 6 units of reference and test product are used. It should have been 12 units each (as per ICH guidelines). Also submit protocol/ method of performing CDP.	In data submitted initially in Module 3, the drug release at 10 minutes at pH 1.2 was around 88%, in response wherein firm has submitted data of 12 units, the release at 15 minutes is around 35%. Same is case as all 3 pH values. This indicates issue of data integrity.
3.2.P.5 System suitability is not performed as per USP monograph. (it requires use of Cis isomer of drug substance)	Firm has only submitted a statement that they have performed it as per USP monograph, but no supporting evidence is submitted.
Decision	
Deferred	
Deferred for product specific inspection by panel constituted by chairman Registration Board to verify the genuineness of submitted data.	
25	
Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Himont Pharmaceuticals (Pvt.) Ltd. 17-km Ferozpur Road, Lahore (000231)
Application Form Dy. No / Tracking ID & date of submission	(A5E-Z7A-URQS, 2025-10-07)
Detail of Fee Submitted	38700, 2025-09-05,
The proposed proprietary name / brand name	Tigra 50mg Tablet
Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....50mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's-De-Controlled

	Shelf Life (Unit)	24 Year(s)Store at 25°C or below
	For generic drugs (me-too Status)	I-Pill 50mg by genix Pharma
	Pharmacotherapeutic Group of (API)	G04BE03 Sildenafil citrate is a phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical
	Detail of stability batches of drug product	3 batches, 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Viagra 50mg Tablet B. No. MAL38597744AM
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV-a Conditions
	The status in reference regulatory authorities	Viagra 50mg Tablet Mnaufactured by Pfizer
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 09.08.2024 is submitted
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 06.12.2024 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. The application fulfils all codal formalities.	
26	Decision	
	Approved	
	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Himont Pharmaceuticals (Pvt.) Ltd. 17-km Ferozpur Road, Lahore (000231)
	Application Form Dy. No / Tracking ID & date of submission	(JGL-DLV-9X8L, 2025-10-13)
	Detail of Fee Submitted	38700.0, 2025-09-05,
	The proposed proprietary name / brand name	Tigra 100mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 25°C or below
	For generic drugs (me-too Status)	I-Pill 100mg by genix Pharma
	Pharmacotherapeutic Group of (API)	G04BE03 Sildenafil citrate is a phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical
	Detail of stability batches of drug product	3 batches, 2500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Performed with Viagra 100mg Tablet B. No. 4049500

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Performed at Zone IV-a Conditions
	The status in reference regulatory authorities	Viagra 100mg Manufactured by Pfizer
	GMP status of the firm	GMP certificate valid till 09-08-2027
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 06.12.2024 is submitted.
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. The application fulfils all codal formalities.	
	Decision	
	Approved	
27	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(BAQ-X3D-W9AG, 2025-09-03)
	Detail of Fee Submitted	75000.0, 2025-02-21,
	The proposed proprietary name / brand name	Vnosil 100mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSFeild, PSI of WNSfeild has been conducted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viara 100mg Tablet B. No. VS114676
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	Renewal in 2025
	Evidence of approval of manufacturing facility	Renewal letter dated 06.02.2025 is submitted
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. Application fulfils codal formalities.	
	Decision	
	Approved	
28	Case Category	Any Other (Adil Saeed)

Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
Application Form Dy. No / Tracking ID & date of submission	(GQX-8XT-G53V, 2025-07-22)
Detail of Fee Submitted	75000.0, 2025-04-25,
The proposed proprietary name / brand name	Viglo 50mg Sublingual Tablet
Label Claim	Each Sublingual Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 25°C
For generic drugs (me-too Status)	N/A
Pharmaceutical Group of (API)	G04BE03 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	3 batches having batch size of 1200 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	-----
Pharmaceutical Equivalence and Comparative Dissolution Profile	-----
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	Renewal in 2024
Evidence of approval of manufacturing facility	Renewal letter dated 11.06.2024 is submitted
Evaluation Remarks	
Priority as per decision of 214th meeting of Authority.	
Observation: In TGA Australia, reference product is a sublingual wafer, not tablet, while you have applied for sublingual tablet. Please clarify. Also clarify how sublingual wafer is different from Orodispersible film for which monograph is available in BP.	
Response: Firm has requested to withdraw their application.	
Decision	
Rejected	
Application is disposed off on request of firm to withdraw it.	
29	Case Category
	Routine (Adil Saeed)
Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
Application Form Dy. No / Tracking ID & date of submission	(RLS-T66-QU9E, 2024-06-24)
Detail of Fee Submitted	30000.0, 2024-06-14,
The proposed proprietary name / brand name	Prulax 1mg Tablet
Label Claim	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride..... 1mg
Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	1x10-As per SRO
Shelf Life (Unit)	24 Year(s)Room Temperature
For generic drugs (me-too Status)	Pru-cic 1mg Tablet
Pharmacotherapeutic Group of (API)	A06AX05 Other drugs for constipation
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Nuray chemicals private limited
Detail of stability batches of drug product	3 batches, 5000 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Resolor 1mg Tablets Mfg Janssen Pharma B. No. KLL1004
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 24 months
The status in reference regulatory authorities	Resolor 1mg Tablet-Italy
GMP status of the firm	GMP certificate issued on basis of inspection dated 25.05.2023 is submitted
Evidence of approval of manufacturing facility	Renewal letter dated 07.07.2021 is submitted
Evaluation Remarks	
Application fulfils all codal formalities.	
Decision	
Approved	
Case Category	Any Other (Adil Saeed)
Name, address of Applicant.	Sante (Private) Limited A-97, SITE Superhighway, Karachi. (000702)
Application Form Dy. No / Tracking ID & date of submission	(SL2-6NT-UMR3, 2025-10-01)
Detail of Fee Submitted	38700.0, 2025-08-26,
The proposed proprietary name / brand name	SILDORA 25MG TABLET
Label Claim	Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil..... 25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1x10's-De-Controlled,1x14's-De-Controlled,1x2's-De-Controlled,1x20's-De-Controlled,1x30's-De-Controlled,1x4's-De-Controlled,1x6's-De-Controlled,1x8's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at (20°C-25°C). Excursion permitted between 15°C-30°C.
For generic drugs (me-too Status)	Hilagra Tablets 25mg, Hilton Pharma (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	G04BE03 Drugs used in erectile dysfunction
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Century Pharmaceuticals Limited
Detail of stability batches of drug product	3 batches, 6666 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of 2kg drug substance is submitted.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hilagra 25mg B. No. 159628 Mfg Hilton
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viagra 25mg tablet, PFIZER LABORATORIES, USFDA Approved
	GMP status of the firm	GMP Certificate No. 17/2024-DRAP(K) Valid till 24th Jan 2027
	Evidence of approval of manufacturing facility	Approved Section Letter No. F.2-12/2006-Lic (Vol-III) Dated 20th Sep 2021 is attached
	Evaluation Remarks	
	Priority as per decision of 214th meeting of Authority. The application fulfils all codal formalities.	
	Decision	
	Approved	
31	Case Category	Routine (Adil Saeed)
	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	(L4X-58W-L7YW, 2025-09-17)
	Detail of Fee Submitted	37000.0, 1700 2025-07-18, 2025-09-12
	The proposed proprietary name / brand name	Vesopride 25mg Tablet
	Label Claim	Each Tablet Contains; Levosulpiride 25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10,s 20,s 30,s (as per SRO)-As per SRO
	Shelf Life (Unit)	24 Year(s)Storage conditions 30°C ± 2°C and 65% ± 5% RH
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	N05AL07 Atypical antipsychotic (Benzamide Derivative)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Cureworth Drugs & Intermediates Pvt. Ltd. PlotNo:N-49, Additional MIDC Zone, Anand Nagar, Ambernath(East), Ambernath-421506, Maharashtra, India. Contact Persons: Mr. Ramchandra Nishad (Managing Director) Mrs. Swati Nishad (Director) Mobile no.+91
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Aulton, Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Levopraid 25mg tablet B. No. LN2710T Mfg M/s Pacific Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVb, upto 48 months.
	The status in reference regulatory authorities	Aifa Italy Approved.

	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Section approval letter dated 08.06.2021
	Evaluation Remarks	
	The application fulfils codal formalities.	
32	Decision	
	Approved	
	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(QQX-S4R-DU18, 2025-11-17)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Osin 0.4mg Capsule
	Label Claim	Each Capsule contains: Tamsulosin HCl SR pellets Equivalent to Tamsulosin...0.4 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and dry place.
	For generic drugs (me-too Status)	Tamsol 0.4mg by Global Pharmaceuticals PVT Ltd.
	Pharmacotherapeutic Group of (API)	G04CA02 alpha-1A and alpha-1D adrenergic receptor antagonist alpha blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Detail of stability batches of drug product	1000 Capsules is for each batch. 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Purchased from m/s Vision pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution is taken place Against Tamsol 0.4mg by Global Pharmaceuticals PVT Ltd. B. No. 25A347
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability submitted of zone iv A.
	The status in reference regulatory authorities	USFDA Approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Section approval letter dated 17.02.2023 is submitted.
	Evaluation Remarks	
	Observation	Response
	3.2.P.2.2 CDP is performed using 6 units only at each pH, please follow ICH guidelines for performing CDP.	Firm has submitted CDP performed by using 12 units of each test and reference product. Supporting chromatograms are not submitted.
	3.2.P.5 As per USP monograph, propylparaben is to be used as internal standard which you have not used. The testing should comply to USP monograph.	Firm has submitted following response; "With humble request, it is stated that the internal standard was used .Now at the next stability study time point and is in compliance with the USP monograph. The system

suitability report is attached for reference."
Chromatograms are not submitted.

Decision

Deferred

Deferred for submission of complete reply with all relevant supporting data.

33	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(L3Z-ZGB-JRP5, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Fusipec 2% cream
	Label Claim	Each gm Cream Contains: Fusidic Acid 20MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Fusiderm Cream 2% by Seatlle Private Limited
	Pharmaceutical Group of (API)	D06AX01 Other antibiotics for topical use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ANHUI HAIKANG –PHARMACEUTICAL CO; (LTD). NO.21 HAUNCHENG WEST ROAD,DAGUAN DISTRICT,ANQING CITY,ANHUI PROVINCE,CHINA
	Detail of stability batches of drug product	3 batches of 50 packs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	ANHUI HAIKANG –PHARMACEUTICAL CO; (LTD). NO.21 HAUNCHENG WEST ROAD,DAGUAN DISTRICT,ANQING CITY,ANHUI PROVINCE,CHINA.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence performed against Fusil Cream 2% by Tabros Pharma B. No. 407A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions.
	The status in reference regulatory authorities	Fusipec 2% cream By MHRA approved.
	GMP status of the firm	Firm has been granted new DML including section of “semi solid” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evidence of approval of manufacturing facility	Firm has been granted new DML including section of “semi solid” vide letter no. F.1-9/2016-Lic issued by Secretary CLB dated 17-02-2023.
	Evaluation Remarks	
	OBSERVATION	RESPONSE
	3.2.P.5 as per BP monograph, reference standard to be used is diethanolamine fusidate, but you have used fusidic acid. Same is mentioned in analytical method submitted.	The firm has submitted following response; "We have used the attached Certificate of Analysis (COA) for the secondary working standard. Once the products are registered, we will purchase the primary reference standard." COA of diethanolamine fusidate is not submitted.

3.2.P.8 In chromatograms submitted retention time of fusidic acid id 4 to 5 minutes. As per BP monograph, it should be 18 minutes.	The firm has stated that they have tested is as per 2020 BP monograph, and once the product is registered, the testing method will be updated to the most recent monograph and method.

Decision

Deferred

Deferred for submission of following.

1. Evidence of procurement of reference standard required as per BP monograph
2. Submission of drug product analytical method and its verification report as per BP monograph.
3. Supporting data of method verification and product testing including chromatograms and calculations.

34	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(XLP-Q9E-B76Z, 2025-04-10)
	Detail of Fee Submitted	37000.0, 2025-02-14,
	The proposed proprietary name / brand name	Vmidon 5mg/5ml Suspension
	Label Claim	Each 5ml Suspension Contains: Domperidone 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C in cool and dry place.
	For generic drugs (me-too Status)	Motilium Oral Suspension by Aspin Pharma.
	Pharmaceutical Group of (API)	A03FA03 PROPULSIVES
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S VASUDHA PHARMA CHEM LIMITED UNIT-V,PLOT NO.24, 24A & 24B, APSEZ, DENOTIFIED AREA, ATCHUTAPURAM,RAMBILLI (M), ANAKAPALLI DISTRICT- 531011 ANDHRA PRADESH,INDIA(India)
	Detail of stability batches of drug product	3 batches, 75 packs each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Medisave, clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vomilux 1mg/ml suspension B. No. PJ013J Mfg. Atco Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60months.
	The status in reference regulatory authorities	MHRA approved.
	GMP status of the firm	New License. Issued in 17.02.2023
	Evidence of approval of manufacturing facility	Section approval letter dated 17.02.2023 is submitted

	Evaluation Remarks	
	Application fulfils all codal formalities.	
	Decision	
	Approved	
35	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(Y12-B9Z-MBSS, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2024-11-20,
	The proposed proprietary name / brand name	Monti-R 10mg Tablet
	Label Claim	Each Film coated tablet contains: Montelukast sodium eq. to Montelukast.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO.-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Montiget 10mg Tablet BY Getz Pharma (Pvt.) Limited
	Pharmacotherapeutic Group of (API)	R03DC03 Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	METROCHEM API PRIVATE LIMITED Flat no 302,Bhanu Enclave,Sunder Nagar,Erragada Hyderabad-500 038 A.P.India
	Detail of stability batches of drug product	3 batches, 1500 Tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted. Taken loan from M/s Fahmir
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Montiget 10mg Film coated tablet. B. No. F19013 M/s Getz
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	SINGULAIR 10mg tablet, by Organon of USFDA Approved.
	GMP status of the firm	New License
	Evidence of approval of manufacturing facility	Copy of section approval letter dated 17.02.2023
	Evaluation Remarks	
	Observation	Response
	3.2.P.2 In CDP it appears that 6 units of reference and test product are used. It should have been 12 units each (as per ICH guidelines). Also submit protocol/ method of performing CDP.	Firm has submitted CDP as per guidelines, but there is significant difference between initially submitted results and the one submitted in reply. e.g. After 10min at pH 1.2 release is 54.79% as per response, but in initial submission it was 87.35%.
	3.2.P.5 System suitability is not performed as per USP monograph. (it requires use of Cis isomer of drug substance)	Firm has only submitted their response that it is performed as per USP monograph. But as per submitted data it has not been performed as per USP monograph. (It required degradation of Montelukast to its cis-isomer)

	Decision	
	Deferred	
	Deferred for product specific inspection by panel constituted by chairman Registration Board to verify the genuineness of submitted data.	
36	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(PGJ-W92-R8G5, 2024-06-10)
	Detail of Fee Submitted	30000.0, 2024-03-04,
	The proposed proprietary name / brand name	Neuvanco 1gm Powder for solution for Injection
	Label Claim	Each vial contains Vancomycin Hydrochloride eq. Vancomycin.....1000 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	01-As per SRO
	Shelf Life (Unit)	18 Month(s)Store between 15 - 30°C in a dry place, protect from light
	For generic drugs (me-too Status)	Vancomycin HCl Injection by Abbot
	Pharmacotherapeutic Group of (API)	J01XA01 Glycopeptide antibacterials
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. Address: No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, P. R. China
	Detail of stability batches of drug product	3 batches, 300 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vinjec 1000mg Injection B. No. VN230022 Mfg M/s Bosch Pharma Pvt. Ltd.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	5C upto 36 months
	The status in reference regulatory authorities	Vancocin CP by Aspen Pharmacare
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 14.04.2022 is submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 29.01.2019 is submitted,
	Evaluation Remarks	
	Application fulfils codal formalities.	
	Decision	
	Deferred	
	The board deferred the case for further deliberation regarding manufacturing of vancomycin in general powder injectable section. The firm shall be asked to provide evidence of practices of RRA countries regarding this product i.e. whether vancomycin injection is manufactured in general injectable section or otherwise.	

37	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(9SL-56H-5X3A, 2024-06-26)
	Detail of Fee Submitted	30000.0, 9400 2023-11-02, 2026-01-02
	The proposed proprietary name / brand name	Neuflo Cream
	Label Claim	Each Gm contains: Eflornithine (as Hydrochloride monohydrate)....115mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15 - 30°C in a dry place, protect from light
	For generic drugs (me-too Status)	Eflogen Cream
	Pharmacotherapeutic Group of (API)	D11AX16 Other dermatologicals
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 80 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of AD attested invoice is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Depilus Cream M/s Atco Laboratories, B No. CU002L
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa upto 24 months.
	The status in reference regulatory authorities	Vaniqa Cream EMC
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 14.04.2022 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter is submitted.
	Evaluation Remarks	
	Application fulfils codal formalities.	
	Decision	
	Approved	
38	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(HLH-E5E-24ES, 2024-07-30)
	Detail of Fee Submitted	30000.0, 2024-02-23,
	The proposed proprietary name / brand name	Scanty
	Label Claim	Each 5ml contains: Hyoscine butyl bromide 5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's (120ml)-De-Controlled,1's (30ml)-De-Controlled,1's (60ml)-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C in dry cool environment

	For generic drugs (me-too Status)	Spasler-P by AGP Pharma
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prism Industries Private Limited Survey No. 637/23/A1, Khambhat Dhuvaran Road, At:Kalamsar, Ta. Khambhat,Dist. Anand, State: Gujarat, INDIA.PIN – 388 640
	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	Gastrosoothe Oral liquid 1mg/ml BY AFT Pharmaceuticals
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The case was deferred in 344th meeting due to nonavailability of RRA reference. Firm has stated that similar products are available in market of Pakistan (e.g Spasler-P and Spacure) and its also available in market of Singapore. Firm has still not submitted valid RRA reference.	
	Decision	
	Deferred	
	Deferred for policy decision for products with me-too reference but not having any RRA reference.	
39	Case Category	Routine (Adil Saeed)
	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	(JS8-JM5-TUQA, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	Thiocar 4mg/2ml IM Injection
	Label Claim	Each 2ml Ampoule contains; Thiocolchicoside 4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2ml x 5s -As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 C.
	For generic drugs (me-too Status)	Muscoril 4mg/2ml Injection by Sanofi-aventis Pakistan Limited
	Pharmaceutical Group of (API)	M03BX05 MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, Other centrally acting agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S: Sarv BioLabs Pvt. Limited Address: A-77/1, Wazirpur Industrial Area New Delhi – 110 052

		India
	Detail of stability batches of drug product	3 batches, 1000 ampoules.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted. Taken loan from M/s Linear pharma.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Muscoril 4mg/2ml Injection B No. PY035 M/s Sanofi-aventis.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVb, upto 72 months.
	The status in reference regulatory authorities	MIOREL 4 mg/2 ml solution for injection (IM) in ampoule ANSM France Approved
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 22.02.2022 is submitted.
	Evidence of approval of manufacturing facility	renewal letter dated 04.07.2022 is submitted wherein Liquid ampoule section is mentioned.
	Evaluation Remarks	
	Application fulfils codal formalities.	
	Decision	
	Approved	
40	Case Category	New Molecule/Formulation (Adil Saeed)
	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	(WL1-SAH-63GE, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2025-01-17,
	The proposed proprietary name / brand name	Sildem 25mg Tablets
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per zone-IVA
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors. ATC code: G04BE03
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceutical Limited
	Detail of stability batches of drug product	03 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 Form-6 No. DIL-C0119E2 dated 13-06-2024 mentioning 2 kg of Sildenafil citrate from M/s Century Pharmaceuticals, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablet B. No. 9506, Mfg Pfizer Saudia Limited
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.

	The status in reference regulatory authorities	Viagra 25mg, 50mg & 100mg (sildenafil) tablets, USFDA approved.
	GMP status of the firm	Copy of GMP certificate No. 40/2023-DRAP (K) dated 02-06-2023 on the basis of inspection conducted on 29-05-2023 is submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 2-44/84-Lic (Vol-IV) dated 20-09-2021 is submitted mentioning Tablet (General) section.
	Evaluation Remarks	
	The case was deferred in 345th meeting for following; • Submission of PE and CDP studies against the innovator product. • Pictorial evidence of the innovator product with visible details of batch number, expiry date and name of manufacturer. • Clearance certificate or GD certificate for import of API with approval from DRAP.	
	Firm has submitted satisfactory reply. Application fulfils codal formalities.	
	Decision	
	Approved	
41	Case Category	Priority As Per 257-M of RB (Adil 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	(EQP-TR8-B3YQ, 2025-08-12)
	Detail of Fee Submitted	300000.0, 2025-06-25,
	The proposed proprietary name / brand name	AZAVI 100mg/Vial
	Label Claim	Each vial contains: Azacitidine..... 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	36 Year(s)Store the drug in a cool, dry place at a temperature of 30°C ± 2°C.
	For generic drugs (me-too Status)	AZATAJ Azatidine 100mg/Vial Manufacturer: Sartaj Pharma's: MAH In Pakistan: Indus Pharmacy
	Pharmacotherapeutic Group of (API)	L01BC07 Anti-Metabolite
	Name, address of Manufacturing site:	Kindos Pharmaceuticals Co., Ltd. -No.8-9 Kexin Road. Chengdu Hi-Tech Comprehensive Bonded Zone.Chengdu, Sichuan, 611731, P. R. China - China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The basis of the proposed abbreviated new drug application [ANDA] for Azacitidine for Injection 100 mg/vial is the approved reference listed drug [RLD] VIDAZA® (Azacitidine for Injection), 100 mg/vial, the subject of an approved NDA 050794, held by CELGENE CORP and approved on May 19, 2004, as listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as Orange Book.
	Name, address of Marketing Authorization Holder:	Meitheal Pharmaceuticals Inc., , 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631

	United States of America , United States of America																												
Details of Certificates (CoPP/FSC/cGMP):	Valid																												
Details of Authorization Letter :	NA																												
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies conducted at 30°C ± 2°C and 60% ± 5% RH for 36 months confirmed that Azacitidine remains stable. The recommended storage conditions are 30°C ± 2°C, light-resistant, with a shelf life of 36 months. Accelerated stability testing at 40°C ± 2°C and 75% ± 5% RH for 6 months also showed stability, simulating long-term storage conditions.																												
The status in reference regulatory authorities	VIDAZA® Strength: 100 mg Azacitidine per vial Manufacturer: Bristol Myers Squibb USFDA Approved																												
Evaluation Remarks																													
Copy of Letter of Authorization from M/s Mithel Pharmaceuticals Inc, 8700 W. Bryn Mawr, Ste. 600s, Chicago, IL 60631, USA is submitted.																													
Copy of COPP issued by USFDA is submitted. As per COPP MA holder is M/s Mithel Pharmaceuticals Inc, 8700 W. Bryn Mawr, Ste. 600s, Chicago, IL 60631, USA. Manufacturer is Kindos Pharmaceuticals Co., Ltd., No. 8-9 Kexin Road, Chengdu Hi-Tech Comprehensive Bonded Zone, Chengdu, Sichuan 611731 CHINA																													
The application fulfils codal formalities.																													
Decision																													
Approved																													
Approved as per policy for inspection abroad.																													
42	<table> <tr> <td>Case Category</td><td>New License (Adil Saeed)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Medevo (Pvt.) Limited Plot No. 94, Sundar Industrial Estate, Raiwind Road, Lahore (000962)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(Y18-32Q-9J5W, 2024-01-10)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>30000.0, 2023-10-31,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>SURGILAST 0.05% Ophthalmic Solution</td></tr> <tr> <td>Label Claim</td><td>Each ml contains: asAzelastine HCl ... 0.5mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>5ml-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s)Store below 28°C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>AZELAST Ophthalmic Solution (0.5%) of M/s Innvotek Pharmaceuticals</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>S01GX07 Other antiallergics</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>CORAL DRUGS Private Limited</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>data of 3 batches upto 6 months is submitted.</td></tr> </table>	Case Category	New License (Adil Saeed)	Name, address of Applicant.	Medevo (Pvt.) Limited Plot No. 94, Sundar Industrial Estate, Raiwind Road, Lahore (000962)	Application Form Dy. No / Tracking ID & date of submission	(Y18-32Q-9J5W, 2024-01-10)	Detail of Fee Submitted	30000.0, 2023-10-31,	The proposed proprietary name / brand name	SURGILAST 0.05% Ophthalmic Solution	Label Claim	Each ml contains: asAzelastine HCl ... 0.5mg	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	5ml-As per SRO	Shelf Life (Unit)	2 Year(s)Store below 28°C	For generic drugs (me-too Status)	AZELAST Ophthalmic Solution (0.5%) of M/s Innvotek Pharmaceuticals	Pharmacotherapeutic Group of (API)	S01GX07 Other antiallergics	Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	CORAL DRUGS Private Limited	Detail of stability batches of drug product	data of 3 batches upto 6 months is submitted.
Case Category	New License (Adil Saeed)																												
Name, address of Applicant.	Medevo (Pvt.) Limited Plot No. 94, Sundar Industrial Estate, Raiwind Road, Lahore (000962)																												
Application Form Dy. No / Tracking ID & date of submission	(Y18-32Q-9J5W, 2024-01-10)																												
Detail of Fee Submitted	30000.0, 2023-10-31,																												
The proposed proprietary name / brand name	SURGILAST 0.05% Ophthalmic Solution																												
Label Claim	Each ml contains: asAzelastine HCl ... 0.5mg																												
Reference to Finished product specifications	United States Pharmacopeia																												
Proposed Pack Size	5ml-As per SRO																												
Shelf Life (Unit)	2 Year(s)Store below 28°C																												
For generic drugs (me-too Status)	AZELAST Ophthalmic Solution (0.5%) of M/s Innvotek Pharmaceuticals																												
Pharmacotherapeutic Group of (API)	S01GX07 Other antiallergics																												
Name, address of Manufacturing site:	Self Manufacturing																												
Name & address of API manufacturer	CORAL DRUGS Private Limited																												
Detail of stability batches of drug product	data of 3 batches upto 6 months is submitted.																												

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted. Taken loan from M/s Innvotek Pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Azelast 0.05%W/v eye drops M.s Innvotek B. No. 6069
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 36 months.
	The status in reference regulatory authorities	USFDA Approved (**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	Section approval letter dated 08.11.2022 is submitted.
	Evaluation Remarks	
	The case was deferred in 339th meeting for following; 1. Clarification regarding 'optical rotation test for Hyoscyamine', mentioned in submitted stability study sheets for Drug Substance. 2. Stability Studies for newly formulated batches.	
	Now firm has submitted new stability data sheets of different batches of drug substance wherein testing is done as per USP. Stability data of drug product is submitted as per guidance document.	
	Application fulfils codal formalities.	
	Decision	
	Approved	
43	Case Category	Export Facilitation (Adil Saeed)
	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	(MYP-X5Z-M6YB, 2024-02-29)
	Detail of Fee Submitted	30000.0, 45000.0 2023-11-23, 2023-12-08
	The proposed proprietary name / brand name	Scipride 12.5mg/ml
	Label Claim	Each 2ml Ampoule Contains: Levosulpiride 25mg (As per Innovators Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5 x 2ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Levopraid 25mg/2ml injection
	Pharmacotherapeutic Group of (API)	N05AL07 ANTIPSYCHOTICS, Benzamides/ prokinetic
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd.-PLOT # 129 SUNDER INDUSTRIAL ESTATE, LAHORE-
	Name & address of API manufacturer	Infinity Laboratories Pvt. Ltd.Gulabgarh-Behra Road,P.O.Rampur Sainia Tehsil:DeraBassi140507,Punjab,India.
	Detail of stability batches of drug product	3 batches, 5000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice is submitted.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Levopraid 25mg/2ml Injection M/s Pacific pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Aifa Italy Approved., Levosulpiride Ferrer 25 mg soluzione iniettabile o per infusione
GMP status of the firm	Submitted
Evidence of approval of manufacturing facility	Section approval letter dated 07.02.2014 is submitted.

Evaluation Remarks

The case was deferred in 345th meeting for following;

1- It is advised to attach searchable pdf file and bookmark the relevant documents as per CTD pre-submission checklist of Module 1 to expedite your application. 2- Kindly submit the Differential fee for contract manufacturing case, As per E.app desk your firm mentioned paid fee of 30,000. it is further advised to Upload copy of submitted fee challan and update the details of submitted differential fee in online portal.

Firm has submitted their response and its found satisfactory.

Application fulfils codal formalities.

Decision

Approved

44	Case Category	New Molecule/Formulation (Adil Saeed)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(E38-WM5-38PH, 2024-12-17)
	Detail of Fee Submitted	75000.0, 2024-11-26,
	The proposed proprietary name / brand name	Neogra 20mg Tablet
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....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 Year(s)Store in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Drugs used in erectile dysfunction ATC code: G04BE
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ultra Tech India Ltd. Add: Plot Nos. 24, 25 & 26, New Chemical Zone, M.I.D.C. Taloja, Tal. Panvel, Dist. Raigad-410208, Maharashtra, India
	Detail of stability batches of drug product	03 batches having batch size of 800 Tablets each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of Form-6 No. K-3191532692346 issued in the name of M/s Asian Continental, Karachi dated 06-06-2024 mentioning 1kg of Sildenafil citrate USP from M/s Ultra Tech, India. Firm has also submitted copy of loan agreement dated 02-08-2024 with M/s Asian continental, Karachi wherein M/s Asian continental

		has provided 1kg of Sildenafil as loan to M/s Wimits pharmaceuticals.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP and PE studies are performed against Sildenafil 20mg tablets and values are in acceptable ranges.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 60 months.
	The status in reference regulatory authorities	REVATIO (sildenafil) tablets, USFDA approved.
	GMP status of the firm	Firm has submitted copy of cGMP certificate No. 188/2023-DRAP(AD/3489860170) Dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet (General Human) section approved vide No.F.1-51/2004-Lic dated 07-02-2014 is approved.
	Evaluation Remarks	
	Application was deferred in 345th meeting for clarification regarding the claimed indication for applied strength of the product.	
	The proposed indication for 20mg sildenafil is pulmonary hypertension.	
	Along with this 20mg strength, firm had also applied for 25 mg 50 mg and 100 mg. Those applications were initially approved in 345th meeting and then were rejected in 349h meeting due to negative outcome of PSI. This application of 20mg was submitted along with those applications of which data was not verified.	
	Decision	
	Deferred	
	Deferred for submission of product development and stability data of new trial batches.	
45	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(7A2-9NE-E985, 2024-06-24)
	Detail of Fee Submitted	30000.0, 38700 2024-04-29, 2026-01-06
	The proposed proprietary name / brand name	FLUCINOL N OINTMENT
	Label Claim	Each gram of Ointment contains Fluocinolone Acetonide.....0.25mg (0.025% w/w) Neomycin Sulfate....3250IU (0.5%w/w)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25C
	For generic drugs (me-too Status)	Synalar N Ointment by Pharma Health Pakistan
	Pharmacotherapeutic Group of (API)	Corticosteroids, dermatological preparations; Corticosteroids, potent, combinations with antibiotics ATC code: D07CC02
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prachem Laboratories PVT Ltd. Name: Prachem Laboratories Address No. Plot No. 3109, Phase-III, G.I.D.C. Chhatral, Ta. Kalol, Dist. Gandhinagar,

		Gujarat-382729, Sichuan Long March Pharmaceutical Co., Ltd. 448 Changqing Road, Leshan, Sichuan 614000, People's Republic China
	Detail of stability batches of drug product	3 batches, 80 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoices are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Synalar N Ointment B. No. SP011 M/s Pharma Health Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Fluocinolone Zone IVb upto 36 months. Neomycin Sulfate Zone IVa, upto 42 months.
	The status in reference regulatory authorities	Synalar N Ointment MHRA Approved.
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.04.2022 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 04.07.2022 is submitted where in cream/ointment section is mentioned.
	Evaluation Remarks	
	Application fulfils codal formalities.	
	Decision	
	Approved	
46	Case Category	New License (Adil Saeed)
	Name, address of Applicant.	AUSPEC PHARMACEUTICALS PVT LTD 21, Km, Raiwind Road, Lahore. (000964)
	Application Form Dy. No / Tracking ID & date of submission	(U7D-7UX-Y3XQ, 2025-04-07)
	Detail of Fee Submitted	37000.0, 2025-01-07,
	The proposed proprietary name / brand name	Calit DS 250mg/5ml Dry Suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Clarithromycin (Taste Mask micro pellets) Eq. to Clarithromycin... 250mg (USP Specification).
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO.-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Klaricid DS 250mg/5ML by Abbot Laboratory.
	Pharmacotherapeutic Group of (API)	J01FA09 Macrolides
	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	3 batches, 100 bottles each.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchase from M/s Vision.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Klaricid DS suspension M/s Getz B. No. 472175XV
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IVa conditions.

	The status in reference regulatory authorities	Clarithromycin 250mg/5ml suspension MHRA approved.
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Section approval letter dated 17.02..2023 is submitted.
	Evaluation Remarks	
	Application fulfils codal formalities.	
	Decision	
	Approved	
47	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	High-Q Pharmaceuticals Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (000597)
	Application Form Dy. No / Tracking ID & date of submission	(6H4-7WX-W57W, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-13,
	The proposed proprietary name / brand name	S-Panto
	Label Claim	Each vial contains: Pantoprazole sodium equivalent to Pantoprazole 40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	ZENTRO INJECTION 40mg (Manufactured by Bosch Pharmaceuticals Pvt Ltd)
	Pharmacotherapeutic Group of (API)	A02BC02 Proton pump inhibitors
	Name, address of Manufacturing site:	M/s Novamed Pharmaceuticals (Pvt.) Ltd.-28-km Ferozepur Road, Lahore – Pakistan-
	Name & address of API manufacturer	M/s Rajasthan Antibiotics Ltd, Bhiwadi,, Dist Alwar (raj.) India
	Detail of stability batches of drug product	3 batches, 2800 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted, mentioning 5kg drug substance.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Zetro 40mg Injection M/s Bosch B. No. Z0240001
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IVb conditions upto 36 months.
	The status in reference regulatory authorities	PROTIUM I.V. 40 MG POWDER FOR SOLUTION FOR INJECTION manufactured by Takeda GmbH Germany and MAH is Takeda UK Limited. (MHRA Approved)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.11.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 25.10.2023 is submitted for
	Evaluation Remarks	

The application fulfils codal formalities.		
Decision		
Approved		
48	Case Category	Routine (Dr. Farhad Ullah)
	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	(PWM-ME8-GL9X, 2024-06-28)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	Baclosol 10mg Tablets
	Label Claim	Each Uncoated Tablet Contains; Baclofen 10mg (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 30°C
	For generic drugs (me-too Status)	Baclin 10mg Tablets, Manufacturer: Genome Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	gamma-aminobutyric acid (GABA) agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Panchsheel organic Ltd.
	Detail of stability batches of drug product	3 batches having batch size of 1500 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted a request letter for borrowing of API (indicating Baclofen 0.2kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 26-10-2023 specifying 25kg Baclofen in name of M/s Seraph Pharmaceuticals
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Baclin10mg Tablets by M/s Genome Pharmaceuticals(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	Lioresal 10mg Tablets, Manufacturer: Novartis Ireland Limited (Registered in Ireland)
	GMP status of the firm	New DML issued dated 17-01-2024
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Tablet Section-I (General).
Evaluation Remarks		
Sr. No	Shortcomings	Firm's Response
1.	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 a letter from Food Administration Madhya Pradesh. The letter states that Panchsheel Organic Limited, B6 - B7 Sector, Industrial Estate, Sanwer Road, Indore (M.P.) India is holding Manufacturing License No. 25/7/1991 & 25/7/1992 valid upto 31.12.2021. The

		deposited requisite online fee for retention of 1 per this office record vide application No. IND & INDB2128R1024 In view of above as per G dated 27.10.2017 the above mentioned license permission (As per list enclosed) is deemed to a period of 5 years i.e. up to 31.12.2026.
2.	Copy of executed BMR is required	Submitted
3.	Copies of drug substance specifications and analytical procedure duly signed by drug substance manufacturer on their letterhead are required	Submitted
4.	Justify the dissolution results of more than 90% in 0.01N hydrochloric acid in batch analysis of drug product since less than 80% dissolution results are obtained with 0.1N hydrochloric acid in CDP studies .	Dissolution method in CDP i.e. Apparatus: A RPM: 50 rpm Medium: 0.01 N hydrochloric a 1000 ml while in routine testing is Apparatus: A RPM: 50 rpm Medium: 0.01 N hydrochloric a 500 ml according to UPS for 10 mg tablets. TI in dissolution volume effect the final concentra may cause slightly difference the Dissolutio compared to routine testing but in overall th CDP are about 80% in acid medium and com the results of reference product.
5.	Stability study data of applied product at 6th month time point shall be submitted	Submitted
6.	Loan letter and intimation of API loan submitted to DRAP is required	Firm has submitted loan intimation, requ borrowing of API (indicating Baclofen 0.2k agreement between M/s Solaris life scienc Seraph pharmaceuticals for API loan

Decision

Deferred

Deferred for submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin

49	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Aptcure (PVT.) Ltd 8th Pharma city , 30-km, multan road lahore (000648)
	Application Form Dy. No / Tracking ID & date of submission	(2BH-57M-XSUQ, 2024-05-14)
	Detail of Fee Submitted	30000.0, 2024-04-16,
	The proposed proprietary name / brand name	APTGREL 75mg
	Label Claim	Each film coated tablet contains clopidogrel as (bisulphate).....75mg (USP specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-As per SRO
	Shelf Life (Unit)	24 Year(s)At room temperature below 25 degree centrigrade
	For generic drugs (me-too Status)	Cloplad 75 mg tab by Alliance pharmaceuticals Pvt. ltd Registration Number 044745
	Pharmacotherapeutic Group of (API)	Anti-platelet agent
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer		AARTI DRUGS LIMITED Plot No. G 60 M.I.D.C. Tarapur Tal. Palghar Dist Thane 401 506, Maharashtra
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)		Not submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP studies performed against Lowplat 75mg Tab by M/s PharmEvo
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		CLOPIDOGREL Tablets 75 mg by Milpharm Limited Ares Block, Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom MHRA Approved
GMP status of the firm		Firm has submitted copy of cGMP certificate of the firm based on inspection dated 01-03-2023.
Evidence of approval of manufacturing facility		Firm has submitted copy of letter of renewal of DML dated 06-03-2019 specifying Tablet (General) section.
Evaluation Remarks		
Sr. No	Shortcomings	Firm's Response
1.	Valid copy of DML or receiving of application submitted in Licensing Division for renewal of DML shall be submitted	Valid copy of DML submitted
2.	Clarify why innovator's specifications have been applied in module I while the product is available in the pharmacopeia.	i-The application of Innovator specifications error. It was later identified that the product is the USP Pharmacopoeia. After six months, the rectified by revising the product specifications in accordance with the USP requirements. stability study was subsequently conducted for 6 months as per USP. Please find attached Testing SOP, Product Specifications, Real-Time Stability Reports, Raw Data sheets, HPLC charts and HPLC audit trail. ii-The fee for change of specifications is submitted via challan No. 4969995610In An
3.	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 cGMP certificate of manufacturer issued by Food & Drug Administration (Gujarat State) India valid till 2026.
4.	Clarification is required as the submitted specifications on the drug substance manufacturer's letterhead mention Clopidogrel Bisulphate USP but correspond to Vonoprazan Fumarate. Please submit duly signed copies of the correct specifications and analytical procedures used for routine testing of the drug substance.	Correct specifications and analytical procedures for Clopidogrel bisulphate from drug substance manufacturer used for routine testing of the drug substance is submitted
5.	Copies of the Drug substance specifications and analytical procedures used for routine testing of	Submitted

	the Drug substance by Drug product manufacturer is required.	
6.	Provide the results of the CDP study, including the calculated f_1 and f_2 factors, mean dissolution profiles, and a conclusion on the similarity between the test and reference products.	Results of the CDP study, including the calculated factors, mean dissolution profiles is submitted
7.	Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP	Firm has submitted copy of clearance certificate dated 11-2022 specifying 0.6kg Clopidogrel Bisulphate
8.	Batch analysis of at least two batches of drug product shall be submitted	Batch analysis of two batches of drug product with the raw data sheets and HPLC chromatograms,

Decision

Approved

50	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(6Y8-1JY-7N23, 2024-05-22)
	Detail of Fee Submitted	30000.0, 2024-05-08,
	The proposed proprietary name / brand name	Omergo 12.5mg Tablet
	Label Claim	Each Film Coated Tablet contains: Omarigliptin.....12.5mg (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 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Omaril Tablet by Genix Pharma
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S ARKER PHARMACEUTICALS TECHNOLOGY CO., LTD
	Detail of stability batches of drug product	3 batches having batch size of 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy loan intimation, MoU between the firms for procurement of API. Firm has submitted copy of form 6 dated 06-04-2023 specifying 1.001kg Omarigliptin in name of weatherfolds pharma
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Omarigliptin tablet by Genom Pharma CDP studies performed against Marizen 12.5mg Tablets by M/s Kissei Pharmaceutical Japan
	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	Marizev tablets 12.5mg PMDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.

Evidence of approval of manufacturing facility		
Evaluation Remarks		
Sr. No	Shortcomings	Firm's Response
1.	Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	Firm has submitted copy of renewal of DML 2014 specifying Tablet (General) section.
2.	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 cGMP certificate of manufacturer issued by Food and Drug Administration China valid upto 28-12-2020 Firm has also submitted copy DML#20160 of manufacturer issued by Inner Mongolia Medical Administration China valid upto 28-12-2025.
3.	Copy of executed BMR shall be submitted	Submitted
4.	Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug product manufacturer is required.	Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug product manufacturer is submitted.
5.	Analytical method verification report of drug substance performed by drug product manufacturer is required	Submitted
6.	Clarification is required as the manufacturing date of the drug substance is mentioned as January 04, 2023 and retest date as January 03, 2025 in the COA provided by the drug substance manufacturer, whereas it is stated as 08/2020 and 07/2023 in the COA provided by the drug product manufacturer.	Firm has submitted revised COA from drug substance manufacturer in which manufacturing and retest date corrected as per drug substance manufacturer
7.	Submit pictorial evidence of comparator product indicating name of manufacturer, batch number, manufacturing date and expiry date against which pharmaceutical equivalence studies has been performed	Firm has submitted pictorial evidence of comparator product
8.	Submit the results 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, standard deviations, and graphical representation comparing test and reference products.	Results of the Comparative Dissolution Profile studies conducted in three physiological media including individual and mean dissolution data, standard deviations, and graphical representation comparing test and reference products submitted
9.	Detailed analytical procedures of all tests given in finished product specifications shall be submitted	Submitted
10.	CoA of Primary / Secondary Reference Standard used in testing of trial batches shall be submitted	Submitted
11.	Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP or copy of goods declaration, airway bill and commercial invoice.	Copy of form 6, loan intimation and Memo of procurement.
Decision		
Approved		

51	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		(468-TJN-PLTX, 2024-02-13)
	Detail of Fee Submitted		75000.0, 2024-01-29,
	The proposed proprietary name / brand name		D4U
	Label Claim		Each ml contains: 1.56mg of cholecalciferol, equivalent to.....50,000 IU of Vitamin D3
	Reference to Finished product specifications		As per Innovators Specification
	Proposed Pack Size		1's, 5's, 10's-As per SRO
	Shelf Life (Unit)		24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)		Not Applicable
	Pharmaceutical Group of (API)		Vitamin D
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		M/s Fermenta Biotech Limited
	Detail of stability batches of drug product		3 batches: 100 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)		13-03-2023: Clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Videsil oral soluion: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		3 batches as per Zone IV-A
	The status in reference regulatory authorities		Videsil by Gebro Pharma Laboratories, Spain approved
	GMP status of the firm		06-06-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility		06-06-2023: GMP certificate specifies oral liquid section
Evaluation Remarks			
Deferred in 347th meeting of RB;			
Sr. No	Deferment reason	Firm's Response	
1.	The innovator's product is available as a single dose ampoule containing 1ml solution while the applied product is multidose bottle containing 10ml solution.	In order to provide a convenient and ann option for patient we have using multido contains 10 doses of 50,000 I.U per ml. Keep current socio-economic condition of Pakistan burden and makes the product more pocl Furthermore, our product is therapeutically e the innovator product and there are no differences in terms of safety and efficacy.	
2.	Justify how the dose of the applied product will be delivered for patient as per recommended dose of the innovator's product.	To ensure the dosing accuracy we will provid dosing device to ensure accurate measure dosing volume. Each ml contains: cholecalciferol, equivalent to.....50,000 IU D3	

Decision		
Rejected		
Rejected as the applied formulation is not available in Reference Regulatory Authorities in applied filled volume		
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	(7PM-G76-EBZY, 2024-02-13)
	Detail of Fee Submitted	75000.0, 2024-01-29,
	The proposed proprietary name / brand name	D4U
	Label Claim	Each ml contains: 2.50mg of cholecalciferol, equivalent to.....100,000 IU of Vitamin D3
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's, 10's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Fermenta Biotech Limited
	Detail of stability batches of drug product	3 batches: 100 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	13-03-2023: Clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Videsil oral soluion: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	Videsil by Gebro Pharma Laboratories, Spain Approved
	GMP status of the firm	06-06-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	06-06-2023: GMP certificate specifies oral liquid section
Evaluation Remarks		
Deferred in 347th meeting of RB;		
Sr. No	Deferment reason	Firm's Response
1.	The innovator's product is available as a single dose ampoule containing 1ml solution while the applied product is multidose bottle containing 10ml solution.	In order to provide a convenient and cost-effective for patient we have using multidose container doses of 100,000 I.U per ml. Keep in view socio-economic condition of Pakistan it create and makes the product more pocket friendly. Our product is therapeutically equivalent to the product and there are no significant difference safety and efficacy.

2.	Justify how the dose of the applied product will be delivered for patient as per recommended dose of the innovator's product.	To ensure the dosing accuracy we will provide dosing device to ensure accurate measurement of dosing volume. Each ml contains: cholecalciferol, equivalent to..... 100,000 IU of Vitamin D3

Decision

Rejected

Decision; Rejected as the applied formulation is not available in Reference Regulatory Authorities in applied filled volume

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	(BMH-RE2-SVG3, 2024-02-13)
	Detail of Fee Submitted	75000.0, 2024-01-29,
	The proposed proprietary name / brand name	D4U
	Label Claim	Each ml contains: 0.625 mg of cholecalciferol, equivalent to.....25,000 IU of Vitamin D3
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's, 10's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Vitamin D
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Fermenta Biotech Limited
	Detail of stability batches of drug product	3 batches: 100 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	13-03-2023: Clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Videsil oral soluion: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	Videsil by Gebro Pharma Laboratories, Spain Approved
	GMP status of the firm	06-06-2023: GMP certificate inspection date
	Evidence of approval of manufacturing facility	06-06-2023: GMP certificate specifies oral liquid section
	Evaluation Remarks	
	Deferred in 347th meeting of RB;	
	Sr. No	Firm's Response
	1.	The innovator's product is available as a single dose ampoule containing 1ml solution while the applied product is multidose bottle containing 10ml solution.
		In order to provide a convenient and cost-effective for patient we have using multidose container doses of 25,000 I.U per ml. Keep in view the economic condition of Pakistan it create less

		makes the product more pocket friendly. Further, the product is therapeutically equivalent to the product and there are no significant difference in safety and efficacy.
2.	Justify how the dose of the applied product will be delivered for patient as per recommended dose of the innovator's product.	To ensure the dosing accuracy we will provide dosing device to ensure accurate measurement of dosing volume. Each ml contains: 0.025mg cholecalciferol, equivalent to.....25,000 IU of Vitamin D3

Decision

Rejected

Rejected as the applied formulation is not available in Reference Regulatory Authorities in applied filled volume

54	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(T45-98Q-YBDM, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-01-04,
	The proposed proprietary name / brand name	Cyanokob injection
	Label Claim	Each 1ml ampoule contains: Cyanocobalamin 1000mcg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100's-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 30 Celsius
	For generic drugs (me-too Status)	Cyanocobalamin injection, Venus Pharma, reg. No. 012082
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hebei North China Pharmaceutical Huahang Pharmaceutical Co.,Ltd
	Detail of stability batches of drug product	3 batches having batch size of 1500 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared dated 17-12-2020 specifying 0.025kg Cyanocobalamin (Vit Amin B12)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Cyanocobalamin 1mg/ml injection by Venus 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	Cytamen 1000micrograms/mL Injection MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 08-02-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section dated 18-12-2020 specifying Liquid Ampoule (SVP) (General) (New).
	Evaluation Remarks	
	Deferred in 352nd meeting of RB;	

S No.	Deferment Reason	Firm Response
1	Deferred for submission of valid copy of DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Hebei Medical Products Administration China Valid upto 05-03-2028

Decision

Approved

55	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(W1Q-N9D-R54W, 2024-06-28)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	IDOPAM 250mg tablet
	Label Claim	Each Film Coated Tablet Contains: Methyldopa (USP).....250MG
	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 Celcius
	For generic drugs (me-too Status)	Cara Dopa 250mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-
	The status in reference regulatory authorities	METHYLDOPA TABLETS 250mg MHRA Approved
	Detail of previous approval	Medopa 250mg Tablet in 343rd meeting of RB

Evaluation Remarks

S No.	Deficiencies	Firm Response
1	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023. In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. extract of the minutes of the relevant meeting of Registration	Firm has submitted module I, undertaking and copy of registration letter of approved product.

	Board and 3. undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification	
	Decision	
	Approved	
56	Case Category	New Section (Dr. Farhad Ullah)
	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	(WPD-AJH-3SJ3, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	HY-KOR 500MG INJECTION
	Label Claim	Each Vial Contains:Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....500mg(Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)20-25C
	For generic drugs (me-too Status)	Cortizone 500mg Injection by M/s Vision Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroids for Systemic use;
	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 500 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 26-06-2023 specifying 30kg Hydrocortisone Sodium succinate buffered sterile in name of M/s Horizon Healthcare (Pvt.) Ltd., Firm has also submitted copy of loan letter from M/s Horizon Healthcare Pvt., Ltd.,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Hyzonate 500mg Injection
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV
	The status in reference regulatory authorities	SOLU-CORTEF (hydrocortisone sodium succinate for injection,) 100mg/vial, 250mg/vial, 500mg/vial, 1gm/vial; USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-06-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional Section dated 13-05-2024 specifying Dry Powder for Injection (steroid)-Additional.

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1.	Standardize the applied label claim as per the reference formulation considering the salt factor	Hydro-Wen 500mg Injection (sterile powder for Reconstitution) Each Vial Contains: Hydrocortisone Sodium Succinate eq. to Hydrocortisone 500mg (USP Specifications)
2.	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Submitted
3.	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.	The sterile powder has already been freeze-dried by the API manufacturer through the lyophilization process. Since our product is a ready-to-fill sterile lyophilized powder, we directly proceed with filling. For reference, the COA is attached.
4.	Submit evidence of applied product in reference regulatory which indicate that the applied product is manufactured by direct filling technique	We would like to respond that; The Solu-Cortef label describes the product only as "sterile powder" or "powder for solution for injection" and does not mention the word "lyophilised" anywhere on the label. In regulatory language, if a product is freeze-dried, the label must state "lyophilized powder" or "freeze-dried powder" because this is a specific manufacturing process that affects stability, appearance, and reconstitution characteristics. Since Solu-Cortef is labelled simply as "sterile powder", this indicates that the product is not lyophilised. Instead, it is manufactured as a dry sterile powder and filled directly into vials under aseptic conditions. This is a standard, approved presentation in SRA-regulated markets when the drug substance is sufficiently stable without lyophilisation.
5.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	Submitted. However, method of assay test is different than USP monograph
6.	Analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer for drug substance shall be submitted.	Submitted
7.	Clarification is required regarding brand name as you have applied HY-KOR 500mg Injection in module I of your application while Hydonate 500mg Injection in module III	We have already registered other strength with the brand of Hydro-Wen, which shall be adopted at the time of registration letter of this strength too.
8.	Submit complete analytical procedure of all test used for analysis of applied product	Analytical procedure of all test for applied product is submitted

9.	Analytical Method Verification studies of drug product performed by the Drug Product manufacturer shall be submitted.	As our product is sterile and involve in direct filling so Analytical method verification studies of drug substance/product is same and attached
10.	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
11.	Copy of loan agreement for API between the firms and intimation of borrowing of API submitted in DRAP shall be submitted	Firm has submitted loan agreement between the firms and intimation of borrowing of API submitted in DRAP.

Decision

Deferred

Registration Board decided to defer the case for further deliberation regarding the manufacturing method whether it is manufactured by freeze-drying as per USP monograph or direct filling technique.

57	Case Category	Export Facilitation (Dr. Farhad Ullah)
	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	(T9T-UPM-56A6, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2025-02-20,
	The proposed proprietary name / brand name	VIBRO Tablets 75mg
	Label Claim	Each Film Coated Tablet Contains: Vibegron 75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-De-Controlled
	Shelf Life (Unit)	24 Month(s)20°C to 25°C (68°F-77°F); excursions are permitted between 15°C and 30°C (59°F and 86°F)
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs for urinary frequency and incontinence,
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Porton Pharma Solutions 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 form 6 issued dated 23-07-2024 specifying 0.6kg VIBEGRON. Firm has also submitted copy of goods declaration and commercial invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against GEMTESA (vibegron) Tablets 75 mg by Urovant Sciences, Inc..
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV till 18th months
	The status in reference regulatory authorities	Gemtesa (vibegron) 75mg tablets approved by USFDA

GMP status of the firm		Firm has submitted copy of cGMP certificate issued based on inspection dated 07-03-2024.
Evidence of approval of manufacturing facility		Firm has submitted copy of letter for Regularization of Sections dated 28-12-2020 specifying Tablet (General) section.
Evaluation Remarks		
Deferred in 352nd meeting of Registration Board		
S No.	Deferment Reason	Firm's Response
1	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 DML of AP manufacturer issued by Chongqing Municipal Medical Products Administration China valid upto 13-05-2030
2	DMF Authenticity certificate as results for water content test in updated stability study data of drug substance appear to have been altered.	Firm has submitted declaration; We, Porton Pharma Solutions Ltd. hereby declare that the updated stability data based on batch 104178-102-00001/104178-102-00002/104178-102-00003 are from validation batches and should be considered as official part of stability data in DMF open part.
Decision		
Approved		
Case Category		New Section (Dr. Farhad Ullah)
Name, address of Applicant.		Sayed Pharmaceutical (pvt) Ltd plot 67/2 , phase 3, industrial Estat Hattar (000697)
Application Form Dy. No / Tracking ID & date of submission		(AG7-133-9JB4, 2025-01-23)
Detail of Fee Submitted		37000.0, 2024-11-07,
The proposed proprietary name / brand name		Vitasyd-D
Label Claim		Each 1ml ampoule contains: Cholecalciferol.....5mg
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		1's-As per SRO
Shelf Life (Unit)		2 YearStore below 25°c in cool & dry place protect from light.
For generic drugs (me-too Status)		INDROP-D
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Jiangxi Tianxin 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		ANSM
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Deferred in 347th meeting of Registration Board		
S No.	Deferment Reason	Firm's Response
1	For justification of importing drug substance without getting prior approval from relevant DRAP I&E office.	Vitamin D3 API Sample was received free of cost directly from API manufacturer Jiangxi tianxin pharmaceutical Co, Ltd for trials batches of product development and conducting stability studies and submitting CTD Dossier to DRAP. Invoice, DHL Slip and confidentiality Agreement document which was signed on demand of DMF from supplier are attached below.
Decision		
Deferred		
Registration Board defer the case for verification of the authenticity of the submitted stability data and procurement documents of API by the panel constituted by the Chairman, Registration Board.		
59	Case Category	New Section (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	(GRD-MHG-6DNZ, 2024-11-12)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	Trim-Z Cream
	Label Claim	Each gram of cream contains: Clotrimazole...10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10gm-As per SRO
	Shelf Life (Unit)	24 Month(s)30 degree
	For generic drugs (me-too Status)	Canesten cream by Manufactured by Novartis Pharma (Pakistan) Limited ; Manufactured For Bayer Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antimycotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NB Healthcare Pvt. Ltd, Survey No. 784/2, Village; Adroda, Tal.- Bavla, District.- Ahmedabad- 382 220
	Detail of stability batches of drug product	3 batches of 200 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued by DRAP I&E Lahore in nam eof M/s Fynk Lahore, by I&E DRAP Lahore along with intimation letter to DRAP dated 08-03-2024 regarding borrowing of API.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Against Clotrimazole cream
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IV

	The status in reference regulatory authorities		Clotrimazole Cream 1% by Generics [UK] Limited t/a Mylan Station Close, Potters Bar, Herts EN6 1TL (MHRA Approved)
	GMP status of the firm		New section of Cream/Ointment (General) granted on 29-02-2024)
	Evidence of approval of manufacturing facility		New section of Cream/Ointment (General) granted on 29-02-2024)
	Evaluation Remarks		
	Deferred in 344th meeting of Registration Board		
	S No.	Deferment Reason	Firm's Response
	1	Analytical record including chromatograms for the drug product stability studies shall be submitted since, firm has submitted drug substance stability data reports in section 3.2.P.8.3	Complete stability study data including summary data sheets, raw data sheets and chromatogram are submitted
	2	6th month time point stability data shall be submitted for drug product	Submitted
	Decision		
	Approved		
60	Case Category		New License (Dr. Farhad Ullah)
	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		(PWV-LTB-L284, 2024-08-28)
	Detail of Fee Submitted		30000.0, 2024-03-22,
	The proposed proprietary name / brand name		Cezo 5mg/5ml Oral Solution
	Label Claim		Each 5ml contains: Cetirizine HCl ... 5mg
	Reference to Finished product specifications		British Pharmacopeia
	Proposed Pack Size		1's (30ml) -As per SRO, 1's(120ml)-As per SRO, 1's(60ml)-As per SRO
	Shelf Life (Unit)		2 Year(s) Store below 30°C
	For generic drugs (me-too Status)		RIGIX 5mg/5ml ORAL SOLUTION of M/s
	Pharmacotherapeutic Group of (API)		R06AE07: ANTIHISTAMINES FOR SYSTEMIC USE
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		Supriya Lifesciences Ltd., India.
	Detail of stability batches of drug product		03 Batches, 41 Bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)		Loan agreement for 0.025Kg API from Novamed Pharma, along with copy of DRAP I&E Clearance has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Pharmaceutical Equivalence conducted against RIGIX 5mg/5ml ORAL SOLUTION.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability Studies conducted on Zone IV by Drug Substance Manufacturer.

The status in reference regulatory authorities	ZYRTEC 5mg/5ml Oral Solution, USFDA **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*
GMP status of the firm	New License w.e.f. 25-10-2023
Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Syrup Section (General) has been submitted.

Evaluation Remarks

Deferred in 347th meeting of Registration Board

S No.	Deferment Reason	Firm's Response
1	Deferred for submission of justification from Importer for point 4 mentioned above, "Loan has been obtained for 0.025Kg material from Novamed Pharma. The quantity was imported for Test/analysis purpose by Novamed Pharma. Please justify whether & why the material was not utilized by Importer for its own test/analysis".	We M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. do hereby submitting Justification for Non-Utilization of Imported Material. At the time of import, we NovaMed Pharmaceuticals (Pvt.) Ltd procured the material for evaluation purpose and source development. However, there was no immediate internal requirement for the material, as the associated development activities were scheduled for a later phase. Instead of allowing the imported API to go unused and potentially expire or require disposal, Novamed Pharma extended support by providing the unused test sample as a loan to air pharma, which was in the process of initiating trial formulation development and analytical method verification for the same molecule. In order to ensure timely and efficient utilization of the imported quantity, we decided to "Loan The Material To Air Pharmaceuticals, Strictly For Testing And Analysis Purposes". This action reflects a common and acceptable industry practice, especially in cases where collaboration and optimization of resources help the pharmaceutical sector as a whole. We hope this provides sufficient clarity.

Decision

Approved

61	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 339th meeting of RB for below cited shortcomings;		
Section#	Deferment Reason	Firm's Response
1.6.5	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Firm has submitted License Validity Certificate to Food & Drugs Control Administration, Gandhinagar India wherein it is stated that applied for retention of the said licence for the 31/05/2021 to 30/05/2026. This licence shall be in force until orders are passed on the application provisions of Drugs & Cosmetics Act 1940 & under.
3.2.S.1	Submitted CAS number and molecular weight for drug substance shall be justified since it varies from that of Nalbuphine HCl.	The CAS was written due to typing error molecular weight mention in dossier was confirmed from drug bank online that is C21H27NO4.HCL (393.6) and C21H27NO4.HCL (393.6) that was in dossier
3.2.S.1.3	Justification shall be submitted for the declared description of water solubility against the reference product literature.	The substance specifications are inhouse and same water solubility as mention in the Drug substance provided by the drug substance manufacturer. However, the submitted water solubility as per 3.2.S.1.3 is "water solubility 10.0mg/ml at 25°C" while reference product literature states its "(35.5 mg/mL @ 25°C)"
	Justification shall be submitted for the declared description of water solubility as given in section 3.2.S.1.3 against the reference product literature.	The specifications of drug substance are in-house mention same water solubility as mention in drug substance provided by the drug substance manufacturer. Justification is submitted. submitted that it is sparingly soluble in water should be dissolved in 30 to 100ml of solvent.

3.2. S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer.	Submitted.
3.2. P.1	Submitted master formulation declares the content of Nalbuphine injection instead of the salt form of Nalbuphine. Revision of master formulation shall be submitted along with applicable fee.	This was due to typing error since in label molecule with salt form is used. The corrected now attached with this letter. Firm has also s Rs. 38,700/- for correction of salt form of nal deposit slip No# 776159548
3.2. P.5.1	Justification shall be submitted for the declared limits of pH test in variation to that recommended by the innovator drug product literature.	The innovator's brand mention pH limit from we mention pH limit from 3.0-4.2 which is m than innovator brand. However, now we revise as per the innovator's brand for your considera However, the limits of pH test as per innovat literature is 3.5 to 3.7.
3.2. P.5.3	Sample concentrations used for performance of accuracy parameter are not as per those applied in Assay method.	Sample concentration used for performance parameter are as per those applied in Assa submitted along with accuracy test result
3.2. P.5.4	COAs of drug product stability batches shall be submitted.	Stability summary sheets is submitted instead c
3.2. P.7	Justification shall be submitted for use of Type II glass ampoule, since reference product has used Type I glass ampoule.	It was due to typing mistake
3.2. P.8.3	· Documents confirming procurement of drug substance with approval of DRAP I&E office shall be submitted.	· Firm has submitted copy of commercial inv dated 03-01-2022 specifying 0.35kg of Nalb Firm has also submitted copy of form 6 clear 01-2022 specifying 0.35kg of Nalbuphine HCl
	· Evidence of availability of "Liquid Particle Counter. Required for the performance of "particulate matter" test, shall be submitted.	· Firm has submitted copy of log book record has been used for performance of different f Firm has also submitted pictorial evidence o Liquid particle counter LE100 made of C validation has been performed by dawn analyt and calibrators. Firm has submitted results o performed on LPC.
	· As evident form submitted raw data sheets the sample and standard preparation method applied for stability studies is different form that declared in section 3.2.P.5.2. Justification shall be submitted in this regard.	· The firm submitted that final concentration same as required.
	· Justification shall be submitted for the variation in retention time reported in chromatograms of Assay test at different time points of stability studies.	· One HPLC system is not specific for speci Sometimes one HPLC system is busy at tha other HPLC system has been used. It is actual when we use different HPLC system for c retention time may vary from each other. Re after 03 months on "water's HPLC 5.049" a time "Shimadzu HPLC 6.37"
	· Justification shall be submitted regarding the "modifications" reported in the Audit trail of the chromatograms of stability studies.	· We are unable to change the record of ch during analysis or after analysis in our softwar solution (HPLC). Our system (HPLC) is CFI any relief. When we made any addition or cl method, all the changes are recorded with re system (HPLC). Our system is fully loaded

auto sampler & with cooling features. “Real time” is a software point in which we made our analysis. In this scheme we add these things about analysis: 1- Name 2- Sample ID 3- Tray 4- Vials # 5- Injection 6- Data file 7- Method file 8- Batch file 9- Raw file. In ‘sample name’ two names are added, one is sample name and second is sample ID. In standard means known and sample means unknown. We are using 5 standards injections in each analysis. In standards chromatographs are used in finding suitability test means Relative Standard Deviation by calibration curve. Then word ‘Modification’ is added in the audit trail (as modified post-run batch). When we want to make a new analysis schedule, we use old scheme format by our requirements, then word ‘Modifications’ developed in the audit trail (as modified real-time batch process). The word ‘Modifications’ developed by system indicates that calibration curves are used in our requirements that is RSD etc.

Justification shall be submitted for the dispensed quantity of drug substance reported in batch manufacturing record of drug product stability batches, against the potency of drug substance determined during drug substance analysis.

The assay of the nalbuphine HCl was 91.0% of label claim. The calculation for the material for the stability study is as follows; $10/91 \times 100 = 10.989 \text{ mg/ml}$ or per ampoule. 2000 ampoules we required API $10.989 \times 2000 = 21978 \text{ mg}$ of Nalbuphine HCl required to produce 2000 ampoules of same quantity of API used for the production of batches and the attached dispensing sheet also shows same quantity.

Decision

Deferred

Deferred for submission of following;

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Justification for the declared description of water solubility as given in section 3.2.S.1.3 against the reference product literature.
- Justification for the declared limits of pH test in variation to that recommended by the innovator drug product literature.
- COAs of drug product stability batches
- Evidence of availability of “Liquid Particle Counter. Required for the performance of “particulate matter” test,

62	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(EJM-SEW-BJP6, 2024-10-16)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-07, 2024-10-02
	The proposed proprietary name / brand name	Penro (Meropenem) Injection 2g

Label Claim	Each vial contains: Meropenem USP.....2g as Meropenem Trihydratecontains 180.4mg of Sodium as Sodium Carbonate.	
Reference to Finished product specifications	United States Pharmacopeia	
Proposed Pack Size	1's-As per SRO	
Shelf Life (Unit)	3 Year(s)Store Below 30°C and prevent from moisture. Preserve at 20°C - 80°C after reconstitution.	
For generic drugs (me-too Status)	Merem Injection 2g	
Pharmacotherapeutic Group of (API)	Carbapenem antibiotic	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Shenzhen Haibin Pharmaceutical Co., Ltd. 1) No. 2003 Shenyang Road, Yantian District, Shenzhen City, Guangdong Province, People's Republic of China. 2) Dedong Clock, High-Tech Industrial Development Zone, Xinxiang, Henan Province, People's Republic of Ch	
Detail of stability batches of drug product	3 batches of 600 vials each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued by DRAP I&E office kaarchi submitted	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted against Meropenem injection 2gm	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per Zone IV conditions	
The status in reference regulatory authorities	Italian Medicine Agency (AIFA)	
GMP status of the firm	GMP certificate dated 07-08-2024	
Evidence of approval of manufacturing facility	GMP certificate dated 07-08-2024 confirms Carabapenem Dry powder injection section	
Evaluation Remarks		
Deferred in 345th meeting of Registration Board:		
S No.	Deferment Reason	Firm's Response
1	Scope of production in the submitted DML of drug substance manufacturer does not declare the availability "Carbapenem" section.	Firm has submitted copy of renewal of DML dated 30-06-2020 specifying Dry Powder Injectable (Carbapenem) with warehouse
2	Justify the limits of sodium content declared in drug substance specifications with respect to the claimed content of sodium in label claim of drug product.	For the pre-mix powder of the sterile mixture of Meropenem and sodium carbonate, the sodium content range as per the COA of the drug substance manufacturer is 5.6% -8. 7%, which aligns with the claimed content of sodium in the label claim of the drug product. For each gram of Meropenem, it contains approximately 90 mg of sodium. Limit of sodium content declared in drug substance specification: 5.6%-8.7% Content of sodium in label claim of drug product: For each gram of Meropenem (anhydrous potency), the vial contains approximately 90 mg of sodium. Meropenem (as the trihydrate): 1.14 grams Equivalent to anhydrous Meropenem: 1 gram Sodium carbonate (approx.): 0.208 grams

		Sodium content: 0.090 grams Formula: Sodium Content/ Meropenem as trihydrate with sodium $0.090 / 1.23 = 7.3\%$ sodium content Conclusion: As the drug substance is a 'pre-mix powder of the sterile mixture of Meropenem and sodium carbonate, which comes in a sterile container, and after the potency calculation of the content per vial, the above calculation justifies and correlates the limit of sodium content declared in the drug substance specification with the claimed content of sodium in the label claim of the drug product
3	Justify the limits of Meropenem in drug substance specifications, considering the content of sodium carbonate and LOD% in pre-mix powder.	Drug substance is a Sterile Mixture of Meropenem and sodium carbonate and all the manufacturing procedures are finished in the grade A environment of the grade B clear area. For Pre -mix powder of sterile mixture of Meropenem and sodium carbonate, blending is the critical step. Manufacturer performs Manufacturing process validation of Meropenem and sodium carbonate mixture and justify the limit of Meropenem in drug substance specification. Enclosed: 5.2.5 Process validation and/ or Evaluation 5.2.5.1 Manufacturing process Validation of Meropenem and Sodium Carbonate Mixture.
4	Justification shall be submitted for variation in limits of sodium content, in drug substance, between those specified by drug substance manufacturer and those declared by drug product manufacturer.	The variation in limit of sodium content in drug substance manufacturer's specification and the drug product manufacturer's specification was an inadvertent error. Enclosed is the revised specifications in which the sodium content limit is aligned with the drug substance manufacturer's specifications. We would appreciate for the consideration of the same.
5	Justification shall be submitted for using Type I glass vial for the drug product since reference product approved by MHRA of UK declares use of Type II glass vial.	Meropenem (Meropenem) injection from Pfizer is filled in Type I vials (reference attached) and the pharmaceutical equivalence study was performed using a reference product that is also filled in Type I vials. To ensure pharmaceutical equivalence, it is important to maintain consistency with the reference product in terms of formulation, stability, and packaging. Therefore, selecting Type I vials ensures that product matches the packaging conditions used in the reference product, which can be critical for regulatory approval.
6	The volume of diluent specified for reconstitution shall be submitted.	Meropenem injection 2.0 grams reconstitute with sterile water for injection 40ml
7	Justification shall be submitted for not including test of sodium content in the pharmaceutical equivalence studies.	We performed sodium content test as per the required specifications and apologize that the corresponding data was not included in our previously submitted pharmaceutical equivalence data. Kindly find enclosed the updated

		pharmaceutical equivalence data, which now includes the sodium content analysis report.
8	Details of the reference product i.e., Manufacturer, country of origin shall be submitted.	Firm has submitted details of reference product. Product Name; Meropenem for Injection, Batch no; 23J05341, Expiry Date; 09-2026, Manufacturer for; WG Critical Care, LLC Paramus, NJ 07652, Country of Origin; Made in Italy
9	Compatibility study with the reconstitution diluents shall be submitted.	Compatibility of developed product and reference product with above mentioned reconstituted solution has been established as per procedure to check the compatibility with diluents as per prescribed condition. The results of Penro injection 2 grams {Developed product} found compatible with recommended diluent solution and equivalent with comparison of Meropenem for Injection 2 grams (Reference Product).
10	Results of the filled weight variation shall be declared in terms of numerical value instead of general statement of complies.	The filled weight variation of the Penro 2 grams per vial injection was determined during stability testing. The results are now provided as numerical values rather than a general statement of compliance. Enclosed: Stability summary and 06 month stability data (Annexure 14)
11	COAs of the reference/working standard used for the analysis of drug product stability studies shall be submitted.	Submitted
12	Justify the amount of dispensed drug substance per unit vial considering the potency of drug substance determined in drug substance analysis.	Drug Information: Product: Penro Injection 2 grams Each vial contains Meropenem (as Trihydrate) 2 grams. Potency of Meropenem (as Trihydrate) is 74.33% as per the analysis. Formula for dispensed quantity Penro 2 grams per vial dispensed quantity = 2.0 grams/ QC Potency x 100 Where The required drug amount per vial is 2.0 grams (desired amount of active ingredient). QC Potency is the measured potency of Meropenem, which is 74.33% Calculation Using the given formula, the dispensed quantity of the drug substance per vial is calculated as follows; Penro 2.0 grams per vial dispensed quantity = 2.0 grams/ 74.33 x 100 Penro 2.0 grams per vial dispensed quantity = 2.691 grams Conclusion The dispensed quantity of 2.691 grams per vial is justified based on the 74.33% potency of Meropenem (as Trihydrate).
13	In-use stability study shall be submitted for reconstituted injection	Submitted
14	Drug product stability data for 6th month time point shall be submitted	Submitted

Decision

Approved

63	Case Category		Routine (Dr. Farhad Ullah)
	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		(WRD-AZ2-E4TG, 2024-06-03)
	Detail of Fee Submitted		30000.0, 9400 2024-04-29, 2025-12-23
	The proposed proprietary name / brand name		Baclosol 20mg Tablets
	Label Claim		Each un-coated Tablet Contains; Baclofen 20mg (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 30°C
	For generic drugs (me-too Status)		Baclin 20mg Tablets, Manufacturer: Genome Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)		gamma-aminobutyric acid (GABA) agonist
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		Panchsheel organic Ltd.
	Detail of stability batches of drug product		3 batches having batch size of 1500 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)		
	Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP studies performed against Baclin 20mg Tablets by M/s Genome Pharmaceuticals(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		Baclofen 20mg Tablets Manufacturer: Sanis Health INC. (Registered in Canada)
	GMP status of the firm		New DML issued dated 17-01-2024
	Evidence of approval of manufacturing facility		Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Tablet Section-I (General).
Evaluation Remarks			
Sr. No	Shortcomings	Firm's Response	
1.	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 a letter from Food Administration Madhya Pradesh. The letter states Panchsheel Organic Limited, B6 - B7 Sector, Estate, Sanwer Road, Indore (M.P.) India is holding Manufacturing License No. 25/7/1991 & 2 Form 25 & 28 Valid upto 31.12.2021. The deposited requisite online fee for retention of license per this office record vide application No. IND & INDB2128R1024 In view of above as per G dated 27.10.2017 the above mentioned license permission (As per list enclosed) is deemed to a period of 5 years i.e. up to 31.12.2026.	

2.	Copy of executed BMR is required	Submitted
3.	Copies of drug substance specifications and analytical procedure duly signed by drug substance manufacturer on their letterhead are required	Submitted
4.	Justify the use of 500ml dissolution medium since USP recommends the use of 1000ml dissolution medium for products containing more than 10 mg of baclofen	The Dissolution medium for 10 mg tablets according to USP, and for more than 10 mg it but we used 500 ml for both 10mg tablets tablets and the dissolution sample of 20 mg to a final concentration of 0.02 mg/ml to Meet concentration used for dissolution studies. Th revised according to USP and the dissolution changed to 1000 ml. the dissolution studie using 1000 ml dissolution the results are sin obtained using 500 ml dissolution medium. N revised for Analytical method according to U retesting results of dissolution using 1000 method are enclosed herewith in covering le kind consideration. Firm has also submitted fe deposit slip#61257442369 for revision o method.
5.	Stability study data of applied product at 6th month time point shall be submitted	Submitted
6.	Submit procurement documents of API including loan letter, clearance certificate and loan intimation to DRAP	Firm has submitted loan intimation, requ borrowing of API (indicating Baclofen 0.2k agreement between M/s Solaris life scienc Seraph pharmaceuticals for API loan
7.	Stability study data documents like chromatograms, Raw data sheets and COA shall be submitted	Submitted
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	Submitted

The application fulfills codal formalities.

Decision

Deferred

Deferred for submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin

64	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	Variant Pharmaceuticals (Pvt.) Ltd Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhpura (000914)
	Application Form Dy. No / Tracking ID & date of submission	(RH2-RRE-2T3W, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-04-19,
	The proposed proprietary name / brand name	VARI-D INJECTION
	Label Claim	Each ml contains Cholecalciferol.....5mg (eq.to 200000 IU)

Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	1'-As per SRO	
Shelf Life (Unit)	24 MonthStore below 25 degree centigrade, away from sunlight and heat	
For generic drugs (me-too Status)	Miura-D 5mg per ml by Getz pharma Pvt Ltd, Registration Number 067547	
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Sichuan Yuxin Pharmaceutical Co Ltd No.51, West Section of Changjiang Road, Shifang Economic Development Zone, South Area, Sichuan	
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	VITAMIN D3 GOOD 200000 IU/ML IM by BOUCHARA-RECORDATI by ANSM Approved	
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Deferred in 339th meeting of RB for below cited shortcomings;		
Section#	Deferment Reason	Firm's Response
1.5.7	Justification shall be submitted for claiming both IM & Oral route of administration for the applied formulation against the literary reference of the innovator drug product.	According to the leaflet of vitamin D3 BON 200000 IU/1mL, ANSM approved, the injection can also be given orally. The leaflet is attached with this letter
1.6.5	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	DML of another API manufacturer is submitted than that details of which are given in module I and module III
	The API manufacturer stated in module I and module III of your application is Sichuan Yuxin Pharmaceutical Co Ltd., whereas DML of Jiangxi Tianxin Pharmaceutical Co., Ltd is submitted. Submit valid DML/cGMP certificate for the drug substance manufacturer as declared in the application.	Firm has submitted copy of DML of M/s Sichuan Yuxin Pharmaceutical Co., Ltd. issued by Sichuan Provincial Drug Administration China valid upto 03-07-2030.
3.2.S.4	· Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. · Reference of drug substance specifications shall be submitted. · Submitted drug substance specifications from drug substance	· Submitted · USP · Submitted

	manufacturer shall be signed and stamped.	
3.2.S.4.4	Submitted COA of drug substance from M/s Variant pharmaceutical does not include performance of bacterial endotoxin test. Justification shall be submitted in this regard.	The bacterial endotoxin test is now included in specifications of drug substance. The BET of drug substance was performed and COA with BET results have been submitted
3.2.P.1	· Selection of excipients for the applied drug product shall be justified against the innovator drug product. · Justification shall be submitted for use of “Butylated hydroxy anisole” as reference product, against the innovator drug product literature.	Two excipients were added in the formulation of Vari-D injection; 01- Caproic acid; That is medium chain triglyceride of Caprylic acid, used by the innovator’s brand. 02- Butylated hydroxy anisole is an antioxidant to prevent the product from oxidation. The used quantity is 0.02%. The data from handbook of excipients is attached for the use of this material in pharmaceutical product.
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	We selected the competitor product based on WHO technical report series No. 902, 2002. The innovator’s brand was not available and we choose the best available brand based on company reputation and product quality. The WHO Technical report series No. 902, 2002 is attached.
3.2.P.3.3	Reference shall be submitted for performance of terminal sterilization of the applied formulation.	We performed the steam sterilization test as general practice according to the conditions mention in USP for liquid ampoules.
3.2.P.5.1	Justification shall be submitted for the declared upper limit of Assay test as 120%, while no overage has been reported in the formulation.	It was a typographic mistake the actual limit of the assay was 90-110% and all our stability results of the product fall within this range. The corrected specifications is now attached.
3.2.P.5.3	· Sample concentrations used for performance of accuracy parameter are not as per those applied in Assay method · Justification shall be submitted that how the “specificity” of the applied method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.	· Sample concentration used for performance of accuracy parameter are as per those applied in Assay method is submitted along with accuracy test result · Specificity with peak purity test is submitted
3.2.P.8.3	· Evidence of availability of “Liquid Particle Counter. Required for the performance of “particulate matter” test, shall be submitted. · Complete raw data sheets for the Assay test performed during stability studies shall be submitted declaring the details of sample and standard solution preparation. · Justification shall be submitted regarding the “modifications” reported in the Audit trail of the chromatograms of stability studies.	· Firm has submitted copy of log book record where LPC has been used for performance of different formulations. Firm has also submitted pictorial evidence of instrument Liquid particle counter LE100 made of China whose validation has been performed by dawn analytical supplies and calibrators. Firm has submitted results of some tests performed on LPC. · Complete raw data sheets for the Assay test performed during stability studies is submitted. · We are unable to change the record of chromatograph during analysis or after analysis in our software that is

		Lab solution (HPLC). Our system (HPLC) is CFR21 with no any relief. When we made any addition or change in our method, all the changes are recorded with reasons in our system (HPLC). Our system is fully loaded means with auto sampler & with cooling features. “Real time Batch” is a software point in which we made our analysis scheme. In this scheme we add these things about analysis, 1- Sample Name 2- Sample ID 3- Tray 4- Vials # 5- Injection volume 6- Data file 7- Method file 8- Batch file 9- Report format file In ‘sample name’ two names are added, one is standard and second is sample, follow ‘sample ID’ in which standard means known and sample means unknown. We are using 5 standards injections in each analysis. These five standards chromatographs are used in find the system suitability test means Relative Standard Deviation (RSD) by calibration curve. Then word ‘Modifications’ develops in the audit trail (as modified postrun batch processing). When we want to make a new analysis schedules in “Real time Batch”, we use old scheme format by changing the requirements, then word ‘Modifications’ develops in the audit trail (as modified realtime batch processing). The word ‘Modifications’ developed by system in audit trail indicates that calibration curves are used in finding the requirements that is RSD etc.
	Justification shall be submitted for the dispensed quantity of drug substance reported in batch manufacturing record of drug product stability batches, against the potency of drug substance determined during drug substance analysis.	Label claim of manufacturer for Vitamin D3=40,000,000 IU/gm; Assay of Vitamin D3 by Variant pharma=99.21%; According to assay the IU units having this lot=39,684,000 IU/gm; Label claim of vari-D injection=200,000 IU/ml or ampoule; Calculation for one ampoule or one ml= 1gm or 1000mg of vitamin D3 contain IU=39,684,000; 1mg of vitamin D3 Contain IU= 39,684,000/1000=39684; 200,000 IU present in = 1/39684 x 200,000 =5.04mg; 5.04 mg of vitamin D3 contains IU= 200,000; Quantity required for 2500 ampoule= 5.04*25000= 12600mg or 12.600gm; Same quantity was mention in the BMR
The application fulfills codal formalities		
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.		
65	Case Category	Priority As Per 257-M of RB (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		(HZ8-L3Q-MHWM, 2024-08-20)
Detail of Fee Submitted		75000.0, 2024-08-06,
The proposed proprietary name / brand name		Derfare Lotion
Label Claim		Each gram contains Halobetasol propionate 0.1 mg (0.01%)Tazarotene 0.45 mg (0.045%)
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		10g, 15g, 45g, 60g, -As per SRO
Shelf Life (Unit)		2 Year(s)Store between 20°C to 25°C, protect from freezing
For generic drugs (me-too Status)		Not Applicable
Pharmacotherapeutic Group of (API)		Antipsoriatic for topical use
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Avik Pharmaceutical Limited A-1/7 & A-1/8, Phase – 1, GIDC, VAPI (Gujarat) - 396195. India,Chongqing Huapont Shengchem Pharmaceutical Co., Ltd No. 666 Rongjun Road, Nanjin Avenue, Hechuan District, Chongqing, P. R. China (401520)
Detail of stability batches of drug product		3 batches, 100 tubes of 45g each (4.5kg)
Documents for the procurement of API with approval from DRAP (in case of Import)		Clearance certificate is issued by DRAP, Karachi for both APIs
Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted PE against DUOBRII Lotion 0.01% / 0.045% by Bausch Health Americas
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Halobetasol 5C; 25C, 60% RH; Tazarotene 25 C, 60 %RH; 40C, 75% RH
The status in reference regulatory authorities		DUOBRII Lotion 0.01% / 0.045% by Bausch Health Americas
GMP status of the firm		GMP certificate issued on the basis of evaluation conducted on 06-06-2023 is submitted
Evidence of approval of manufacturing facility		OCG and Lotion (general) section is approved
Evaluation Remarks		
Deferred in 345th meeting of Registration Board:		
S No.	Deferment Reason	Firm's Response
1	3.2.S: As per drug substance part, Halobetasol exhibits polymorphism. Further it has been submitted that Polymorph III has been used by the applicant. Justify with credible evidence that the polymorphic form used by you is stable and pharmacologically active.	We would like to inform you that, based on literature studies, Halobetasol Propionate exhibit total six polymorphic form among them Form II & III of Halobetasol Propionate (HBP) are more stable form compare to other form. Published literature indicating that the commercially available marketed product ULTRAVATE® also contains Form III. We are also manufacturing the same polymorphic form-III of Halobetasol Propionate.
2	3.2.S.7: Long term Stability studies data of Tazarotene raw material is submitted at 25 C	Long term Stability studies data of Tazarotene raw material at 30°C and 65 % RH till 36th month is submitted

	and 60%RH. The stability data shall be submitted at 30 C and 65 % RH.	
3	3.2.P.8: Real time and accelerated stability studies data for 6 month time point shall be submitted.	Submitted
4	The applied product contains steroidal molecule (Halobetasol). Evidence of separate dispensing facility for steroidal drugs shall be submitted.	We have manufactured this product in general manufacturing facility with conditions that we will manufacturing with safety and protective measures for our staff and personnel which remains in direct contact or are involved in close handling of this drug
5	· Evidence of separate dispensing facility for steroidal drugs shall be submitted. · Submit a copy of the inspection report (DML renewal or cGMP inspection) clearly indicating the availability of a separate dispensing facility at the manufacturing site.	· Firm has submitted revised layout plan approved dated 06-10-2025 indicating dispensing area for steroids. · Firm has referred to letter dated 23-06-2021 of Renewal of DML, Regularization of Manufacturing facility & Grant of additional/ revised section of M/s Genix Pharma Inspection thereof, in which inspection report stated that, Panel inspected the firm as per Approved Layout Plan approved By The DRAP Authority Islamabad
6	As the applied product is a new chemical entity, following additional details are required: · Evidence of approval of applied product in reference regulatory authority (RRA) other than USFDA, as approved by the Registration Board in its 275th meeting; · Details of discontinued/ withdrawn status in any of the RRA as approved by the Registration Board in its 275th meeting, · Indications and precautions (if any) for the applied drug product.	Firm has submitted following response; · SRA Reference is enclosed from Health Canada https://pdf.hres.ca/dpd_pm/00082162.PDF · Product are available in SRA countries i.e Health Canada link attached. · https://health-products.canada.ca/dpd-bdpp/dispatch-repartition · Indication; DUOBRII (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045% is indicated for the topical treatment of plaque psoriasis in adults.

The application fulfills codal formalities

Decision

Approved

66	Case Category	New Section (Dr. Farhad Ullah)
	Name, address of Applicant.	NovaMed Pharmaceuticals(Pvt.)Ltd 28-KM Ferozepur Road Lahore (000590)
	Application Form Dy. No / Tracking ID & date of submission	(WHL-YQ5-YP8Q, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-11-07,
	The proposed proprietary name / brand name	Vironov
	Label Claim	Each Vial Contains: Acyclovir Sodium eq. to Acyclovir.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -As per SRO

Shelf Life (Unit)	2 Year(s)Store away from direct sunlight, heat and moisture below 30C
For generic drugs (me-too Status)	Acyclovir injection 500mg by M/s Abbott Laboratories (Reg#21397)
Pharmacotherapeutic Group of (API)	Antivirals
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	RAJASTHAN ANTIBIOTIC LTD.,
Detail of stability batches of drug product	3 batches having batch size of 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate cleared dated 27-12-2023 specifying 01kg Acyclovir sterile powder. The invoice is cleared by AD (I&E) DRAP.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Acyclovir 500mg injection manufactured by M/s Abbot Laboratories Ltd.
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-A
The status in reference regulatory authorities	Zovirax for Injection 500mg, USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of additional sections dated 25-10-2023 specifying Dry powder for Injection (General) section.
Evaluation Remarks	
Deferred in 352nd meeting of RB;	
Deferment Reason	Firm's Response
Deferred for submission of clarification of the applied formulation as pre-lyophilized ready-to-fill powder and evidence of availability of the lyophilization facility.	We would like to clarify that the proposed product Acyclovir Powder for Injection is formulated as a pre-lyophilized ready-to-fill (RTF) sterile powder, and no lyophilization step is performed at the finished dosage form level. The active pharmaceutical ingredient (Acyclovir) used in the formulation is supplied as a pre-lyophilized sterile API, which complies with the relevant pharmacopeial specifications and it is evident from · API import license, · GMP of API manufacturer · 3.2.S drug substance (DMF) The finished product manufacturing process consists of aseptic dispensing, filling, and sealing under Grade A conditions, followed by terminal inspection. Therefore, lyophilization of the filled vials is not required. 3.2.P.3.3 – Manufacturing process flow diagram clearly showing no lyophilization step · Manufacturing Process state aseptic filling of pre-lyophilized powder Batch manufacturing record (BMR) absence of lyophilization Since lyophilization is not part of the finished product manufacturing process, availability of a lyophilization facility is not applicable for the proposed product. Kindly approve applied

	product as per our label claim which does not mention lyophilized. The supporting documents are also attached.	
	The application fulfills codal formalities	
	Decision	
	Rejected	
	Registration Board decided to reject the instant application since the firm does not have lyophilization facility and applied formulation is manufactured by freeze-drying technique	
67	Case Category	Export Facilitation (Dr. Farhad Ullah)
	Name, address of Applicant.	Herbion Pakistan (Pvt.) Ltd. Industrial Triangle, Kahuta road, Humak, Islamabad (000795)
	Application Form Dy. No / Tracking ID & date of submission	(R2Y-1BB-Q5QX, 2024-03-15)
	Detail of Fee Submitted	30000.0, 2023-11-28,
	The proposed proprietary name / brand name	vidaglu
	Label Claim	Each film coated tablet contains: Vildagliptin.....50mg (Innovator specifications)
	Reference to Finished product specifications	As per Innovators Specificatio
	Proposed Pack Size	2*7's & 2*14's -As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 C
	For generic drugs (me-too Status)	Galvus 50 mg tablet by Novartis
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Venkata Narayana Active Ingredients Private Limited Venkata Narayana Towers, 3rd Floor, New No. 60, Old No. 35, Venkatanarayana Road, T.Nagar district Andhra
	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	https://www.ema.europa.eu/en/medicines/human/EP
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Replied submitted on e-App general request form tracking ID; ETP-M2T-MM9G Deferred in 340th meeting of Registration Board:	
	S No.	Firm's Response
	1	Submitted

2	Stability conditions have been overwritten in the submitted drug substance stability study reports. Justification shall be submitted in this regard.	Upon the appointment of a new technical team member, we experienced an oversight during dossier review process. Unfortunately, due to the urgency of submitting the data, a typographic error occurred, leading to the incorrect stability conditions being recorded. We acknowledge the importance of maintaining rigorous standards in our submissions and understand the implications of this oversight. Moving forward, we have implemented additional checks and balances within our review process to prevent similar issues from arising in the future. Our team is committed to ensuring compliance with all regulatory requirements and upholding the integrity of our data.
3	Long term stability studies data till claimed shelf life shall be submitted at Zone IV conditions.	Long term stability studies data of API as per zone IV-B till 36th months is submitted.
4	Documents confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted.	Firm has submitted copy of form 6 cleared dated 09-08-2021 specifying 1.5kg VILDAGLIPTIN In-House in name of Herbion Pakistan Pvt. Ltd. Firm has also submitted copy of commercial invoice cleared dated 16-08-2021 specifying 1.5kg VILDAGLIPTIN In-House in name of Herbion Pakistan Pvt. Ltd.
5	Stability data of 6th month time point shall be submitted.	Submitted

The application fulfills codal formalities

Decision

Approved

68	Case Category	Routine (Dr. Farhad Ullah)
	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	(JWJ-XDM-PRY1, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	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-As per SRO
	Shelf Life (Unit)	2 Year20-25C
	For generic drugs (me-too Status)	Postpon-M Tablet by OBS Pharma 073532
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-

The status in reference regulatory authorities	MHRA approved
Detail of previous approval	Norista 5mg Tablet in 352nd meeting of RB

Evaluation Remarks

S No.	Deficiencies	Firm Response
1	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. extract of the minutes of the relevant meeting of Registration Board and 3. undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification	Firm has submitted module I, undertaking, copy of Registration Board minutes and copy of registration letter of approved product.

Decision

Approved

69	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(AUV-6GP-TZSZ, 2024-05-10)
	Detail of Fee Submitted	30000.0, 2023-09-05,
	The proposed proprietary name / brand name	Tacrowin Ointment 0.03%
	Label Claim	Each gm Contains: Tacrolimus (as Monohydrate).....0.3mg (0.03%w/w) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Aimus Ointment by Aims Pharma
	Pharmacotherapeutic Group of (API)	Immunosuppressants ATC Code; L04AD
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	FISHFA BIOGENICS, Survey No. 43/2/2, 47/2, 50/1/2, 50/2, kuwadva Wankaner Road, Surya Rampara – 360003, Dist: Rajkot, Gujarat, India

Detail of stability batches of drug product		3 batches having batch size of 1200 tubes each
Documents for the procurement of API with approval from DRAP (in case of Import)		Firm has submitted copy of form 6 dated 04-02-2022 specifying 20gm Tacrolimus
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE studies performed against ECZEMUS 0.03% Ointment by Brookes Pharma
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability study data not readable
The status in reference regulatory authorities		Tacrolimus Accord 0.03% ointment MHRA Approved
GMP status of the firm		Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
Evidence of approval of manufacturing facility		Firm has submitted copy of grant of additional section dated 03-06-2016 specifying Cream/Ointment/Gel (General) section.
Evaluation Remarks		
Sr. No	Shortcomings	Firm's Response
1.	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 cGMP certificate of manufacturer issued by Food & Drugs Control Administration Gandhinagar, Gujarat State, India upto 18-04-2027
2.	Copy of executed BMR shall be submitted	Submitted
3.	Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug product manufacturer is required.	Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug product manufacturer is submitted.
4.	Analytical method verification report of drug substance performed by drug product manufacturer is required	Submitted
5.	Clear readable copies of stability study data of API as per zone IV-A till claimed life shall be submitted	Clear readable copies of stability study data of zone IV-A till 24th months is submitted
6.	Submit pictorial evidence of comparator product indicating name of manufacturer, batch number, manufacturing date and expiry date against which pharmaceutical equivalence studies has been performed	Firm has submitted pictorial evidence of product
		Brand name; Eczemus 0.03% ointment, Batch# , Manufacturing date; 03-2023, Expiry date; 03-2026, Manufacturer; Brooks Pharma
7.	Detailed analytical procedures of all tests given in finished product specifications shall be submitted	Submitted
8.	Submit the analytical method validation protocol and report confirming that the validated method is	Submitted

	identical with the submitted analytical procedure.	
9.	The result of pH test has not been report in batch analysis report as given in specifications	The pH of each batch was noted in the analyst mistakenly missed to write in analysis report, finish products having pH is attached
10.	CoA of Primary / Secondary Reference Standard used in testing of trial batches shall be submitted	Submitted
11.	Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP	Firm has submitted copy of form 6 attested b DRAP field office. Firm has also submit invoice.
The application fulfills codal formalities		
Decision		
Approved		
70	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
	Application Form Dy. No / Tracking ID & date of submission	(LPL-HNR-LEM2, 2024-05-09)
	Detail of Fee Submitted	75000.0, 2024-05-08,
	The proposed proprietary name / brand name	BEGENT OINTMENT
	Label Claim	EACH GRAM CONTAINS: BETAMETHASONE DIPROPIONATE 0.64MG EQUIVALENT TO BETAMETHASON.....0.5MG GENTAMICIN SULPHATE 1.7MG EQUIVALENT TO GENTAMICIN.....
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	15gm-As per SRO,30gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool dry place, below 30oC.
	For generic drugs (me-too Status)	RELIGENT-B OINTMENT BY RELIANCE PHARMA
	Pharmacotherapeutic Group of (API)	Betamethasone Dipropionate(Corticosteroids) ATC code: D07XC01 Gentamicin Sulfate (Aminoglycoside Antibiotics) ATC code: J01GB03
	Name, address of Manufacturing site:	Global Pharmaceuticals Pakistan-Plot 8, Street No. S-8, R.C.C.I, Industrial Estate Rawat, Islamabad-Pakistan-
	Name & address of API manufacturer	ENVEE DRUGS PVT LTD ADDRESS: N . H . No. 8, DUMRAL-387 355, TA. NADIAD, DIST KHEDA GUJRAT, INDIA.,Fuan Pharmaceutical group Yantai justaware Pharmaceutical Co. Ltd. ADDRESS: No. 1 Yanfu Road, Zhifu District, Yantai, Shandong Province

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 loan letter from M/s Reliance pharma to M/s Global pharmaceuticals for procurement of API. Firm has submitted copy of clearance certificate dated 13-06-2023 and 14-07-2023 specifying 05kg Betamethasone Dipropionate and 30gm Gentamicin Sulphate respectively in name of M/s Global Pharmaceuticals
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Effigenta Ointment manufactured by M/s Mass 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	Diprogenta ointment Germany Approved
GMP status of the firm	Applicant; Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-01-2022. Manufacturer; Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-01-2022.
Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 04-07-2022 specifying Ointment/Cream Section (General)

Evaluation Remarks

Sr. No	Shortcomings	Firm's Response
1.	Copy of cGMP certificate / GMP inspection report of both applicant and contract manufacturer conducted within last three years shall be submitted	Applicant; Firm has submitted copy of cGMP certificate of firm based on inspection dated 02-05-2024. Manufacturer; Firm has submitted copy of cGMP certificate of firm based on inspection dated 19-01-2022.
2.	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for betamethasone and gentamycin issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate manufacturer for betamethasone issued by Food and Drug Control administration Gujarat state India valid upto 04-08-2025. Firm has submitted copy of cGMP certificate manufacturer for Gentamycin issued by Shanghai Food and Drug administration China valid upto 2024.
3.	Module 2 of your application has not been uploaded	Submitted
4.	Copy of executed BMR shall be submitted	Submitted
5.	Submit the analytical methods used for the assay of Gentamycin API by both the drug substance manufacturer and the drug product manufacturer.	Both drug substance manufacturer and drug product manufacturer have referred to microbiological assay for antibiotics.
6.	Submit the analytical method for the assay of Gentamycin in the applied drug product Begent Ointment.	Firm has referred to bio-assay method for assay of gentamycin
7.	Submit the method validation protocol and report for Gentamycin in the applied drug	Submitted

	product Begent Ointment.	
8.	Clarification is required as stability study data has been submitted for only two batches, whereas at least three batches with scientifically justified batch sizes sufficient to perform testing throughout the claimed shelf life are required.	Firm has referred to the DRAP guidelines for s testing of specialized preparations, such as aeros specialized other preparations, specify the minimum batch size for stability studies is ge 500 units to ensure meaningful results through product's shelf life. This is in line with intern practices as outlined by the ICH and EMA. In our submission, stability study data has provided for two batches of Begent Ointment, have been manufactured and tested followi established protocol for stability analysis.
The application fulfills codal formalities		
Decision		
Deferred		
Deferred for submission of following;		
• Copy of cGMP certificate / GMP inspection report of contract manufacturer conducted within last three years • Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for betamethasone and gentamycin issued by relevant regulatory authority of country of origin		
71	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(JXW-TZH-AS56, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Empamet 10/1000mg XR Tablet
	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....10mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Xenglu-Met 10mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Provided for 3 batches for long-term and accelerated at Zone IV-a
	Documents for the procurement of API with approval from DRAP (in case of Import)	Provided

Pharmaceutical Equivalence and Comparative Dissolution Profile		CDP data but no report
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Provided for both APIs
The status in reference regulatory authorities		Synjardy 10mg/1000mg XR tablet by M/sBoehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
GMP status of the firm		Provided
Evidence of approval of manufacturing facility		Provided
Evaluation Remarks		
Deferred in 351st meeting of RB;		
S No	Deferment Reason	Panel Inspection Observations/Remarks and conclusion
1	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that 'they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format.' Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trial report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.
Decision		
Deferred		
The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection		
72	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(GY4-242-X6BM, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Empamet 12.5mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)
	Label Claim	Each Film Coated Extended Release tablet contains: Empagliflozin.....12.5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Empaa M XR(Empagliflozin + Metformin HCl) 12.5mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Provided for 3 batches long-term and accelerated as per Zone IV-a
Documents for the procurement of API with approval from DRAP (in case of Import)	Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP data but not complete report
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided for both APIs
The status in reference regulatory authorities	SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 12.5mg/1000mg M/s BOEHR
GMP status of the firm	Provided
Evidence of approval of manufacturing facility	Provided

Evaluation Remarks

Deferred in 351st meeting of RB;

S No	Deferment Reason	Panel Inspection Observations/Remarks and conclusion
1	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that 'they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format." Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trial report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

73	Case Category	Routine (Dr. Farhad Ullah)

Name, address of Applicant.		Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
Application Form Dy. No / Tracking ID & date of submission		(J31-8S2-A29E, 2024-03-12)
Detail of Fee Submitted		30000.0, 2024-01-26,
The proposed proprietary name / brand name		Empamet 25mg/1000mg XR Tablet (EMPAGLIFLOZIN+METFORMINHCl)
Label Claim		Each Film Coated Extended Release tablet contains: Empagliflozin.....25mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
Reference to Finished product specifications		As per Innovators Specification
Proposed Pack Size		1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)		2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)		Empaa M XR(Empagliflozin + Metformin HCl) 25mg/1000mg M/s Weather Folds PHARMACEUTICALS Registration # 105282
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		
Detail of stability batches of drug product		Provided for 3 batches for long-term and accelerated studies at Zone IV-a
Documents for the procurement of API with approval from DRAP (in case of Import)		Provided
Pharmaceutical Equivalence and Comparative Dissolution Profile		CDP data but not the report
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Provided for both APIs
The status in reference regulatory authorities		SYNJARDY XR- empagliflozin, metformin hydrochloride tablet, extended release 25mg/1000mg M/s BOEHRIN
GMP status of the firm		Provided
Evidence of approval of manufacturing facility		Provided
Evaluation Remarks		
Deferred in 351st meeting of RB;		
S No	Deferment Reason	Panel Inspection Observations/Remarks and conclusion
1	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that 'they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format.' Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not

available in the online report formats. Conclusion:
Considering the firm's response that HPLC software was not 21CFR compliant and audit trial report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

74	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(7SP-NHV-459J, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2024-01-26,
	The proposed proprietary name / brand name	Empamet 5/1000mg XR Tablet
	Label Claim	Each film coated extended release tablet contains: Empagliflozin.....5mg (Immediate release coat) Metformin HCl.....1000mg (Extended release core)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Xenglu-Met 5mg/1000mg XR tablet by M/s Hilton Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Synjardy 5mg/1000mg XR tablet by M/s Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT06877
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deferred in 351st meeting of RB;	

S No	Deferment Reason	Panel Inspection Observations/Remarks and conclusion
1	The Registration Board directed to conduct a Product Specific Inspection to verify the audit trail by a panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that 'they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format.' Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trial report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

75	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	(1MT-SDS-731U, 2024-06-27)
	Detail of Fee Submitted	30000.0, 2024-06-24,
	The proposed proprietary name / brand name	Elgolix 200mg Tablet
	Label Claim	Each film coated tablet contains; Elagolix (as Elagolix sodium) 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,28s-As per SRO,56s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C (Excursions permitted between 15°C to 30°C)
	For generic drugs (me-too Status)	Elgozon 200mg tablet by M/s Horizon
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonists Used for management of conditions like pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Chongqing Kangle Pharmaeutical Co. ltd.,
	Detail of stability batches of drug product	Batches: 258B23, 259B23, 260B23 (Batch size: 2500 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)	Form 6 dated 08-09-2023 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 Orlissa 200mg tablet by Abbvie USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months real time and 06 months acc data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Product is USFDA approved. ORILISSA 200MG TABLET, Manufactured by: ABBVIE
	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
	Dissolution testing has not been included in PE studies whereas CDP data is included. Please performed dissolution testing under PE studies and submit the results	Dissolution testing under PE studies against Orlissa 200mg Tablet by M/s Ab
	Provide documents confirming import of drug substance including clearance certificate, GD, bill of lading/airway bill, invoice etc since only form 6 is submitted.	Form 6 dated 08-09-2023 for 2.5kg Copy of airway bill, unattested invoice,
76	The application fulfills the codal formalities.	
	Decision	
	Approved	
	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	(ELD-QNT-UR3U, 2024-07-02)
	Detail of Fee Submitted	30000.0, 2024-06-24,
	The proposed proprietary name / brand name	Elgolix 150mg Tablet
	Label Claim	Each film coated tablet contains; Elagolix (as Elagolix sodium) 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,28s-As per SRO,56s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 25°C (Excursions permitted between 15°C to 30°C)
	For generic drugs (me-too Status)	a. Manufacturer: M/s CCL Pharmaceutical (Pvt.) Ltd. b. Brand Name: ELIX 150mg Tablet c. Strength: 150MG d. Composition: Each film coated tablet contains; Elagolix sodium eq to Elagolix.... 150mg e. R
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonists Used for management of conditions like pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids.
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	
Detail of stability batches of drug product	Batches: 255B23, 256B23, 257B23 (Batch size: 2500 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)	Form 6 dated 08-09-2023 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 Orilissa 150mg tablet by Abbvie USA.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	24 months real time and 06 months acc data of 03 batches according to zone IV-A.
The status in reference regulatory authorities	Product is USFDA approved. ORILISSA 150MG TABLET, Manufactured by: ABBVIE
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
Dissolution testing has not been included in PE studies whereas CDP data is included. Please performed dissolution testing under PE studies and submit the results	Dissolution testing under PE studies have been performed against Orilissa 200mg Tablet by M/s Abbvie USA.
Provide documents confirming import of drug substance including clearance certificate, GD, bill of lading/airway bill, invoice etc since only form 6 is submitted.	Form 6 dated 08-09-2023 for 2.5kg material is submitted, Copy of airway bill, unattested invoice, copy of packing list.
The application fulfills the codal formalities.	
Decision	
Approved	
77	Case Category
	Routine (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
	(534-NUJ-Y5QL, 2025-09-17)
	Detail of Fee Submitted
	37000.0, 1700 2025-07-18, 2025-09-12
	The proposed proprietary name / brand name
	Vesopride 50mg Tablet
	Label Claim
	Each tablet contains: Levosulpiride USP 50 mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	10,s 20,s 30,s-As per SRO
	Shelf Life (Unit)
	24 Year(s)Storage conditions 30°C ± 2°C and 65% ± 5% RH
	For generic drugs (me-too Status)
	Levopraid tablet by M/s Pacific Pharma
	Pharmacotherapeutic Group of (API)
	Atypical antipsychotic (Benzamide Derivative)

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Cureworth Drugs & Intermediates Pvt. Ltd. PlotNo:N-49, Additional MIDC Zone, Anand Nagar, Ambernath(East), Ambernath-421506, Maharashtra, India. Contact Persons: Mr. Ramchandra Nishad (Managing Director) Mrs. Swati Nishad (Director) Mobile no.+91
Detail of stability batches of drug product	(Batch Nos.: LVS004T, LVS005T, LVS006T) Batch size: 1000 tablets long-term (30°C ± 2°C / 65% RH ± 5% RH) and accelerated (40°C ± 2°C / 75% RH ± 5% RH) conditions.
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Aulton Pharma for 250grams of material is submitted. CLearnce certificate dated 19-02-2024 from M/s Aulton Pharmaceuticals is submitted,
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Levopraid 50mg tablet by M/s Pacific Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	(Batch nos.:LVS004T, LVS005T, LVS006T) Long-term conditions: 30°C ± 2°C / 65% RH ± 5% RH for Zone IVa). Accelerated conditions: 40°C ± 2°C / 75% RH ± 5% RH.
The status in reference regulatory authorities	AIFA Italy Approved
GMP status of the firm	New License approved w.e.f. 02-06-2021
Evidence of approval of manufacturing facility	Tablet Geneal Section is approved
Evaluation Remarks	

Observations	Response
1. Submission clearance certificate of M/s Aulton Pharma.	CLearnce certificate dated 19-02-2024 from M/s Aulton Pharmaceuticals is submitted,
2. Clarification since you have developed UV-spectrophotometric method instead of HPLC method for dissolution testing.	Levosulpiride tablet is non pharmacopeial drug product and its monograph is not available in any pharmacopoeia. HPLC method for the assay of product was selected and validated to check contents or any degraded product or any interference of excipients, however UV method for dissolution is generally acceptable for the product as levosulpiride gives a strong, well defined UV absorption at 232nm, therefore UV method was adopted for dissolution. Moreover, in many pharmacopoeias specifically USP most of the dissolution methods are given by UV method while assay is given by HPLC method, e.g., Ciprofloxacin tablet, Levofloxacin tablet and many more. Additionally, many research studies use the UV method for dissolution testing of Levosulpiride as well. Therefore, form this evidence it can be concluded that UV method is acceptable for dissolution for non-pharmacopeial and pharmacopeial products unless otherwise specified by individual monograph or innovator.
3. Submission BMRs of stability batches.	Submitted
The application fulfills all the codal formalities.	
Decision	
Approved	
Subject to verification of loan letter.	
78	Case Category
	Routine (Farooq Aslam)
	Name, address of Applicant.
	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission
	(NUM-52T-7TN7, 2024-05-22)
	Detail of Fee Submitted
	75000.0, 2024-05-16,
	The proposed proprietary name / brand name
	Nebicare-H Tablet 5mg + 12.5mg
	Label Claim
	Each film coated tablet contains: Nebivolol Hydrochloride equivalent to Nebivolol.....5mg Hydrochlorothiazide.....12.5mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	14's-De-Controlled
	Shelf Life (Unit)
	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)
	Nibovo HCT tablet 5/25 Reg No. 125084 by M/s Scilife
	Pharmacotherapeutic Group of (API)
	Anti-hypertension
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	CTX LifeScineces pvt. limited.,Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd.,

Detail of stability batches of drug product	Batches: EXP-T-1198 (1000 tab), PLT-T-179 (2000 tab), PLT-T-180 (2000 tab) 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)	Nebivolol: Clearance certificate dated 22-03-2022 for 15kg material HCT: Clearance certificate dated 03-10-2022 for 50kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product Nebilet Plus tablet 5/12.5 by M/s Berlin-Chemie AG, Germany.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Nebivolol: 06 months accelerated and 48 months real time stability data according to the conditions of zone IV -A for 03 batches. HCT: 06 months accelerated and 72 months real time stability data according to the conditions of zone IV -A for 03 batches.
The status in reference regulatory authorities	Nebilet Plus 5mg + 12.5mg Tablet HPRA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 02-11-2023.
Evidence of approval of manufacturing facility	.Tablet General Section is approved as per submitted GMP.

Evaluation Remarks	
1	1. The first sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
2	2. The second sentence is well-written and provides a clear example of the concept.
3	3. The third sentence is a bit repetitive and could be rephrased to avoid redundancy.
4	4. The fourth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.
5	5. The fifth sentence is a good start, but it is a bit long and could be split into two sentences for better readability.
6	6. The sixth sentence is well-written and provides a clear example of the concept.
7	7. The seventh sentence is a bit repetitive and could be rephrased to avoid redundancy.
8	8. The eighth sentence is a good conclusion, but it could be strengthened by adding more evidence or examples.

Observations	Response
Provide PE and CDP studies along with the details of the product against which the studies have been performed including brand name of, manufacturer and analytical record	PE and CDP studies have been performed against 5-25 by M/s Berlin-Chemie AG, Germany.
complete analytical record for AMV studies.	Submitted
Provide complete calculation for final weight adjustment of powder for potency for drug substance.	Submitted
It has been observed that the reference product i.e. Nebilet Plus tablet (as per the reference provided in submitted dossier) is not approved in available database of Germany, instead, Nebelit tablet with single ingredient is approved. https://portal.dimdi.de/amguifree/am/searchresult.xhtml Please provide approval status of the applied product in any reference regulatory authority	Submitted. Nebilet Plus 5mg + 12.5mg Tablet is a medicine/for-human-use/authorised- medicinal product. Data=eyJpZCI6bnVs bCwicz2tpcCI6MCwidG8iOm51bGwsImFkd mVydGlzaW5nQ29 uZGI0aW91bGwsImFk dmVydGlzaW5 nQ29uZGI0a W91bGwsImFk dmlsaXR5Ijpu dWxsLCJhdGNDb 2RIljpGx9f Q%3D%3D

The application fulfills all the codal formalities.

Decision

Approved

79	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Barrett Hodgson Pakistan (Pvt.) Ltd F/423, Site, Karachi (000457)
	Application Form Dy. No / Tracking ID & date of submission	(6W4-G5Z-EWXA, 2024-05-20)
	Detail of Fee Submitted	75000.0, 2024-05-16,

The proposed proprietary name / brand name	Nebicare-H Tablet 5mg + 25mg
Label Claim	Each film coated tablet contains: Nebivolol Hydrochloride equivalent to Nebivolol.....5mg Hydrochlorothiazide.....25mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Nibovo HCT tablet 5/25 Reg No. 125084 by M/s Scilife
Pharmacotherapeutic Group of (API)	Anti-hypertension
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CTX LifeScineces pvt. limited.,Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd.,
Detail of stability batches of drug product	Batches: EXP-T-1199 (1000 tab), PLT-T-181 (2000 tab), PLT-T-181 (2000 tab) 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)	Nebivolol: Clearance certificate dated 22-03-2022 for 15kg material HCT: Clearance certitiae dated 03-10-2022 for 50kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product Nebilet Plus tablet 5-25 by M/s Berlin-Chemie AG, Germany.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Nebivolol: 06 months accelerated and 48 months real time stability data according to the conditions of zone IV -A for 03 batches. HCT: 06 months accelerated and 72 months real time stability data according to the conditions of zone IV -A for 03 batches.
The status in reference regulatory authorities	Nebilet Plus 5mg + 25mg Tablet, HPRA Approved.
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 02-11-2023.
Evidence of approval of manufacturing facility	Tablet General Section is approved as per submitted GMP.
Evaluation Remarks	
Observations	Response
Provide PE and CDP stduies along with the details of the product against which the studies have been performed including brand name of,manufacturer and analytica record	PE and CDP studies have been performed against the re Nebilet Plus tablet 5-25 by M/s Berlin-Chemie AG, Ger
complete analytical record for AMV studies.	Submitted
Provide complete calculation for final weight adjustment of powder for potency for drug substance.	Submitted
It has been observed that the reference product i.e. Nebilet Plus tablet (as per the reference provided in submitted dossier) is not approved in available database of Germany, instead, Nebelit tablet with single ingredient is approved.	Submitted. Nebilet Plus 5mg + 25mg Tablet, HPRA App https://www.hpra.ie/find-a-medicine/for-human-use/authlmedicines?data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MT,TmViaWxldCBQbHVzIiwib3JkZXIiOiJMYXN0VXBkYX

	https://portal.dimdi.de/amguifree/am/searchresult.xhtml Please provide approval status of the applied product in any reference regulatory authority	Iiwic3RhdHVzIjoiQXV0aG9yaXNlZCIsImZpbHRlcuMn VsbCwidG8iOm51bGwsInJvdXRlcyI6bnVsbCwicGxhOm 51bGwsImFkdmVydGlzaW5nQ29uZGl0aW9ucyI6bnV0aW5nQXZha WxhYmlsaXR5IjpudWxsLCJhdGNDb2RlljpudWxsLCR5cGUiOm51bGx9fQ%3D%3D
	The application fulfills all the codal formalities.	
	Decision	
	Approved	
80	Case Category	Routine (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	(B6H-9GL-16Q8, 2024-05-21)
	Detail of Fee Submitted	75000.0, 9400 2024-05-03, 2025-10-31
	The proposed proprietary name / brand name	Aclovir Eye Ointment 30mg/g
	Label Claim	Each gram contains: Acyclovir.....30mg/g (3%w/w)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5g, 10g and 15g -As per SRO
	Shelf Life (Unit)	24 Year(s)Store Below 25°C
	For generic drugs (me-too Status)	could not be confirmed
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hubei Yitai Pharmaceutical Co., Ltd, Fengchengyuan, Sub urban District of Tianmen City, Hubei Province, China
	Detail of stability batches of drug product	Batches: 23SB-518-01, 23SB-518-01, 23SB-518-02 (Batch size: 100 tubes * 10g) 06 months real time and 06 months accelerated stability data according to zone IV-A, submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearnce certificate dated 23-06-2023 for 50kg of material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against Zovirax 30mg/g ointment by M/s glaxo smit kline.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 month accelerated stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Zovirax Ointment 30mg/g by Glaxo Operations UK Limited, Barnard Castle, Durham DL12 8TD, UK/Mhra
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 06-06-2023 (Genix)
	Evidence of approval of manufacturing facility	Ointment/Cream/Gel/Lotion (General) Section is approved (Genix)

Evaluation Remarks

The method is not as per BP 2025, please submit the requirement. Moreover, system suitability as per BP is performed by spiking the dilution with impurity C. Please submit the required results.	The firm has submitted revised specifications as per B.P along with analytical method verification studies. Fee challan number 176664813948 dated 31-10-2025 (Rs. 9400). But the firm did not submit the system suitability testing.
The firm was asked to provide system suitability testing according to BP by spiking the testing solution with impurity C.	Submitted

The application fulfills all the codal formalities.

Decision

Approved

81	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(7VL-TP4-163G, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	Voferin (Iron as Ferric Carboxymaltose) Injection 500mg / 10mL
	Label Claim	Each 10mL vial contains: Iron as Ferric Carboxymaltose 500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10mL x 1's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C
	For generic drugs (me-too Status)	FCM Injection 500mg / 10mL
	Pharmacotherapeutic Group of (API)	Antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical Co. Ltd., China. Address: No. 18 Jichang Road, Lishui Economic and Technological Development Zone, Nanjing City, Jiangsu Province, China. Postal code: 211200
	Detail of stability batches of drug product	Batches: TR-VOFERIN-03, TR-VOFERIN-04, TR-VOFERIN-02, (Batch Size: 250 vials) 06 months real time and 06 months accelerated stability data according to the conditions of zone V-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearnce certificate dated 23-02-2023 for 10Kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e Ferinjet Injection

		500mg/10mL, by M/s IDT Biologicka GmbH., Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data according to Zone IV-A for 03 batches submitted.
	The status in reference regulatory authorities	(MHRA Approved)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 14-02-2024.
	Evidence of approval of manufacturing facility	Liquid injectable ampoule section is approved.
	Evaluation Remarks	
	Observations	Response
	You have adopted Titration method for analysis of Iron content instead of AAS, please clarify.	As informed by our R&D department, we would like to inform that, since the product is non-pharmacopoeial, there is no compendial method available for assay determination. The testing method provided by the API Manufacturer is based on titration, which has been considered appropriate for the analysis of the drug product to ensure consistency in results between the API and finished product stages. Accordingly. titration method was adopted for analysis.
	Analytical method validation studies performed by drug product manufacturer for DS.	Submitted.
	The method submitted by drug product manufacturer describes the determination end point by indicator while the rug substance manufacturer has used potentiometer for determination of end point in assay method, Screen shot of the submitted method was forwarded to the applicant. The method from drug substance manufacturer describes the end point determination through potentiometer while the finished product manufacturer has described visual method.	
	Decision	
	Approved	
82	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	(P5S-BYL-7J1U, 2024-08-28)
	Detail of Fee Submitted	, 75000.0 , 2022-10-17
	The proposed proprietary name / brand name	Anelta (lefamulin) Tablets 600mg
	Label Claim	Each Film Coated Tablet contains: Lefamulin (as Lefamulin Acetate).....600mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	4 Year(s)Store at room temperature 20°C - 25°C
	For generic drugs (me-too Status)	this strength cannot be confirmed
	Pharmacotherapeutic Group of (API)	Pleuromutilin Antibiotic/Other antibacterial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Yibin Hongguang Pharmaceutical Co., Ltd. Address: Luolong County Nanxi District, Yibin

	City, Sichuan Province, China, PC - 644100
Detail of stability batches of drug product	Batches: TR-LET-02, TR-LET-03, TR-LET-04 (Batch size: 600 tablets) 06 months accelerated and 06 months real time data is submitted according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 06-03-2023 is submitted for 1.5kg material. Unattested invoice is submitted. The API is Form B as per declaration by the DS manufacturer.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Xenelta tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 09 months real time stability data according to the conditions of zone IV-A for 03 batches.
The status in reference regulatory authorities	Health Products Regulatory Authority (HPRA)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 29-01-2024.
Evidence of approval of manufacturing facility	PE and CDP studies have been performed against the reference product i.e. Xenelta 600mg tablet by M/s Nabriva Therapeutics, Dublin, Ireland.
Evaluation Remarks	
Observations	Response
Submit clearance certificate 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.	Form 6 dated 06-03-2023 is submitted for 1.5kg material. Unattested invoice is submitted.
Provide details about the absolute stereochemistry of the drug substance used in your studies, since the API manufacturer has not performed any specific test.	The XRD Structure Analysis spectrum (Absolute stereochemistry) of the drug substance Lefamulin Acetate is submitted.
Specify the polymorphic form of the drug substance used in the manufacturing of stability batches.	As informed by our R&D Department, we would like to inform you that the Lefamulin Acetate polymorphic form B is used in the manufacturing of stability batches. The certificate of analysis of API used in manufacturing of trial batches mentioning polymorphic form B is
Submit 6th month stability study data.	Submitted
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.	As informed by our R&D Department, we would like to inform you that the Lefamulin is considered a semi-synthetic antibiotic, which means it is chemically modified after being derived from a natural product (pleuromutilin). While the initial process involves fermentation, the final product undergoes chemical synthesis, and it is not classified as a biologic.
The application fulfills all the codal formalities.	
Decision	

	Approved	
83	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(HYV-TH6-EJ1X, 2024-05-29)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	Artu-M Tablet
	Label Claim	Each film coated tablet contains: Ertugliflozin as L-Pyroglutamic Acid.....7.5mg Metformin HCl.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	A blister pack of 1 -As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30 C, store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Ertuvia-M tablet by Ferozsos
	Pharmaceutical Group of (API)	blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Zhejiang Hongyuan Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Batches: EMT-7.5/1000-T001 , EMT-7.5/1000-T002 , EMT-7.5/1000-T003 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Ertugliflozin: AD attested invoice no. HY200108-I dated 26-02-2020 issued vide dy.no. 2281/202-DRAP dated 04-03-2020 for 918grams material. Metformin: Clearance certificate dated 18-09-2022 for Metformin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Segluromet tablet 7.5/1000 by M/s Pfizer, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ertugliflozin: 06 months accelerated and 24 months real time stability data accoridng to zone iv-a for 03 batches. Metformin: 06 months accelerated and 48 months real time stability data acc to zone iv-a for 03 batches.
	The status in reference regulatory authorities	SEGLUROMET tablets Merck & Co., Inc. USFDA
	GMP status of the firm	DML is renewed w.e.f. 07-04-2025
	Evidence of approval of manufacturing facility	Tablet General Section is approved
84	Evaluation Remarks	
	The application fulfils all the codal formalities.	
	Decision	
	Approved	
84	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)

	Application Form Dy. No / Tracking ID & date of submission	(J43-RAX-727X, 2024-05-23)
	Detail of Fee Submitted	30000.0, 2024-04-19,
	The proposed proprietary name / brand name	Artu-M Tablet
	Label Claim	Each film coated tablet contains: 3.24 mg Ertugliflozin L-Pyroglutamic Acid (Equivalent to 2.5mg of Ertugliflozin) Metformin HCl....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	A blister pack of 1 -As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 30 C, store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Ertuvia-M tablet 2.5/1000mg
	Pharmaceutical Group of (API)	blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited,Zhejiang Hongyuan Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	Batches: EMT-2.5/1000-T001 , EMT-2.5/1000-T002 , EMT-2.5/1000-T003 (Batch size: 1000 tablets) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Ertugliflozin: AD attested invoice no. HY200108-I dated 26-02-2020 issued vide dy.no. 2281/202-DRAP dated 04-03-2020 for 918grams material. Metformin: Clearance certificate dated 18-09-2022 for Metformin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Segluromet tablet 2.5/1000 by M/s Pfizer, Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ertugliflozin: 06 months accelerated and 24 months real time stability data accoridng to zone iv-a for 03 batches. Metformin: 06 months accelerated and 48 months real time stability data acc to zone iv-a for 03 batches.
	The status in reference regulatory authorities	SEGLUROMET tablets Merck & Co., Inc. USA https://www.accessdata.fda.gov/drugsatfda_docs/lab
	GMP status of the firm	DML is renewed w.e.f. 07-04-2025
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The application fulfils all the codal formalities.	
	Decision	
	Approved	
85	Case Category	Routine (Farooq Aslam)
	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	(2NN-E9S-JE59, 2024-06-10)

Detail of Fee Submitted	75000.0, 2024-04-23,
The proposed proprietary name / brand name	Diclom
Label Claim	Each hard gelatin capsule contains: Diclofenac sodium (as MR pellets) 75mg Omeprazole (as enteric coated pellets).....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	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)	could not be confirmed
Pharmacotherapeutic Group of (API)	NSAID/PPI
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Vision Pharmaceuticals (Pvt.) Ltd, Address: Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan,M/s Alphamed Formulations Private Limited, Address: Sy.no.225, sampanbole village, shamirpet mandal,medchal- malkajgiri district, telangana 500101, sampanbole village, shamirpet mandal, medchal - mal
Detail of stability batches of drug product	Batches: TF-01, TF-02, TF-03 (Batch size: 500 capsules) 06 months acc and 06 months RT stability data according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Diclofenac Sodium MR Pellets: Form 6 dated 22-12-2021 for 1kg material is submitted along with AD attested invoice. Omeprazole pellets: Invoice from M/s Vision Pharma dated 21-04-2023 for 1 kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the product i.e. DicloDuo Combi by M/s Haupt Pharma Amareg GmbH.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Omeprazole ECP: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A. Diclofenac Sodium: 06 months accelerated and 36 months real time stability data according to zone IV-A for 03 batches.
The status in reference regulatory authorities	MHRA Approved (Diclopram MR hard capsules)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023.
Evidence of approval of manufacturing facility	Capsule General Section is approved.
Evaluation Remarks	
Observation	Response
As per the literature of innovator's product, the hard capsule contains 25mg of gastro resistant pellets and 50mg prolonged release pellets, therefore, the submitted testing of drug substance should support the innovator's formulation as per the dissolution test of drug substance for 25mg of gastro resistant pellet, the test on acidic medium has not been performed, please clarify with	During stability studies of the capsule, dissolution in 0.1N HCl has been performed for confirming the enteric coating of Omeprazole pellets in respect of acid resistance. As per submitted chromatograms: No Diclofenac Sodium peak was detected in acid stage dissolution testing confirming the no release of Diclofenac prolonged release pellets and gastro resistant pellets in acidic medium.

scientific justifications. Furthermore, there should be separate development studies along with testing method and stability studies etc for 25mg (gastro resistant) and 50mg (prolonged release pellets) whereas in your application, the submitted studies support the formulation of only one type of pellets i.e. prolonged release. Please submit scientific clarification with supporting data.	

Decision

Deferred

for submission of dissolution data in acidic medium for gastro-resistant pellets (DS) for verification of two distinct release profiles of the two pellets i.e. 25mg gastro resistant and 50mg prolonged release pellets.

86	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
	Pharmaceutical 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.
Decision	
Deferred	
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.	
87	Case Category
Name, address of Applicant.	Routine (Farooq Aslam)
Application Form Dy. No / Tracking ID & date of submission	Scilife Pharma Private Limited FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837)
Detail of Fee Submitted	(HE8-9WQ-73U3, 2025-09-26)
The proposed proprietary name / brand name	37000.0, 2025-05-07,
Label Claim	N-GIL 6.4MG TABLET
Reference to Finished product specifications	Each sustained release tablet contains: Glyceryl trinitrate (as Diluted Nitroglycerine USP)...6.4mg
	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.

Decision

Deferred

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.

88	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Bosch Pharmaceuticals (Pvt) Ltd. Plot No. 221-223, Sector-23, Korangi Industrial Area (000350)
	Application Form Dy. No / Tracking ID & date of submission	(Q52-5G6-Z6RJ, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-04-02,
	The proposed proprietary name / brand name	Fermal 30mg
	Label Claim	Each Capsule contains: Iron as Ferric Maltol.....30mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	30's, 60's-As per SRO
	Shelf Life (Unit)	3 Year(s)Store below 25°C
	For generic drugs (me-too Status)	Ferion 30mg Capsule (Reg No. 129619) by Horizon
	Pharmacotherapeutic Group of (API)	Antianemic preparations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Apicore Pharmaceuticals Pvt. Ltd. Address: Block No. 252-253 , Dhobikuwa Village-391440, Opp. Jain Irrigation Company, Padra -Jambusar Highway, Tal.Padra, Dist. Vadodara, Gujrat, India.
	Detail of stability batches of drug product	Batches: TR-FRML-02, TR-FRML-03, TR-FRML-04 (Batch Size: 1500 Capsule) 06 months real time and 06 months accelerated stability data is submitted according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 25-10-2022 for 1.5kg material is submitted. unattested invoice no. YH/EXP/22-23/001 dated 18-04-2022 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Accrufer Capsule 30mg by M/s Shield Therapeutics Inc., UK.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	09 months real time and 06 months accelerated 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 14-02-2024.
	Evidence of approval of manufacturing facility	Capsule General Section is approved.
	Evaluation Remarks	
	Initially, the firm has selected 45minutes time point for dissolution testing and provided the same in finished product specifications while innovator has selected 30minutes as sampling time point. The firm was asked to provide clarification. the firm has now submitted: 1. revised dissolution specifications and fee of Rs. 9400/-. 2. Dissolution testing has been included in PE studies. 3. AMV studies with sampling time point 30minutes indicating release of drug more than 80% (for all the 03 batches)	
	Decision	
	Approved	
89	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Schazoo Zaka (Pvt) Ltd 20 Km Lahore-Jaranwala Road Distt: Sheikhpura (000636)
	Application Form Dy. No / Tracking ID & date of submission	(R73-UQ7-QDDV, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2023-05-03,
	The proposed proprietary name / brand name	Rovidin Tablets
	Label Claim	Each film coated tablet contains: Rosuvastatin (as Calcium) USP 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree Centigrade
	For generic drugs (me-too Status)	Rovista tablets by Getz Pharma
	Pharmacotherapeutic Group of (API)	Anti-hyperlipidemic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nantong Chanyoo Pharmatech co., Ltd.,
	Detail of stability batches of drug product	Batches: RNT-T1-22, RNT-T2-22, RNT-T3-22 (Batch size: 6000 tablet) 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)	Form 6 dated 14-03-2022 vide dy.No. 3121/2022-DRAP for 0.6kg material is submitted (manufacturer is Nantong chanyoo), Clearance certificate dated 01-04-2022. unattested invoice No. CY122024 dated 15-02-2022 (Changzhou) DHL receipt No. PK-LHE-SVC LHC2.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Rovista tablet 5mg by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Last inspection report dated 17-08-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	

Observation	Response
As per Module I, M/s Changzhou Pharmaceutical Factory, China is mentioned while submitted S part is from M/s Nantong Chanyoo Pharmatech Co., Ltd., China (DML/GMP of M/s Changzhou Pharmaceutical Factory, China are submitted,	Nantong Chanyoo Pharmatech Co. Ltd. is a core enterprise under Shanghai Pharmaceutical Group, a wholly-owned subsidiary of Changzhou Pharmaceutical Factory Co., Ltd. Kindly follow the given link to check, http://en.chanyoopharma.com/
Form 6 issued for Nantong Chanyoo, Invoice is from Changzhou, also note that the product has been developed using drug substance from Nantong Chanyoo as per submitted module III.	As it is clear from reply 1 that Nantong Chanyoo is a subsidiary of Changzhou Pharmaceutical Factory Co., Ltd. The Invoice was from Changzhou but API was manufactured by its subsidiary Nantong Chanyoo. DML, GMP and Form 6 of Nantong Chanyoo are attached
Please specify the test adopted for dissolution i.e. Test-1, Test-2 or Test-3 since USP specifies 03 tests for dissolution.	USP test I
Latest inspection report valid within the last 03 years.	Submitted
Provide 6 months stability data of the drug product.	Submitted
The application fulfills all the codal formalities.	
Decision	
Approved	
90	
Case Category	Routine (Farooq Aslam)
Name, address of Applicant.	Healthtek Pvt. Ltd. Plot No.14, Sector 19, Korangi Industrial Area Karachi - Pakistan (000618)
Application Form Dy. No / Tracking ID & date of submission	(8BU-S2Y-4ZJ4, 2024-06-11)
Detail of Fee Submitted	30000.0, 2024-03-26,
The proposed proprietary name / brand name	VECTAZID
Label Claim	Each vial contains: Ceftazidime Pentahydrate equivalent to Ceftazidime.....2g Avibactam Sodium equivalent to Avibactam.....0.5g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Do not store over 30°C, protect from heat, light and moisture
For generic drugs (me-too Status)	Zavicefta Injection by Pfizer Pakistan Ltd.
Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic / beta lactamase inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Zhuhai United Laboratories Co., Ltd
Detail of stability batches of drug product	Batches: TBH-075H, TBH-076H, TBH-077H (Batch size: 101 vials) 24 months real time and 06 months accelerated stability data according to the conditions of zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 17-03-2022 for 1.5kg material is submitted. GD No. KPAF-1670-2022 dated 04-03-2022 is submitted.

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against reference product i.e. Zovicefta powder for solution for inject by M/s Pfizer Ireland.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Drug substance is a sterile mixture in ratio on 4:1 for ceftazidime and Avibactam respectively. 06 months accelerated and 24 months real time stability data is submitted for 03 batches according to the conditions of zone IV-A.
The status in reference regulatory authorities	AVYCAZ Injection, USFDA Approved.
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-03-2023 is submitted.
Evidence of approval of manufacturing facility	Sterile dry powder for injectable (Ceph) is approved as per submitted GMP certificate.

Evaluation Remarks

Observation	Response
The innovator has established the product in Type I glass vial whereas the applied product is developed in Type III glass vial. Type III glass is recommended for oral solutions/syrups. Please clarify.	The firm has referred to USP General Chapter 660: Glass containers meeting Type III performance (e.g., soda-lime silica) usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that containers meeting Type III performance are satisfactory. The firm has submitted 24 months real time and 06 months accelerated stability data.

Decision

Approved

The firm shall manufacture the commercial batches using USP Type I glass vial as primary container closure.

91	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(WHJ-QYZ-T6L4, 2025-10-31)
	Detail of Fee Submitted	38700, 2025-10-17,
	The proposed proprietary name / brand name	Tadalox 10mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-De-Controlled,14-De-Controlled,20-De-Controlled,28-De-Controlled,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Fildil 10mg Tablet by Highnoon
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	(1)RND/Tab25-1/T004/S1,(2)RND/Tab25-1/T004/S2 (3)RND/Tab25-1/T004/S3 (Batch size:

		2000 tablets) 06 months real time and 06 months accelerated stability data according to the conditions of zone iIV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-03-2025 for 1kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile have been established against Fildill 10mg tablet by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Cialis tablet 10mg [USFDA approved]
	GMP status of the firm	Tablet General Section (General) was approved vide letter dated 04-02-2025.
	Evidence of approval of manufacturing facility	Tablet section[General] against DML No.[000977]
	Evaluation Remarks	
	Observation	Response
	The submitted chromatograms of standard solution do not contain the peak for 6R,12aS diastereomer, please perform the test as per USP method given in the following and submit the results along with analytical record. System suitability solution: To partially convert tadalafil to the 6R,12aS diastereomer, transfer 25 mL of the Standard solution into a suitable container. Add 0.25 mL of 5 N sodium hydroxide, mix well, and let stand for 30 min. Neutralize the solution to pH 7 by drop-wise addition of trifluoroacetic acid.	Chromatograms submitted with reference to the peak of 6R,12aS diastereomer.
	Submission stability data till 6th month time point.	Submitted.
	The application fulfills the codal formalities.	
	Decision	
	Approved	
92	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Himont Pharmaceuticals (Pvt.) Ltd. 17-km Ferozpur Road, Lahore (000231)
	Application Form Dy. No / Tracking ID & date of submission	(JQ5-S71-8SR5, 2025-10-13)
	Detail of Fee Submitted	38700.0, 2025-09-05,
	The proposed proprietary name / brand name	Suhagra 5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 25°C or below at Dry place
	For generic drugs (me-too Status)	Fildil 5mg tablet (Highnoon Laboratories Ltd)

Pharmacotherapeutic Group of (API)	Tadalafil is a phosphodiesterase type 5 (PDE5) inhibitor
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Century Pharmaceutical
Detail of stability batches of drug product	Stability Performed on three Batches: T-300079, T-300080, T-300081 (Batch size: 2500 tablets) 06 months real time and 06 months accelerated.
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10-02-225 for 0.4kg of material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 5mg Tablet.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 09-08-2024.
Evidence of approval of manufacturing facility	Tablet (General) Section is approved.
Evaluation Remarks	
The case has been processed in compliance to the decision of DRAP Authority.	
Observations	Response
Submission of system suitability results of AMV of drug product as per the method and specifications described by USP (with reference to 6R,12aS diastereomer of tadalafil) along with the analytical record.	Submitted
Submission stability data till 6th month time point.	Submitted.
The application fulfills the codal formalities.	
Decision	
Approved	
93	Case Category
	Any Other (Farooq Aslam)
	Name, address of Applicant.
	Himont Pharmaceuticals (Pvt.) Ltd. 17-km Ferozpur Road, Lahore (000231)
	Application Form Dy. No / Tracking ID & date of submission
	(YV7-SGA-EDDT, 2025-10-24)
	Detail of Fee Submitted
	38700.0, 2025-09-05,
	The proposed proprietary name / brand name
	Suhagra 20mg Tablet
	Label Claim
	Each film coated tablet contains: Tadalafil 20mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	10's-As per SRO
	Shelf Life (Unit)
	24 Year(s)Store at 25°C or below at Dry place
	For generic drugs (me-too Status)
	Fildil 5mg tablet (Highnoon Laboratories Ltd)
	Pharmacotherapeutic Group of (API)
	Tadalafil is a phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Century Pharmaceutical

	Detail of stability batches of drug product	Stability Performed on three Batches: T-300075, T-300076, T-300077 (Batch size: 2500 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 10-02-225 for 0.4kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against Cialis 20mg 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 is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Cialis 20mg Tablet
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 09-08-2024.
	Evidence of approval of manufacturing facility	Tablet (General) Section is approved.
	Evaluation Remarks	
	The case has been processed in compliance to the decision of DRAP Authority.	
	Observations	Response
	Submission of system suitability results of AMV of drug product as per the method and specifications described by USP (with reference to 6R,12aS diastereomer of tadalafil) along with the analytical record.	Submitted
	Submission stability data till 6th month time point.	Submitted.
	The application fulfills the codal formalities.	
	Decision	
	Approved	
94	Case Category	Any Other (Farooq Aslam)
	Name, address of Applicant.	Air Pharmaceuticals(Pvt.)Ltd Plot No's 74, 75-A, Small Industrial Estate, Kasur (000977)
	Application Form Dy. No / Tracking ID & date of submission	(ULZ-HXV-QTV7, 2025-10-23)
	Detail of Fee Submitted	38700, 2025-10-14,
	The proposed proprietary name / brand name	Tadalox 20mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10-De-Controlled,14-De-Controlled,20-De-Controlled,28-De-Controlled,30-De-Controlled
	Shelf Life (Unit)	2 Year(s)store items below 30 C
	For generic drugs (me-too Status)	Fildil 20mg Tablet
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited
	Detail of stability batches of drug product	Batches: (1)RND/Tab25-1/T002/S1, (2)RND/Tab25-1/T002/S2 (3)RND/Tab25-

		1/T002/S3 (Batch size: 2000 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-03-2025 for 1kg of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence and Comparative dissolution profile have been established against Fildill 20mg tablet by Highnoon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 60 months real time stability data of 03 batches is submitted according to the conditions of zone IV-A.
	The status in reference regulatory authorities	Cialis tablet 20mg [USFDA approved]
	GMP status of the firm	Tablet General Section (General) was approved vide letter dated 04-02-2025.
	Evidence of approval of manufacturing facility	Tablet General Section (General) was approved vide letter dated 04-02-2025.
	Evaluation Remarks	
	Observations	Response
	Submission of system suitability results of AMV of drug product as per the method and specifications described by USP (with reference to 6R,12aS diastereomer of tadalafil) along with the analytical record.	Submitted.
	Submission stability data till 6th month time point.	Submitted,
	The application fulfills all the codal formalities. The application was processed in compliance to the decision of DRAP Authority.	
	Decision	
	Approved	
95	Case Category	Routine (Farooq Aslam)
	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	(SS5-JNP-ESA5, 2024-06-14)
	Detail of Fee Submitted	75000.0, 2024-02-12,
	The proposed proprietary name / brand name	Rosez
	Label Claim	Each bilayer tablet contains: Rosuvastatin (as Rosuvastatin calcium).....2.5mg Ezetimibe 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10'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)	could not be confirmed.
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitor / Selective cholesterol absorption inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	EZETIMIBE (GLENMARK LIFE SCIENCES LIMITED) 141-143/160-165/170-172, Chandramouli Sahakari Audhogik Vasahat Maryadit, Pune-Hyderabad Highway, Mohol, Dist.

		Solapur, 413213, Maharashtra, India ,ROSUVASTATIN (CTX LIFE SCIENCES PVT.LTD) Block no 251/P 252/P 253/P to 255, 256/P, 276/P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.
	Detail of stability batches of drug product	Batches: TF-001, TF-002, TF-003 (Batch size: 1000 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)	Rosuvastatin calcium: Form 6 and AD attested invoice No. 288 dated 08-03-2021 (attested on 28-04-2021) for 100grams of material is submitted. Ezetimibe: For 6 dated 09-11-2022 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product Rusuzet 2.5/10mg by M/s Organon, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 60months real time stability data according to the conditions of zone IV- A for 03 batches s submitted. Rosuvastatin: 06 months accelerated and 12months real time stability data according to the conditions of zone IV- A for 03 batches s submitted.
	The status in reference regulatory authorities	Pharmaceuticals and Medical Devices Agency - PMDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application fulfils the codal formalities.	
	Decision	
	Approved	
96	Case Category	Routine (Farooq Aslam)
	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	(S2H-GR2-U13P, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2024-02-12,
	The proposed proprietary name / brand name	Rosez
	Label Claim	Each uncoated bilayer tablet contains: Rosuvastatin (as rosuvastatin calcium).....5mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10'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)	Rovista Ez 5mg/10mg Tablet

	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitor / Selective cholesterol absorption inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX LIFE SCIENCES PVT.LTD (Block no 251/P 252/P 253/P to 255, 256/P, 276/P, 277,278/P 279 to 282 283/P, and 284/P, GIDC, SACHIN, DISTT SURAT, and GUJRAT STATE, INDIA.),GLENMARK LIFE SCIENCES LIMITED(141-143/160-165/170-172, Chandramouli Sahakari Audhogik Vasahat Maryadit, Pune-Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, 141-143/160-165/170-17
	Detail of stability batches of drug product	Batches: TF-001, TF-002, TF-003 (Batch size: 1000 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)	Rosuvastatin calcium: Form 6 and AD attested invoice No. 288 dated 08-03-2021 (attested on 28-04-2021) for 100grams of material is submitted. Ezetimibe: For 6 dated 09-11-2022 for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product Rusuzet 5/10mg by M/s Organon, Japan.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Ezetimibe: 06 months accelerated and 60months real time stability data according to the conditions of zone IV- A for 03 batches s submitted. Rosuvastatin: 06 months accelerated and 12months real time stability data according to the conditions of zone IV- A for 03 batches s submitted.
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-01-2023 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application fulfils the codal formalities.	
	Decision	
	Approved	
97	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	A'raf (Pvt) Ltd 23 KM Raiwind Road Lahore (000685)
	Application Form Dy. No / Tracking ID & date of submission	(MDQ-85L-ZWBA, 2024-05-29)
	Detail of Fee Submitted	30000.0, 2024-04-03,
	The proposed proprietary name / brand name	Zeetam 250mg Tablets
	Label Claim	Each film coated tablet contains: Levetiracetam 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,30's-As per SRO

Shelf Life (Unit)	2 Year(s)Store below 30 degree C
For generic drugs (me-too Status)	Keppra 250mg Tablets (Manufactured By: GSK Pakistan))
Pharmacotherapeutic Group of (API)	Anticonvulsant
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Batches: ZT(A1), ZT(A2), ZT(A3) (Batch size: 3300 tablets)
Documents for the procurement of API with approval from DRAP (in case of Import)	AD Attested invoice No. SO/KE/2122/0007 dated 14-04-21 (Dy.No. 6068/2021-DRAP dated) 21-04-2021) for 100 kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Kepra 250mg tablet by M/s UCB Pharma SA, Belgium.
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-B is submitted.
The status in reference regulatory authorities	USFDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 22-08-2022.
Evidence of approval of manufacturing facility	Tablet General Section is approved.
Evaluation Remarks	
Observation	Response
Provide PE and CDP studies along with the details of the product against which the studies have been performed including brand name of,manufacturer and analytical record.	PE and CDP studies have been performed against the reference product i.e. Kepra 250mg tablet by M/s UCB Pharma SA, Belgium.
complete analytical record for AMV studies.	Submitted
Provide complete calculation for final weight adjustment of powder for potency for drug substance.	Submitted
Complete method of performing system suitability for drug substance as well as drug product.	Submitted.
provide stability summary sheets for drug product for complete 06 months.	Batches: ZT(A1), ZT(A2), ZT(A3) (Batch size: 3300 tablets) 06 months accelerated and 06 months real time stability data is submitted.
latest GMP inspection report valid within the last 03 years.	GMP certificate issued on the basis of inspection conducted on 27-08-2024.
The application fulfils the codal formalities.	
Decision	
Approved	
98	
Case Category	Routine (Farooq Aslam)
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	(P1W-MJW-8GHW, 2024-06-21)

Detail of Fee Submitted	30000.0, 2024-04-29,
The proposed proprietary name / brand name	Sterifluid 5 Infusion 250ml
Label Claim	Each 100ml contains: Dextrose Anhydrous.....5gm
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	250ml-As per SRO
Shelf Life (Unit)	2 Year(s)Room Temperture
For generic drugs (me-too Status)	Medisol 5 % IV infusion 250mL
Pharmacotherapeutic Group of (API)	intravenous fluid and nutrient replenisher
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Batches: 877823, 877623, 877223 (Batch size: 8000 bottles) 06 months accelerated and 09 months real time 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 14-04-2023 for 500000kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Medisol 5% by M/s Medipak.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
The status in reference regulatory authorities	USFDA Approved (250mL 5% by Hospira)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 15-12-2023.
Evidence of approval of manufacturing facility	LVP (General) section is approved.
Evaluation Remarks	
Observation	Response
provide real time stability data of drug substance till shelf life according to the conditions of zone IV-A for 03 batches since only 6 months stability data is submitted	06 months accelerated and 36 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
The application fulfils the codal formalities.	
Decision	
Approved	
The Board further decided that the registration letter shall be issued after clarification by the firm whether the applied product will be manufactured with or without a Euro Cap.	
99	
Case Category	Routine (Farooq Aslam)
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	(TJ9-XX4-J114, 2024-06-13)
Detail of Fee Submitted	75000.0, 2024-04-29,
The proposed proprietary name / brand name	Sterifluid-10 Infusion 250ml
Label Claim	Each 100ml Contains: Dextrose Anhydrous.....10gm

Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	250ml-As per SRO
Shelf Life (Unit)	2 Year(s)Room Tempreture
For generic drugs (me-too Status)	could not be confirmed
Pharmacotherapeutic Group of (API)	intravenous fluid and nutrient replenisher
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Batches: 777323, 778123, 777923 (Batch size: 8000 bottles) 06 months accelerated and 09 months real time 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 14-04-2023 for 500000kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the reference product i.e. Dextrose 10% by B.Braun, USA.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	..
The status in reference regulatory authorities	Dextrose 10% in plastic container is approved in USFDA https://www.accessdata.fda.gov/drugsatfda_docs/lab
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 15-12-2023.
Evidence of approval of manufacturing facility	LVP (General) section is approved.
Evaluation Remarks	
Observation	Response
provide real time stability data of drug substance till shelf life according to the conditions of zone IV-A for 03 batches since only 6 months stability data is submitted	06 months accelerated and 36 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
The application fulfils the codal formalities.	
Decision	
Approved	
The Board further decided that the registration letter shall be issued after clarification by the firm whether the applied product will be manufactured with or without a Euro Cap.	
100	Case Category
	Routine (Farooq Aslam)
	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
	(2SD-BZ9-7BU6, 2024-06-13)
	Detail of Fee Submitted
	30000.0, 2024-05-20,
	The proposed proprietary name / brand name
	V-COBAL 500mcg injection
	Label Claim
	Each 1ml ampoule contains: Mecobalamin.....500mcg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	5-As per SRO
Shelf Life (Unit)	24 Year(s)At room temperature below 25 degree centigrade, away from sunlight
For generic drugs (me-too Status)	Methycobal Injection 500µg, by Hilton pharma (Pvt.) Ltd, Registration Number 010313
Pharmacotherapeutic Group of (API)	Vitamin
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Supriya Lifesciences Limited. India, 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East) MUMBAI - 400 063. INDIA
Detail of stability batches of drug product	Batches: 500BT-001, 500BT-002, 500BT-003 (Batch size: 2000 Ampoules) 06 months real time and 06 months accelerated data is submitted.
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (Dy. No. 19060/2021-DRAP dated 14-12-2021) dated 14-12-2021 for 0.02kg material is submitted. DRAP attested invoice dy.no. 19059/2021-DRAP dated 14-12-2021 for 0.02kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e. Methycobal by M/s Hilton Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	48 months real time and 06 months accelerated stability data is submitted for 03 batches according to zone IV-A.
The status in reference regulatory authorities	METHYCOBAL INJECTION, EISAI CO., LTD, PMDA Approved
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 05-12-2022.
Evidence of approval of manufacturing facility	Liquid injectable (Ampoule & Vial) General Section is approved. (New Section)
Evaluation Remarks	
Observations (deferred in 343rd meeting)	Response
Submit valid GMP certificate/DML of the drug substance manufacturer	License retention certificate valid till 31-03-2028.
Submit drug substance specifications, analytical procedure and analytical method verification studies form M/s Variant.	Submitted
Submit drug substance reference/working standard used for analysis of drug substance by M/s Variant. Moreover, the firm was asked to clarify the difference between COA of WS submitted earlier and COA of WS submitted after deferment	Submitted (B.N. MO/MCB/2139) The firm has stated that the earlier submitted COA of working standard was ok.

The conclusion statement declares the performance of dissolution profile, clarification shall be submitted in this regard	"It was a typing mistake and we had already corrected it."
Clarification shall be submitted whether ampoule filling was done along with nitrogen purging or not.	"It is our standard procedure for liquid ampoules and vials to purge nitrogen at manufacturing and filling stage, however, now we revise our SMP and also mention this procedure in SMP."
justification shall be submitted for the acceptance range of pH test, since it differs for that recommended by the innovator drug product literature. Justification shall be submitted for applying user limit of Assay test as "120%"	"Our pH range was 5-7.5 but the pH range of innovator brand is 5.3-7.3. Our trial stability batches were tested for pH and the results are within the given range of the innovator brand. Now we revise our pH range from 5-7.3 to 5.3-7.3 same as innovator." "We revise our assay limit as 110% and our stability batches did not exceed from 110% till date."
Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". Analytical record for the performance of analytical method validation studies shall be submitted. Clarification shall be submitted for the varied parameters applied for performance of robustness parameter.	The firm has submitted complete analytical method validation studies.
Clarification since innovator product has packed glass ampoule in "Light Protect Easy" pack to avoid photolysis, while the firm has applied no such additive packing. Justification shall be submitted in this regard or else photostability studies shall be submitted.	"Mecobalamine injection is filled in amber colored glass ampoules, which provide effective protection against light exposure. Furthermore, the ampoules are packed in black PVC blisters offering additional shielding from light."
Following shall be submitted: Documents confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted. Complete raw data sheets including details of standard and sample solution preparation details shall be submitted. Complete batch manufacturing record for drug product stability batches.	AD Attested invoice No. SLL/E/21-22/789 dated 20-11-2021 (vide Dy.No. 19059/2021-DRAP dated 14-12-2021). BMRS are submitted. Analytical record is submitted.

	The firm shall submit applicable fee for revision of specification for pH and assay range.	
	Decision	
	Approved	
	Subject to submission of applicable fee for revision of specifications.	
101	Case Category	New Section (Farooq Aslam)
	Name, address of Applicant.	Biogen Life Sciences 8-KM, Chak Beli Road, Rawat, (000911)
	Application Form Dy. No / Tracking ID & date of submission	(PN6-R17-NMZE, 2024-12-09)
	Detail of Fee Submitted	30000.0, 7000.0 2024-05-10, 2024-10-01
	The proposed proprietary name / brand name	FLUTRIKIN CREAM
	Label Claim	Each gram contains: Fluocinolone acetonide 0.01% Hydroquinone.....4% Tretinoin.....0.05%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Flutrim Cream 30gm Registration Number: 065173
	Pharmacotherapeutic Group of (API)	topical corticosteroids
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	chongqing huapont shengchem Pharmaceutical co, ltd. No666 ro ngjun road, nan? n avenue he chuan district chongqing china,GUANGDONG RENREN KANG PHARMACEUTICAL CO., LTD. ADDRESS: NO. 3, PINGDONG 5TH ROAD, NANPING SCIENCE AND TECHNOLOGY INDUSTRIAL PARK, ZHUHAI CITY, CHINA,Tianjin Tianyao Pharmaceuticals Co., Ltd Address: No.19 Xin Ye 9th street, West Area of Tianjin Economic-Technological Development Area, Tianjin 300462, China
	Detail of stability batches of drug product	.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s Valor Pharma is submitted. Bill of lading and invoices are submitted, Fluocinolone Acetonide.....3grams Hydroquinone.....12.5grams Tretinoin.....1.2kg
	Pharmaceutical Equivalence and Comparative Dissolution Profile	P.E studies have been performed agasnt Evion Cap 400mg.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 6 months accelerated data of 03 batches is submitted.
	The status in reference regulatory authorities	TRI-LUMA® Cream (fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%) FDA Approved
	GMP status of the firm	Cream section general is approved w.e.f. 13-02-2020

Evidence of approval of manufacturing facility	soft gel cap section general is approved w.e.f. 13-02-2020																														
Evaluation Remarks																															
Observation (Deferred in 345th meeting)	Response																														
stability data of 3 batches for API Hydroquinone as per zone IV-A.	Data is submitted for 03 batches according to the conditions of zone IV-A.																														
stability data of 3 batches for API Tretinoin as per zone IV-A.	Stability data of 03 batches according to the conditions of zone IV-A is submitted.																														
detail of the product including name of manufacturer, expiry etc against which the pharmaceutical equivalence studies have been performed.	PE studies have been performed against Flutrim Cream manufactured by M/s Biogen Pharma, Rawat. B.No. 2852 DOM: 10-2023																														
documents confirming import of APIs including clearance certificate, invoice form 5 etc.	Loan letter from M/s Valor Pharma is submitted. Bill of lading and invoices are submitted, Flucinolone Acetonide.....3grams (Clearance certificate from M/s Valor Pharma is submitted) Hydroquinone.....12.5grams (clearance certificate dated 23-08-2023 is submitted from M/s Valor) Tretinoin.....1.2kg (Clearance certificate dated 17-08-2023 is submitted from Valor)																														
Decision																															
Approved																															
Subject to verification of loan letters.																															
102	<table> <tr> <td>Case Category</td><td>Routine (Farooq Aslam)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(H53-9ER-E4WN, 2023-12-15)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>30000.0, 2023-11-22,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Jacxel 5mg</td></tr> <tr> <td>Label Claim</td><td>Each film-coated tablet contains: Tofacitinib as citrate 5mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>As per Innovators Specification</td></tr> <tr> <td>Proposed Pack Size</td><td>10s, 20s, 30s-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s) Store below 30C</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Tofajek Tablets 5mg by Hiranis Pharma (110057)</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td></td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Self Manufacturing</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Anhui Haikang Pharmaceuticals Co., Ltd No.21 Huancheng west road Anqing Anhui</td></tr> <tr> <td>Detail of stability batches of drug product</td><td></td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td></td></tr> </table>	Case Category	Routine (Farooq Aslam)	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)	Application Form Dy. No / Tracking ID & date of submission	(H53-9ER-E4WN, 2023-12-15)	Detail of Fee Submitted	30000.0, 2023-11-22,	The proposed proprietary name / brand name	Jacxel 5mg	Label Claim	Each film-coated tablet contains: Tofacitinib as citrate 5mg	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 30C	For generic drugs (me-too Status)	Tofajek Tablets 5mg by Hiranis Pharma (110057)	Pharmacotherapeutic Group of (API)		Name, address of Manufacturing site:	Self Manufacturing	Name & address of API manufacturer	Anhui Haikang Pharmaceuticals Co., Ltd No.21 Huancheng west road Anqing Anhui	Detail of stability batches of drug product		Documents for the procurement of API with approval from DRAP (in case of Import)	
Case Category	Routine (Farooq Aslam)																														
Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)																														
Application Form Dy. No / Tracking ID & date of submission	(H53-9ER-E4WN, 2023-12-15)																														
Detail of Fee Submitted	30000.0, 2023-11-22,																														
The proposed proprietary name / brand name	Jacxel 5mg																														
Label Claim	Each film-coated tablet contains: Tofacitinib as citrate 5mg																														
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 30C																														
For generic drugs (me-too Status)	Tofajek Tablets 5mg by Hiranis Pharma (110057)																														
Pharmacotherapeutic Group of (API)																															
Name, address of Manufacturing site:	Self Manufacturing																														
Name & address of API manufacturer	Anhui Haikang Pharmaceuticals Co., Ltd No.21 Huancheng west road Anqing Anhui																														
Detail of stability batches of drug product																															
Documents for the procurement of API with approval from DRAP (in case of Import)																															

	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA, Approved.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Observations (deferred in 344th meeting)	Response
	Justification shall be submitted for not including citric acid content and chloride content in the specifications of the drug substance as provided by the drug substance manufacturer.	The firm has revised the specifications of DS. The tests for estimation of contents of citric acid and chloride have been performed by drug product manufacturer as per submitted COA.
	Gradient method and concentration of sample solution and standard solution are different from drug substance manufacturer. Clarification shall be submitted.	The firm has submitted revised method along with the concentration of sample and standard solutions.
	Justification shall be submitted for not performing Chloride content and Isomer test on drug substance.	The firm has revised the specifications of DS. The tests for estimation of contents isomer and chloride have been performed by drug product manufacturer as per submitted COA.
	Qualitative composition of the applied formulation is different from that of the innovator product. Clarification shall be submitted.	The applied product has the same composition as that of innovator's.
	Complete six-month time stability data along with raw data sheets shall be submitted	Submitted. 06 month real time and 06 months accelerated for 03 batches.
	Value of uniformity of dosage unit test shall be submitted instead of only writing complies.	values have been added in summary sheets.
	The firm shall submit applicable fee for revision of specifications.	
103	Decision	
	Approved	
	Subject to submission of fee for revision of specifications.	
	Case Category	Routine (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	(NZG-SQL-3GPL, 2025-10-03)
	Detail of Fee Submitted	38700, 2025-09-18,
	The proposed proprietary name / brand name	Fezhil Tablets 45mg
	Label Claim	Each film-coated tablet contains: Fezolinetant..... 45mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30C . Protect from direct heat and sunlight. Keep out of the reach of children
	For generic drugs (me-too Status)	Fezlon tablets 45mg by Nabi Qasim

Pharmacotherapeutic Group of (API)	Neurokinin 3 Receptor Antagonist.
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) Stability data for Fezolinetant by FPP manufacturer is attached in 3.2.S.P.8
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 no. DIL-C-40880B for API namely Fezolinetant is for 1.2kg material. unattested invoice, packing list and GD No. KPAF-6838-05072024 Date: 05-07-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence report & CDP of Fezhil Tablets , performed against Veozza Tablets 45mg and attached in 3.2.P.2
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Accelerated (6 months) & Long term (24 months) Stability data for Fezolinetant by API manufacturer is attached in 3.2.S.7
The status in reference regulatory authorities	FDA Approved - Veozah by Astellas Pharma US, Inc. Northbrook, IL 60062
GMP status of the firm	GMP Certificate no. 13/2025-DRAP(K) dated 20th January 2025 . Valid till 9th Dec 2027 attached in 1.3.5
Evidence of approval of manufacturing facility	Copy of Valid DML (000136) along with approved Sections is attached in Form 5F , section 1.3.4
Evaluation Remarks	
Observations (deferred in 352nd meeting)	Response
For submission forced degradation studies conducted on drug product for all the 03 stability batches.	The firm has performed forced degradation according to the following stress storage conditions: 1. Acidic Hydrolysis 2. Basic Hydrolysis 3. Oxidative Stress 4. Phytolytic Stress 5. Thermal Stress All the 03 stability batches were exposed to the above conditions and limit of total impurities' content is within the limit.
Decision	
Approved	
104	Case Category
	Routine (Farooq Aslam)
	Name, address of Applicant.
	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission
	(47L-YMT-2YR7, 2024-06-14)
	Detail of Fee Submitted
	75000.0, 2024-02-26,
	The proposed proprietary name / brand name
	Artesun Injection 120mg
	Label Claim
	Each vial contains: Artesunate.....120mg
	Reference to Finished product specifications
	The International Pharmacopeia
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store below 25 Degree Centigrade
	For generic drugs (me-too Status)
	Misonate 120mg Injection (manufactured by Tabros Pharmaceutical) Reg. No. 083299)

Pharmacotherapeutic Group of (API)	Antimalarial
Name, address of Manufacturing site:	Palpax Pharmaceutical Pvt. Ltd.-Plot No. FD-46-A8, Street-1, Sector-38, Korangi Creek Industrial Park, Karachi-
Name & address of API manufacturer	Arihantanam Life Care Pvt. Ltd.,
Detail of stability batches of drug product	Batches: TL-001, TL-002, TL-003 (Batch size: 500 vials) 24 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)	AD attested invoice No. EXP-16/20-21 dated 10-10-2020 (Dy. No. 12748/2020) for 03Kg material (Palpex Pharmaceuticals pvt ltd.)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been conducted against G-n-M Injection 120mg by Genix Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	60 months real time and 06 months accelerated stability data of 03 batches according to the conditions of zone IV-A.
The status in reference regulatory authorities	Artesunate Injection 120mg Manufactured by Ryvis Pharma (Canada)
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 08-11-2022.
Evidence of approval of manufacturing facility	Sterile Dry Powder Vial Injection (G) is approved.
Evaluation Remarks	
Observations	Response
Please clarify since you have submitted 02 COAs of drug substances from drug product manufacturer ALCSAR-01-05023 & ALCSAR-01-02520, while as per the reply, the submitted DRAP attested invoice contains the Batch Number ALCSAR-01-02520.	Batch number ALCSAR-01--2520 is used for product development.
The submitted AMV studies of DS have been performed by drug substance manufacturer. You are required to provide the AMV studies performed by drug product manufacturer.	Submitted.
The submitted stability data of DS is not according to the conditions of zone IV-A. Please provide stability data of DS for 03 batches according to zone IV-A till shelf life.	60 months real time and 06 months accelerated stability data of 03 batches according to the conditions of zone IV-A.
Provide compatibility studies of drug product with the diluent used.	Submitted
Provide pharmaceutical equivalence studies by performing all the quality tests against reference/innovator's/comparator's product. Moreover, provide details of the product against which the studies have been performed including batch number, expiry, name of manufacturer and approval status of the product in the country.	PE studies have been conducted against Gen-M Injection 120mg by Genix Pharma. B.No. 01431022

Documents confirming import of drug substance including clearance certificate/DRAP endorsed invoice, GD etc.	AD attested invoice No. EXP-16/20-21 dated 10-10-2020 (Dy. No. 12748/2020) for 03Kg material (Palpex Pharmaceuticals pvt ltd.)
Provide approval status of the applied product in the same strength i.e. 120mg/vial since 110mg/vial is registered in reference regulatory authority.	WHO recommended formulation MA090 WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Decision

Approved

105	Case Category	Routine (Farooq Aslam)
	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	(P2B-7QN-HJ6N, 2024-06-25)
	Detail of Fee Submitted	30000.0, 2024-05-31,
	The proposed proprietary name / brand name	Komplet 4.5MIU Injection
	Label Claim	Each vial contains: 4.5MIU of Colistimethate Sodium eq. to Colistin Base Activity.....150mg
	Reference to Finished product specifications	United States 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)	CBA 150 Injection Imported by Biocare Pharma Lahore Reg. No. 103783
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Livzon goup fuzhou fuxing pharmaceutical Co. Ltd.,
	Detail of stability batches of drug product	Batches: T034, T035, T036 (Batch size: 450 vials) 06 months accelerated and 06 months real time 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)	Loan letter dated 28-09-2023 from M/s Aulton Pharmaceuticals for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Colistim 4.5MIU by M/s Biopharmaseutica.
	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 one IV-A is submitted.

	The status in reference regulatory authorities	Colistamethate sodium 4.5.M.I.U powder for solution for injection (IV) USFDA Approved
	GMP status of the firm	Last GMP inspection report dated 03-04-2023 is submitted.
	Evidence of approval of manufacturing facility	Dry Powder Vial (General) Section is approved.
	Evaluation Remarks	
	Observations	Response
	As per the available literature of the product (MHRA), the base activity should be equal to 71mg of base activity, but you have mentioned 68mg, please clarify so that your application further be processed. Moreover, clarification is required regarding the manufacturing process of the applied product whether it manufactured by filling ready to fill lyophilized powder or lyophilization is done in the vials as per innovator's product	"As per the available MHRA reference literature, 2 MIU Colistimethate Sodium corresponds to a theoretical base activity of 71 mg. The value of 68 mg mentioned in our dossier represents the experimentally determined base activity obtained during routine assay testing of the product." "Our applied product is not lyophilized in-house. We use a ready-to-fill lyophilized powder sourced from an approved manufacturer (Iivzon). Therefore, no separate 'Lyophilization Section Approval Letter' is applicable, as lyophilization is not performed in our facility or as part of our manufacturing process. We only carry out vial filling and sealing of the pre-lyophilized bulk powder."
	Provide valid GMP certificate / drug manufacturing license of drug substance manufacturer.	DML of DS manufacturer valid till 01-07-2030. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9ZDdlZGYxOGQ5MTJlZGY4OTRjMGE5MTY5MWF1YTMzMzcmaXRlbUlKPWZmODM4MDgxOGI2NGIyNDIwMThiN2ZhMjllYjgwYWRj
	Provide details of the product against which PE studies have been performed including name of manufacturer and country, marketing authorization status i.e. the country where it is approved etc.	PE studies have been performed against comparator's product i.e. Colistim IV injection 4.5MIU mfg by M/s Pharmasol. Batch number: 639175-K Mfg date: 03-2023 Exp dated: 03-2026
	As per clearance certificate from M/s Aulton Pharmaceuticals, batch number CMS2203002 was imported while batch number CMS2004002 has been used in product development, please clarify or otherwise submit relevant clearance certificate.	Clearance certificate for batch number CMS2004002 dated 19-09-2022 is submitted.
	The firm shall submit applicable fee for revision of label claim as described by USP.	
	Decision	
	Approved	
	Subject to submission of applicable fee for revision of label claim and verification of loan letter.	
106	Case Category	Routine (Farooq Aslam)
	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	(LG8-WZA-T6X2, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-05-31,

The proposed proprietary name / brand name	Komplet 2MIU Injection
Label Claim	Each vial contains: 2MIU of Colistimethate Sodium eq. to Colistin Base Activity.....71mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 25°C
For generic drugs (me-too Status)	Nogotex 2MIU injection by M/a NabiQasim
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Livzon group fuzhou fuxing pharmaceutical Co. Ltd.,
Detail of stability batches of drug product	Batches: T028, T029, T030 (Batch size: 450 vials) 06 months accelerated and 06 months real time 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)	Loan letter dated 28-09-2023 from M/s Aulton Pharmaceuticals for 1kg material is submitted. Clearance certificate dated 19-09-2022 for 1kg material is submitted (Aulton Pharmaceuticals)
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Colistin 2MIU by M/s Biopharmaseutica.
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 one IV-A is submitted.
The status in reference regulatory authorities	Colistamethate sodium (2.M.I.U and 1.M.I.U) powder for solution for injection (IV) USFDA Approved
GMP status of the firm	Last GMP inspection report dated 03-04-2023 is submitted.
Evidence of approval of manufacturing facility	Dry Powder Vial (General) Section is approved.
Evaluation Remarks	
Observations	Response
As per the available literature of the product (MHRA), the base activity should be equal to 71mg of base activity, but you have mentioned 68mg, please clarify so that your application further be processed. Moreover, clarification is required regarding the manufacturing process of the applied product whether it manufactured by filling ready to fill lyophilized powder or lyophilization is done in the vials as per innovator's product	"As per the available MHRA reference literature, 2 MIU Colistimethate Sodium corresponds to a theoretical base activity of 71 mg. The value of 68 mg mentioned in our dossier represents the experimentally determined base activity obtained during routine assay testing of the product." "Our applied product is not lyophilized in-house. We use a ready-to-fill lyophilized powder sourced from an approved manufacturer (Iivzon). Therefore, no separate 'Lyophilization Section Approval Letter' is applicable, as lyophilization is not performed in our facility or as part of our manufacturing process. We only carry out vial filling and sealing of the pre-lyophilized bulk powder."
Provide valid GMP certificate / drug manufacturing license of drug substance manufacturer.	DML of DS manufacturer valid till 01-07-2030. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9ZDdlZGYxOGQ5MTJlZGY4OTRjM

		GE5MTY5 MWFIYTMzMzcmaXRlbUlKPWZmODA4MDgx OGI2NGIyN DIwMThiN2ZhMjllYjgwYWRj
	Provide details of the product against which PE studies have been performed including name of manufacturer and country, marketing authorization status i.e. the country where it is approved etc.	PE studies have been performed against comparator's product i.e. Colistim IV injection 2MIU mfg by M/s Pharmasol. Batch number: 781008-B Mfg date: 06-2022 Exp dated: 06-2025
	As per clearance certificate from M/s Aulton Pharmaceuticals, batch number CMS2203002 was imported while batch number CMS2004002 has been used in product development, please clarify or otherwise submit relevant clearance certificate.	Clearance certificate for batch number CMS2004002 dated 19-09-2022 is submitted.
	The firm shall submit applicable fee for revision of label claim as described by USP.	
	Decision	
	Approved	
	Subject to submission of applicable fee for revision of label claim and verification of loan letter.	
107	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Horizon HealthCare (Pvt) Ltd plot no 33 sunder industrial estate lahore (000782)
	Application Form Dy. No / Tracking ID & date of submission	(5S6-8RV-LYVT, 2023-12-15)
	Detail of Fee Submitted	75000.0, 2023-11-24,
	The proposed proprietary name / brand name	Pytol Orodispersible 250mg Tablet
	Label Claim	Each Orodispersible tablet contains: Paracetamol 250mg (As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specificatio
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C. Protect from light and moi
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Registered drug by HPRA Health Products Regulatory Authority (HPRA) of Ireland Calpol Six Plus FASTM
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

Background: The applicant has applied for registration of 03 different dosage forms of Paracetamol tablet with the following details: Paracetamol Orodispersible 250mg tablet Paracetamol 500mg film coated tablet Paracetamol Advance 500mg tablet

All of the above-mentioned tablets are different from the conventional Paracetamol Tablet 500mg in pharmacokinetic and pharmacodynamics parameters based on the disintegration and dissolution of the product.

The instant case is Paracetamol Orodispersible 250mg tablet. The same formulation is approved by HPRA Ireland (Calpol Six Plus FASTM). It was deferred in 344th meeting for justification regarding the drug product specifications applied by the firm with reference to the pharmacokinetic & pharmacodynamics features of the applied formulation.

Following justification is submitted by the firm: The specifications applied for Panadol ODT are designed to ensure that the formulation achieves rapid disintegration, dissolution, and absorption, enabling a faster onset of action compared to conventional paracetamol tablets. The ODT formulation is particularly beneficial for patients who have difficulty swallowing conventional tablets, providing ease of administration without compromising therapeutic efficacy.

Evaluation by PEC: The applied product is non-pharmacopoeial. Initially the firm had chosen 15 minutes disintegration time and 15 minutes dissolution time point. However, as per CDER Guidance for Industry: Orally Disintegrating Tablets: A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue. USP General Chapter 1092 defines the immediate release as all those dosage forms the duration of the dissolution procedure is typically 15-60 minutes.

Response by the firm: The firm has submitted revised specifications as 30 seconds disintegration and 10 minutes as dissolution sampling time point (NLT 80% Q). Moreover, the firm has provided tabulated results of Dissolution and Disintegration testing of stability batches wherein the results are within the revised specifications. The firm has not submitted the fee for revision of specifications (as per innovator's).

Decision

Approved

Subject to submission of applicable fee for revision of specifications.

108	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Horizon HealthCare (Pvt) Ltd plot no 33 sunder industrial estate lahore (000782)
	Application Form Dy. No / Tracking ID & date of submission	(MNH-84X-741P, 2023-12-18)
	Detail of Fee Submitted	75000.0, 2023-11-24,
	The proposed proprietary name / brand name	Pytol Actifast 500mg Tablet
	Label Claim	Each film-coated tablet contains: Paracetamol 500mg (As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specificatio
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C. Protect from light and moi
	For generic drugs (me-too Status)	N/A
	Pharmacotheapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi Pharma Limited
	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	Registered drug by UK-MEHRA as Panadol Advance 500 mg Tablets
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Background: The applicant has applied for registration of 03 different dosage forms of Paracetamol tablet with the following details: Paracetamol Orodispersible 250mg tablet Paracetamol 500mg film coated tablet Paracetamol Advance 500mg tablet	
	All of the above-mentioned tablets are different from the conventional Paracetamol Tablet 500mg in pharmacokinetic and pharmacodynamics parameters based on the disintegration and dissolution of the product.	
	The case was deferred in 344th meeting for justification regarding the drug product specifications applied by the firm with reference to the pharmacokinetic & pharmacodynamics features of the applied formulation.	
	The applied product is paracetamol 500mg paracetamol film coated tablet and is approved by MHRA (Panadol ActiFast 500mg Tablet by GlaxoSmithKline Consumer Healthcare). The applied formulation is different from conventional paracetamol tablet 500mg in pharmacokinetic and pharmacodynamic parameters. A detailed comparison in the referred parameters had been compared in 324th meeting where the Board approved the case of Provas Actifast (Paracetamol 500mg film coated tablet) of M/s	

Sami Pharmaceuticals holding the registration of conventional paracetamol 500mg tablet. Following is the comparison presented in 324th meeting.

Parameters	Conventional Panadol	PANADOL ACTIFAST
Disintegration	Within 15 minutes	Within 10 minutes Gamma scintigraphic images of the stomach showed 2 times faster disintegration against Conventional Paracetamol tablets
Absorption	Paracetamol is poorly absorbed in the stomach but well absorbed in the small intestine due to the greater surface area and absorptive capacity. Conventional Paracetamol tablets have no such ingredient(s) to increase the rate of absorption	It is absorbed into the bloodstream at least twice as fast as against conventional (Conventional) Paracetamol Tablets Following administration, Paracetamol has a median time to peak plasma concentrations (tmax) of 25 minutes in fasted subjects and 45 minutes in the fed subjects. Maximum plasma concentrations were reached at least twice as fast than Conventional Paracetamol Tablets in both the fed and fasted state
Dissolution	NLT 80% (Q) in 30 minutes	NLT 80% (Q) in 10 minutes
Gastric safety		
Onset of action	Onset of action is slow, as peak plasma concentrations occur about 30 minutes to 2 hours after ingestion	Due to a combination of faster disintegration and gastric emptying, this new formulation is responsible for the faster rate of absorption of Paracetamol than Conventional Paracetamol formulation
Other attributes	Round conventional shape Uncoated tablets and hence a bitter taste	Oblong shape makes it easy to swallow. The bitter taste of Paracetamol is masked through film coating Product specifications conform to the Innovator's Specifications, being more stringent than USP Specifications

Formulation detail	Each tablet contains Paracetamol Maize starch Povidone Potassium sorbate Soluble starch Purified talc Stearic acid	Each film coated tablet contains: Paracetamol Maize starch Povidone Potassium sorbate Pre-gelatinized starch Silicon dioxide Magnesium stearate Sodium starch glycolate Sodium Bicarbonate Microcrystalline cellulose Hydroxypropylmethyl cellulose E15 Polyethylene glycol 6000 Titanium Dioxide Talcum Powder
The above mentioned details were presented in 324th meeting of Registration Board. The Board approved the case as generic drug product considering the decision taken in its 262nd meeting considering the case of Price Fixation under the Drug Pricing Policy-2015 wherein it was decided that the generic drug product means same molecule and its salt, same strength and dosage form. Communication with the firm for shortcomings:		
Sr No	Observations	Response
1	Justification shall be submitted for using USP reference standard for the analysis of BP grade drug substance.	The analysis method for paracetamol in the British Pharmacopoeia (BP) relies on a titration method. This approach does not require a reference standard because titration directly determines the amount of the active ingredient based on a chemical reaction, such as acid-base or redox reactions. Unlike chromatographic methods, which require a standard to quantify the analyte through comparison, titration measures the analyte stoichiometrically without external calibration. Moreover, the other testing parameters for the analysis of drug substance in B.P are almost similar to USP like identification by IR, loss on drying, and sulfated ash.
2	Clarification shall be submitted regarding the difference between two formulation applied by firm i.e., "Paracetamol Advance" and "Paracetamol Actifast" in terms of Pharmacokinetic and Pharmacodynamic features.	Paracetamol Advance: The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses. Paracetamol Actifast: The mean elimination half-life of paracetamol following administration of Panadol ActiFast is

		2 to 3 hours. Following administration of Panadol ActiFast, paracetamol has a median time to peak plasma concentrations (tmax) of 25 minutes in fasted subjects and 45 minutes in the fed subjects Detailed Difference is given in attachment herewith						
3	Justification shall be submitted for not adopting USP monograph of "Acetaminophen tablets" for the applied formulation.	We adhered to the innovator's specifications for the analysis and quality assessment of our drug product, as the innovator does not strictly follow the methods outlined in the reference pharmacopoeia (such as the BP, USP, or others). Instead, the innovator employs a proprietary method specific to their product formulation and manufacturing process. To ensure the quality of our drug product, we implemented in house developed method and performed it as a validated analytical procedure in compliance with international regulatory requirements.						
4	As per submitted dossier, the dissolution specs specify the sampling point of 15minutes which is for Paracetamol conventional tablet. Moreover, the disintegration time is 30minutes as per submitted, dossier. Please tabulated results for confirmation whether the release is within 10 minutes of otherwise. Moreover, USP specification can not be claimed dissolution timepoint is different from conventional paracetamol.	The firm has submitted revised specifications as follows.						
		<table><tr><td>Old</td><td>Revised</td></tr><tr><td>Dissolution: NLT 80% (Q) in 15 minutes</td><td>Dissolution: NLT 80% (Q) in 10 minutes</td></tr><tr><td>Disintegration Time: NMT 30 min</td><td>Disintegration Time: NMT 10 min</td></tr></table>	Old	Revised	Dissolution: NLT 80% (Q) in 15 minutes	Dissolution: NLT 80% (Q) in 10 minutes	Disintegration Time: NMT 30 min	Disintegration Time: NMT 10 min
		Old	Revised					
		Dissolution: NLT 80% (Q) in 15 minutes	Dissolution: NLT 80% (Q) in 10 minutes					
Disintegration Time: NMT 30 min	Disintegration Time: NMT 10 min							
The results submitted by the firm are within the revised specification. However, the firm has not submitted any fee for revised specifications.								
The firm shall submit the applicable fee for revision of specifications as per innovator's.								
Decision								
Approved								
Subject to submission of applicable fee for revision of specifications.								
109	Case Category	Routine (Farooq Aslam)						
	Name, address of Applicant.	Horizon HealthCare (Pvt) Ltd plot no 33 sunder industrial estate lahore (000782)						
	Application Form Dy. No / Tracking ID & date of submission	(Z6X-XM3-Q8YM, 2023-12-07)						
	Detail of Fee Submitted	75000.0, 2023-11-24,						
	The proposed proprietary name / brand name	Pytol Adavance 500mg Tablet						
	Label Claim	Each film-coated tablet contains: Paracetamol 500mg (As per Innovator’s Specs.)						
	Reference to Finished product specifications	As per Innovators Specificatio						
	Proposed Pack Size	As per SRO-As per SRO						
	Shelf Life (Unit)	24 MonthDo not store above 30°C. Protect from light and moi						
	For generic drugs (me-too Status)	N/A						
	Pharmacotherapeutic Group of (API)							

Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product		
Documents for the procurement of API with approval from DRAP (in case of Import)		
Pharmaceutical Equivalence and Comparative Dissolution Profile		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		
The status in reference regulatory authorities	Registration status of applied drug: Registered drug by UK-MEHRA as Panadol Advance 500 mg Tablets	
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Background: The applicant has applied for registration of 03 different dosage forms of Paracetamol tablet with the following details: Paracetamol Orodispersible 250mg tablet Paracetamol 500mg film coated tablet Paracetamol Advance 500mg tablet		
All of the above-mentioned tablets are different from the conventional Paracetamol Tablet 500mg in pharmacokinetic and pharmacodynamics parameters based on the disintegration and dissolution of the product. The difference between Paracetamol Actifast and Paracetamol Advance is:		
Paracetamol Actifast	Paracetamol Advance	
The mean elimination half-life of paracetamol following administration of Panadol ActiFast is 2 to 3 hours. Following administration of Panadol ActiFast, paracetamol has a median time to peak plasma concentrations (tmax) of 25 minutes in fasted subjects and 45 minutes in the fed subjects. Detailed Difference is given in attachment herewith	The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses.	
The case was deferred in 344th meeting for justification regarding the drug product specifications applied by the firm with reference to the pharmacokinetic & pharmacodynamics features of the applied formulation.		
The applied product is paracetamol Advance 500mg film coated tablet and is approved by MHRA (Panadol Advance 500mg Tablet by GlaxoSmithKline Consumer Healthcare). The applied formulation is different from conventional paracetamol tablet 500mg in pharmacokinetic and pharmacodynamic parameters. A detailed comparison in the referred parameters had been presented in 331st meeting and the Board approved the case of Provas Advance (Paracetamol 500mg film coated tablet) of M/s Sami Pharmaceuticals holding the registration of conventional paracetamol 500mg tablet as well. Following is the comparison presented in 324th meeting.		
Parameters	Conventional Panadol	PANADOL ACTIFAST
Disintegration	Within 15 minutes	Within 10 minutes Human scintigraphy data demonstrate that Panadol Advance 500 mg Tablets generally start to disintegrate by 5 minutes post dose in the stomach 37% faster compared to standard paracetamol tablets It dissolves in 5 minutes and start to relieve pain within 15 minutes Reference attached

		https://www.medicines.org.uk/emc/product/6512/smpc#
Dissolution	NLT 80% (Q) in 30 minutes	NLT 80% (Q) in 10 minutes
Gastric safety		The absorption of Paracetamol occurs in the small intestine and as such is dependent on the rate of emptying of stomach contents into the small intestine and is therefore not associated with gastric irritation. The technology used in Advance formulation 500mg Tablets increases gastric emptying time of the drug
Onset of action	Onset of action is slow, as peak plasma concentrations occur about 30 minutes to 2 hours after ingestion	The unique disintegrant system is used to provide rapid onset of action and allows it to dissolve in 5 minutes and start to relieve pain within 15 minutes. Human pharmacokinetic data demonstrate that the time taken to reach plasma paracetamol therapeutic threshold is at least 37% faster as compared to standard paracetamol tablets
Other attributes	Round conventional shape Uncoated tablets and hence a bitter taste	Capsular shape makes it easy to swallow Bitter taste of Paracetamol is masked through film coating Stomach friendly
Technology/Formulation		
	Standard Paracetamol tablet formulated using conventional wet granulation process	Optizorb technology is used to provide rapid onset of action and allows it to dissolve in 5 minutes and start to relieve pain within 15 minutes
Excipients	Maize starch Povidone Potassium sorbate Soluble starch Purified talc Stearic acid	Pregelatinised starch Calcium carbonate Alginic acid Crospovidone Povidone (K-25) Magnesium stearate Colloidal anhydrous silica

Following are the product registered in different countries:

Reference Regulatory Authority (RRA) /PICs Member States	Conventional formulation	Advance formulation
EMA	Yes	Yes
United Kingdom	Yes	Yes
Australia	Yes	Yes
Ireland	Yes	Yes
Belgium	Yes	Yes

Malaysia	Yes	Yes
United Arab Emirates	Yes	Yes

The above mentioned details were presented in 331st meeting of Registration Board. The Board approved the case as separate registration without referring it to the Pricing Policy. Accordingly, PE&R division has referred the case for fixation of price. The firm has submitted revised specifications as follows.

Old	Revised
Dissolution: NLT 80% (Q) in 15 minutes	Dissolution: NLT 80% (Q) in 10 minutes
Disintegration Time: NMT 30 min	Disintegration Time: NMT 10 min

The results submitted by the firm are within the revised specification. However, the firm has not submitted any fee for revised specifications as per innovator's.

Decision

Approved

Subject to submission of applicable fee for revision of specifications.

110	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 Temperature
	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	
Observations	Response
Clarification since you have not imported USP reference standard and the working standard from the API manufactured has been used in analysis which is not according to the guidelines.	For trial batches we have used API manufacturer's provided reference standard. We shall import reference standard for the commercial batches.
Provide stability studies for drug substance according to the conditions of zone IV-A for 03 batches.	The firm could not provide the stability data of DS according to the conditions of zone IV-A. However, the firm has submitted forced degradation studies as per the decision of 297th meeting of Registrtaion Board.
Submit BMRs of stability batches.	Submitted.
As per the submitted Chromatograms, the submitted forced degradation studies were performed in March, 2025 whereas the query regarding the stability data was forwarded in December, 2025. The firm was asked to submit clarifictaion:	
For the second query it is to clarify that 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.	
Decision	
Deferred	
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.	
111	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 Temperature
	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. Clearance 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	
	Submitted.	
	As per the submitted Chromatograms, the submitted forced degradation studies were performed in March, 2025 whereas the query regarding the stability data was forwarded in December, 2025. The firm was asked to submit clarification:	
	For the second query it is to clarify that 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.	
	Decision	
	Deferred	
	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.	
112	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Aptcure (PVT.) Ltd 8th Pharma city , 30-km, multan road lahore (000648)
	Application Form Dy. No / Tracking ID & date of submission	(88Y-R1U-SUPG, 2023-12-18)

Detail of Fee Submitted	30000.0, 9000.0 2023-10-20, 2025-04-25
The proposed proprietary name / brand name	VONAPT
Label Claim	
Reference to Finished product specifications	As per Innovators Specificatio
Proposed Pack Size	10's & 14's-As per SRO
Shelf Life (Unit)	2 Year25-30 DEG.CENTRIGRADE
For generic drugs (me-too Status)	VOCINTI 10MG TABLAT BY SEARLE
Pharmaceutical Group of (API)	
Name, address of Manufacturing site:	--
Name & address of API manufacturer	XIANQIANG 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	TAKECAB 10MG TABLET BY TAKEDA PHARMA. PMDA APPROVED
GMP status of the firm	
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Reason for deferment (Deferred in 344th meeting)	Response
Label claim shall be changed in online submission as per reference product label claim given in 1.5.2 i.e "Vonoprazan (as fumarate)....10mg".	It was typing error. Please consider label claim as: Each tablet Contains: Vonoprazan (as fumarate)..... 10mg
Valid GMP certificate/report of the applicant shall be submitted	GMP certificate issued on the basis of inspection conducted on 01-03-2023.
Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Polymorphic form has not been mentioned in innovator's literature i.e. Voquezna tablet.
Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.	THE COA of analysis for vonoprazan specifies the purity of the salt form, not percentage of fumarate content. We monitor vonoprazan purity by comparing our sample to a working standard of pure vonoprazan fumarate.
Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted.
Raw data of analytical method validation of drug product shall be submitted.	submitted
Submit COA of reference / working standard actually used in analysis of drug substance and drug product.	Submitted.

The innovator's product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have submitted dissolution test method and limits as follows: "0.1N HCl 900ml at 75rpm for 30 min NLT 80% should be released in 45 min." Revise your specification and submit results as per the innovator's recommendation, along with submission of requisite fee.	The firm has submitted dissolution testing at 24 months time point with specification as per innovator's product.
Executed BMRs of stability batches shall be submitted.	Submitted.
Submit inference of results of CDP studies by calculating f1 and f2 factor.	Submitted.

Decision

Approved

113	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	(1JR-QUN-LUY4, 2025-08-25)
	Detail of Fee Submitted	75000.0, 2025-06-05,
	The proposed proprietary name / brand name	Talmac 10/40mg Tablets
	Label Claim	Each film coated tablet contains: Macitentan.....10mg Tadalafil.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Macitentan: endothelin receptor antagonists (ERAs), Tadalafil: phosphodiesterase type 5 (PDE5) *the product is indicated for pulmonary arterial hypertension.
	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	Batches: 2025-T-22, 2025-T-23, 2025-T-24 (Batch Size: 1000 tablets) 06 months real time and 06 months accelerated stability data is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Macitentan: Copy of form 6 (DIL-C-8AB371) for 0.1kg material, copy of unattested invoice and packing list Tadalafil: Clearance certificate dated 26-03-2025for 1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Opsynvi 10/40mg by

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mecitentan: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted. Tadalafil: 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-B is submitted.
The status in reference regulatory authorities	OPSYNVI® (Macitentan and Tadalafil) tablets, for oral use Initial U.S. Approval: 2024, Actelion Pharmaceuticals US, Inc. a Janssen Pharmaceutical Company Titusville, NJ 08560, USFDA Approved
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	
Reason for deferment (deferred in 352nd meeting)	Response
For clarification of sampling time point for dissolution as the innovator has selected 30 minutes while the applicant has selected 45minutes.	The firm has revised the dissolution specifications as per innovator's product and submitted the test results at 9th month's time point. Initially, the firm was communicated that the innovator has established 30 minutes dissolution time point and you have selected 60 minutes, the firm has replied that the dissolution time is 45 minutes. Now the firm has revised the dissolution time point equal to 30minutes.
Decision	
Deferred	
For Product Specific Inspection (PSI) for verification of authenticity of submitted stability data. The Chairman/Director PE&R shall constitute the panel for the PSI.	
114	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
	(XE5-Q7B-YSJ5, 2025-08-25)
	Detail of Fee Submitted
	75000.0, 2025-08-13,
	The proposed proprietary name / brand name
	Talmac 10/20mg Tablets
	Label Claim
	Each film coated tablet contains: Macitentan.....10mg Tadalafil.....20mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80-As per SRO
	Shelf Life (Unit)
	2 Year(s)Below 30°C
	For generic drugs (me-too Status)
	NA
	Pharmacotherapeutic Group of (API)
	Macitentan: endothelin receptor antagonists (ERAs), Tadalafil: phosphodiesterase type 5 (PDE5) *the product is indicated for pulmonary arterial hypertension.

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	Batches: 2025-T-04, 2025-T-05, 2025-T-06 (Batch Size: 1000 tablets)
Documents for the procurement of API with approval from DRAP (in case of Import)	Macitentan: Copy of form 6 (DIL-C-8AB371) for 0.1kg material, copy of un attested invoice and packing list are submitted. Tadalafil: Clearance certificate dated 26-03-2025 for 1kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Opsynvi 10/20mg by M/s Janssen's UK.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Mecitentan: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A is submitted. Tadalafil: 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-B is submitted.
The status in reference regulatory authorities	OPSYNVI® (Macitentan and Tadalafil) tablets, for oral use Initial U.S. Approval: 2024, Actelion Pharmaceuticals US, Inc. a Janssen Pharmaceutical Company Titusville, NJ 08560, 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	
Reason for deferment (deferred in 352nd meeting)	Response
For clarification of sampling time point for dissolution as the innovator has selected 30 minutes while the applicant has selected 45minutes.	The firm has revised the dissolution specifications as per innovator's product and submitted the test results at 9th month's time point. Initially, the firm was communicated that the innovator has established 30 minutes dissolution time point and you have selected 60 minutes, the firm has replied that the dissolution time is 45 minutes. Now the firm has revised the dissolution time point equal to 30minutes.
Decision	
Deferred	
For Product Specific Inspection (PSI) for verification of authenticity of submitted stability data. The Chairman/Director PE&R shall constitute the panel for the PSI.	
115	
Case Category	Routine (Farooq Aslam)
Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
Application Form Dy. No / Tracking ID & date of submission	(5H8-DE5-QXP5, 2024-05-30)
Detail of Fee Submitted	75000.0, 2024-04-17,

The proposed proprietary name / brand name	Finron 20mg Tablet
Label Claim	Each Film Coated Tablet contains: Finerenone.....20mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2X7's, 1 X 10's, 2 X-As per SRO
Shelf Life (Unit)	2 Year(s)Store in cool and dry place below 30 celcius
For generic drugs (me-too Status)	N.A
Pharmacotherapeutic Group of (API)	Nonsteroidal Mineralocorticoid-Receptor Antagonist
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd M/s Economic Development Zone, Pingyuan County, Dezhou, Shandong, China
Detail of stability batches of drug product	Batches: TFH001, TFH002, TFH002 (Batch Size: 2500 tablets)
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 11-02-2024 for 240 grams of materials submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Kerendi 20mg tablet.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 month accelerated and 06-month real time stability study data of 03 batches conducted under the conditions of zone IV-A.
The status in reference regulatory authorities	KERENDIA(finerenone) 20mg tablet M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
Evidence of approval of manufacturing facility	Tablet General section is approved.
Evaluation Remarks	
Observations	Response
Submission of stability study data of drug product till 6th month time point.	Submitted
The innovator has added 0.1% Tween 20 in dissolution medium for testing of 20mg Finerenone tablet while you have not used the same in the testing as per submitted document.	"The innovator's product has used Acetate buffer pH 4.5 + 0.1% Tween 20 as a dissolution medium while We also used tween 20 it is Overlooked in preparation of method of Analysis While we revised the method of Analysis"
Clarification regarding the submitted dissolution specifications since you have established 30mins for achieving drug release while innovator has selected 15 mins for sampling time for the product.	The Dissolution results obtained at 15 minutes time point is above 75% in CDP which was considered as baseline benchmark for the immediate release dosage form while We are just taking general limit of dissolution Test i.e. NLT 75%(Q) in 30 minutes. The firm has submitted revised dissolution specifications.
Provide clearance certificate GD, airway bill/bill of lading for confirmation of import of API.	GD NO. LPAF-5875-2024 Date: 15-01-2024 is submitted along with form 6.
The firm shall submit applicable fee for revision for sampling time point for dissolution testing.	
Decision	

Approved

Subject to submission of fee for revision of specifications.

116	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(P1X-DH6-PAB9, 2024-05-24)
	Detail of Fee Submitted	75000.0, 2024-04-17,
	The proposed proprietary name / brand name	Finron 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Finerenone.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 X 10's, 2 X 10's, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	N.A
	Pharmacotherapeutic Group of (API)	Nonsteroidal Mineralocorticoid-Receptor Antagonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghuishuangda Pharmaceutical Co.,Ltd M/s Economic Development Zone, Pingyuan County, Dezhou, Shandong
	Detail of stability batches of drug product	Batches: TFG001, TFG002, TFG002 (Batch Size: 2500 tablets)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 11-02-2024 for 240 grams of materials submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Kerendi 10mg tablet.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 month accelerated and 06-month real time stability study data of 03 batches conducted under the conditions of zone IV-A.
	The status in reference regulatory authorities	KERENDIA(finerenone) 10mg tablet M/s Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany (USFDA Approved) NDC 50419-540-01
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
	Evidence of approval of manufacturing facility	Tablet General section is approved.
	Evaluation Remarks	
	Observations	Response
	Submission of stability study data of drug product till 6th month time point.	Submitted
	The innovator has added 0.1% Tween 20 in dissolution medium for testing of 20mg Finerenone tablet while you have not used the same in the testing as per submitted document.	"The innovator's product has used Acetate buffer pH 4.5 + 0.1% Tween 20 as a dissolution medium while We also used tween 20 it is Overlooked in preparation of method of Analysis While we revised the method of Analysis"

	Clarification regarding the submitted dissolution specifications since you have established 30mins for achieving drug release while innovator has selected 15 mins for sampling time for the product.	The Dissolution results obtained at 15 minutes time point is above 75% in CDP which was considered as baseline benchmark for the immediate release dosage form while We are just taking general limit of dissolution Test i.e. NLT 75%(Q) in 30 minutes. The firm has submitted revised dissolution specifications.
	Provide clearance certificate GD, airway bill/bill of lading for confirmation of import of API.	GD NO. LPAF-5875-2024 Date: 15-01-2024 is submitted along with form 6.
	The firm shall submit applicable fee for revision of dissolution sampling time point.	
	Decision	
	Approved	
	Subject to submission of fee for revision of specifications.	
117	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Pacific Pharmaceutical Ltd 30 km Multan Road Lahore (000295)
	Application Form Dy. No / Tracking ID & date of submission	(PA3-NGT-W459, 2024-06-26)
	Detail of Fee Submitted	30000.0, 30000.0 2024-05-20, 2024-05-20
	The proposed proprietary name / brand name	Amlodipine 5mg Tablet
	Label Claim	Each Tablet contains: Amlodipine besylate equivalent to amlodipine.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20s-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Anam-5 Tablet
	Pharmacotherapeutic Group of (API)	Calcium channel blockers
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glochem industries private limited Survey Nos 174 to 176 IDA Bollaram Jinnaram Mandal Sangareddy District 502 325 Telangana State INDIA
	Detail of stability batches of drug product	Provided for six months as per zone IVA
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 21 March 2022 submitted by firm
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as per zone IVA
	The status in reference regulatory authorities	Amlodipine 5mg Tablet by Milpharm Limited
	GMP status of the firm	
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm based on inspection conducted on 01.01.2025 indicate Tablet General section
	Evaluation Remarks	
	Decision	

	Approved	
118	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(S1S-SMV-JEHD, 2025-05-09)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	OTENAZ CAPSULES
	Label Claim	Each capsule contains: Oteseconazole 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,18's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled,9's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Not Store and Transport above 30 degree centigrade.
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd Address: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	Firm has submitted both accelerated and real time stability studies data as per conditions of Zone IV A for six months.
	Documents for the procurement of API with approval from DRAP (in case of Import)	firm has submitted license to import drug for clinical trial purpose.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE': Provided, CDP; Provided,
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted both accelerated and real time stability studies data as per conditions of Zone IV A
	The status in reference regulatory authorities	Approved in USFDA; VIVJOA Capsules Manufactured by Mycovia Pharmaceuticals, Inc. Durham, NC 27703
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 23 July 2024.
	Evidence of approval of manufacturing facility	CLB letter No. 2-5/85-Lic Vol-VI dated 23rd January 2019 shows Capsule (General) Section.
Evaluation Remarks		
The query and response of firm is mentioned in the table below for consideration of Board.		
Queries		Response
On the shared DML following is mentioned (The enterprise shall get the corresponding drug approval number (except the Chinese Herbal Pieces that exempt from the approval No. regulation), and drugs can only be sold on the market after it passes the GMP Compliance		Firm has submitted translated version of a document issued by National Medical Products Administration indicating

	Inspection). does the API "OTESECONAZOLE" got drug approval number (if yes share drug approval number) and passed the GMP inspection or not? Moreover, attach whole document indicating OTESECONAZOLE approval No. and GMP compliance by Zhejiang Medical Products Administration.		registration of Oteseconazol Registration No. Y20230000624 with date of issuance 25.10.2024 with Validity period 24 months
Decision			
Approved			
119	Case Category	New License (Haleema Sharif)	
	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	(3WL-7QB-PETA, 2025-07-04)	
	Detail of Fee Submitted	37000.0, 2025-06-27,	
	The proposed proprietary name / brand name	Clinag	
	Label Claim	Each mL Contains: Clindamycin (as Phosphate).....10 mg (1% w/v) 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 15C-30C	
	For generic drugs (me-too Status)	CLYCIN T 1% Lotion SHAIGAN Pharmaceuticals	
	Pharmacotherapeutic Group of (API)	Antibiotic	
	Name, address of Manufacturing site:	Self Manufacturing	
	Name & address of API manufacturer	Name: Topfond Pharmaceutical Co., Ltd. Address: No. 66 Jianshe Road, High-Tech Industrial Development District City: Zhumadian City Post code: 463000 Province: Henan Country: P.R.China Fax: +86-396-3823655 Tel.: +86-396-3825006 E- mail address: zangwenshen	
	Detail of stability batches of drug product	Stability studies of 3 batches for 6 six is submitted	
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearence certificate is uploaded in Module III by firm	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; provided	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies of drug substance as per zone IVA is submitted.	
	The status in reference regulatory authorities	Approved in MHRA	
	GMP status of the firm	Attached	
	Evidence of approval of manufacturing facility	CLB letter dated 19 Feb 2021 indicated Cream/Ointment/Lotion/Gel section of firm.	
	Evaluation Remarks		

The query and response of firm is mentioned in the table below for consideration of Board.																																													
Queries	Response																																												
Link to verify the excipient of reference product so to match with applied product/otherwise submit drug excipient compatibility studies.	All excipients of all formulation are similar to reference product Dalacin T except Lexemul T. Applied product don't have it.																																												
Decision																																													
Approved																																													
The application is approved, subject to submission of the required fee as per SRO 1324(I)/2024 dated 30-08-2024 for revision of the formulation to align with the innovator (reference) product, following the addition of Lexemul T.																																													
120	<table> <tr> <td>Case Category</td><td>Routine (Haleema Sharif)</td></tr> <tr> <td>Name, address of Applicant.</td><td>SWERA PHARMACEUTICALS PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (000941)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(GQR-21L-2GXT, 2024-02-28)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>75000.0, 2024-01-02,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>CEFERA 1 g IV</td></tr> <tr> <td>Label Claim</td><td>Each Vial Contains: Ceftriaxone Sodium Equivalent to ceftriaxone.....1g</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>1s-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year(s) store below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Oxidil injection of Sami</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin</td></tr> <tr> <td>Name, address of Manufacturing site:</td><td>Evolution Pharmaceuticals (Pvt.) Ltd.- #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-</td></tr> <tr> <td>Name & address of API manufacturer</td><td>Sinopharm Weiqida Pharmaceutical Co., Ltd</td></tr> <tr> <td>Detail of stability batches of drug product</td><td>16500 vials: 3 batches</td></tr> <tr> <td>Documents for the procurement of API with approval from DRAP (in case of Import)</td><td>03-02-2023: clearance certificate submitted</td></tr> <tr> <td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Oxidil Injection of Sami: PE studies performed</td></tr> <tr> <td>Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)</td><td>3 batches as per Zone IV-A</td></tr> <tr> <td>The status in reference regulatory authorities</td><td>USFDA Approved</td></tr> <tr> <td>GMP status of the firm</td><td>(Evolution pharma: 11-01-2023: GMP certificate</td></tr> <tr> <td>Evidence of approval of manufacturing facility</td><td>(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section</td></tr> <tr> <td colspan="2">Evaluation Remarks</td></tr> <tr> <td colspan="2">The query and response of firm is mentioned in the table below for consideration of Board.</td></tr> </table>	Case Category	Routine (Haleema Sharif)	Name, address of Applicant.	SWERA PHARMACEUTICALS PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (000941)	Application Form Dy. No / Tracking ID & date of submission	(GQR-21L-2GXT, 2024-02-28)	Detail of Fee Submitted	75000.0, 2024-01-02,	The proposed proprietary name / brand name	CEFERA 1 g IV	Label Claim	Each Vial Contains: Ceftriaxone Sodium Equivalent to ceftriaxone.....1g	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	1s-As per SRO	Shelf Life (Unit)	2 Year(s) store below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.	For generic drugs (me-too Status)	Oxidil injection of Sami	Pharmacotherapeutic Group of (API)	Cephalosporin	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.) Ltd.- #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd	Detail of stability batches of drug product	16500 vials: 3 batches	Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A	The status in reference regulatory authorities	USFDA Approved	GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate	Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section	Evaluation Remarks		The query and response of firm is mentioned in the table below for consideration of Board.	
Case Category	Routine (Haleema Sharif)																																												
Name, address of Applicant.	SWERA PHARMACEUTICALS PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (000941)																																												
Application Form Dy. No / Tracking ID & date of submission	(GQR-21L-2GXT, 2024-02-28)																																												
Detail of Fee Submitted	75000.0, 2024-01-02,																																												
The proposed proprietary name / brand name	CEFERA 1 g IV																																												
Label Claim	Each Vial Contains: Ceftriaxone Sodium Equivalent to ceftriaxone.....1g																																												
Reference to Finished product specifications	United States Pharmacopeia																																												
Proposed Pack Size	1s-As per SRO																																												
Shelf Life (Unit)	2 Year(s) store below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.																																												
For generic drugs (me-too Status)	Oxidil injection of Sami																																												
Pharmacotherapeutic Group of (API)	Cephalosporin																																												
Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.) Ltd.- #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-																																												
Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd																																												
Detail of stability batches of drug product	16500 vials: 3 batches																																												
Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted																																												
Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed																																												
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A																																												
The status in reference regulatory authorities	USFDA Approved																																												
GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate																																												
Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section																																												
Evaluation Remarks																																													
The query and response of firm is mentioned in the table below for consideration of Board.																																													

Queries	Response
Imported lots of API as per uploaded commercial invoice are Q012105066, Q012105067 & S012102005 but any of the uploaded COA is not of these lots, please upload COA of these lots, as it is not still submitted. also make it clear which lot is used in stability studies of applied formulation.	We confirm that the stability studies for the applied formulation of Ceftriaxone Sodium Injection were conducted using the drug substance from: · Batch No.: Q012105066 · Batch No.: Q01210506 These are the same batches imported under the referenced commercial invoice and used in the primary stability batches for this application. The batch S012102005 (Cefotaxime Sodium) was not used in any stability studies for Ceftriaxone Sodium Injection, as it is a different API
Please upload USP monograph of drug substance manufacturer.	Drug manufacturer specification only says “>84%”, that is not sufficient by itself because: The USP lower limit is 90%, so “>84%” would be below the required minimum for injection grade. The finished product specification always has both a lower and upper limit (e.g., 90–115%), not just a single limit.

Decision

Deferred

The Board rejected the submitted stability study data, as the drug substance manufacturer’s specification stating assay limit “>84%” is not acceptable. This specification does not comply with USP requirements, which set a lower limit of 90% for ceftriaxone for injection (ready to fill powder). Furthermore, ceftriaxone for injection’s specifications must include both lower and upper acceptance limits (e.g., 90–115%), rather than a single limit. Moreover, submitted assay limit is of ceftriaxone sodium(API) not ceftriaxone for injection (ready to fill powder).

The applicant is therefore advised to submit complete product development data and stability studies using appropriate and pharmacopeia-compliant specifications with ceftriaxone for Injection, including defined lower and upper acceptance criteria in line with USP requirements.

121	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbellla road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(Q24-4YU-2VQG, 2024-06-25)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	dexowel 60
	Label Claim	Each capsule contains: 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)Below 30 °C
	For generic drugs (me-too Status)	razodex 60 by Getz phrma
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Name, address of Manufacturing site:	M/S Winlet pharma-30 km lahore sargodha road sargodha-
	Name & address of API manufacturer	Ms surge pharma

Detail of stability batches of drug product	Provided for six months.
Documents for the procurement of API with approval from DRAP (in case of Import)	Uploaded local purchase invoice.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability of pellets is provided by firm.
The status in reference regulatory authorities	Approved in USFDA,
GMP status of the firm	
Evidence of approval of manufacturing facility	CLB letter date 26th February 2018 uploaded by firm in dossier indicated Capsule General section.

Evaluation Remarks

The queries and response of firm is summarized in the table.

Queries	Response
Upload valid copy of DML of both manufacturer and applicant.	Firm has submitted old DML along with copy of application for renewal of DML.
Valid GMP certificate of M/s. Winlet.	GMP certificate issued to the firm based on inspection conducted on 25.11.2022.
Justification for conclusion of comparative dissolution profile by drug product manufacturer.	Firm has submitted comparative dissolution profile with revised conclusion.
Mention steps of manufacturing method of pellets by drug substance manufacturer.	Uploaded by firm.
In uploaded chromatograms of stability studies, it is not clear which chromatogram is of blank, standard or sample. How has the firm distinguished between the chromatograms?	Firm has submitted chromatograms having mentioned standard sample on it.
Purchase invoice for purchase of pellets.	Uploaded by firm
There are only three chromatograms uploaded for stability studies of one batch however in calculation sheets the AUC of 5 standards is mentioned. clarify Please.	Firm has uploaded five chromatograms.

Decision

Approved

122	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	LINZ PHARMACEUTICALS (PVT) LTD. Plot No 31-G & 31-H, Sector-15, Korangi Industrial Area (000540)
	Application Form Dy. No / Tracking ID & date of submission	(493-U4D-ZJ78, 2024-02-29)
	Detail of Fee Submitted	75000.0, 2023-08-07,
	The proposed proprietary name / brand name	Lizobal 500mcg Injection
	Label Claim	Each ampoule contains: Mecobalamin.....500mcg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	-2 Year(s)Protect from light and store below 30°C

For generic drugs (me-too Status)	Methycobal
Pharmacotherapeutic Group of (API)	Antianemic preparations
Name, address of Manufacturing site:	Bosch Pharmaceuticals (Pvt.) Ltd.-Plot No. 221-223, Sector 23, Korangi Industrial Area, Karachi.-
Name & address of API manufacturer	Hebei Huarong Pharmaceutical., Ltd, Located at No. 8, Weier road, ningjin salinization Industrial Park, Xingtai, Hebei Province, China, 055550.
Detail of stability batches of drug product	Submitted for two years
Documents for the procurement of API with approval from DRAP (in case of Import)	firm has submitted clearance certificate dated 02 March 2023
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; Provided.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of drug substance is at 25oC and 60% RH
The status in reference regulatory authorities	Pharmaceutical and Medical Devices (PMDA)
GMP status of the firm	
Evidence of approval of manufacturing facility	CLB letter dated 20th June 2020 indicate Injectable ampoule I section.
Evaluation Remarks	
The queries and response of firm is summarized in the table.	
Queries	Response
Justification of 30% overage by evidence of reference/guideline as for Mecobalamine 5-15% overages usually added.	30% overage of Mecobalamin was initially incorporated into the formulation, considering the potential degradation of the active ingredient over the product's shelf life. In light of the continuous improvement, the pharmaceutical development was conducted between June 2023 to December 2023, for reduction in overages to 10%. The respective Pharmaceutical Development has been attached.
Justification for 90-140% assay limit for drug product as for vitamins assay limit is 120%.	As informed by Bosch Pharmaceuticals (Pvt.) Ltd. (Contract Acceptor) We would like to inform that the assay limit was inadvertently written as 90–140%. The corrected assay limit is 90-120%. The revised Finished Product Specification and the corresponding stability data are attached as Annex II and Annex III respectively.
Clarify endotoxin limits for finished product whether it Less than 400EU/mg (3.2.P.5.4) OR Less than 700 EU/mg because both are mentioned is submitted dossier.	We would like to inform that the Endotoxin limit was inadvertently written as less than 400EU/mg. We hereby confirm that the Endotoxin limit for the finished product is less than 700 EU/mg.
Stability of drug substance and drug product both initiated simultaneously in January 2019, please clarify.	Although firm has not submitted any explanation for this, however firm has submitted revised stability study data.
Your reply dated November 8th, 2025, 2:41 pm is evaluated. it is hereby required to attach audit trail report of 21CFR compliant system for updated stability studies.	Audit trail submitted by firm.
Decision	

Deferred

Registration Board deferred the case for submission of following:

1. API procurement documents.
2. Testing specifications for finished product.
3. Details of current batch manufacturing (batch manufacturing record (BMR), details of the manufacturing process, equipment used, and in-process control data).

123	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	SWERA PHARMACEUTICALS PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (000941)
	Application Form Dy. No / Tracking ID & date of submission	(87M-R7Y-P82M, 2024-02-28)
	Detail of Fee Submitted	75000.0, 2024-01-02,
	The proposed proprietary name / brand name	CEFERA 500mg IM
	Label Claim	Each vial contains: Ceftriaxone as Sodium.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year(s) store below 30°C. Protect from light. Reconstituted solution may be stored at 25°C for 24 hours or between 2-8°C for 7 days.
	For generic drugs (me-too Status)	Oxidil injection of Sami
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Evolution Pharmaceuticals (Pvt.) Ltd.- #: 25 & 26, Street #: S-3, RCCI, National Industrial Zone, Rawat, Islamabad - Pakistan-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd
	Detail of stability batches of drug product	16500 vials: 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	03-02-2023: clearance certificate submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Oxidil Injection of Sami: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	(Evolution pharma: 11-01-2023: GMP certificate
	Evidence of approval of manufacturing facility	(Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section
	Evaluation Remarks	
	The query and response of firm is mentioned in the table below for consideration of Board.	
	Queries	Response

Imported lots of API as per uploaded commercial invoice are Q012105066, Q012105067 & S012102005 but any of the uploaded COA is not of these lots, please upload COA of these lots, as it is not still submitted. also make it clear which lot is used in stability studies of applied formulation.	We confirm that the stability studies for the applied formulation of Ceftriaxone Sodium Injection were conducted using the drug substance from: · Batch No.: Q012105066 · Batch No.: Q01210506 These are the same batches imported under the referenced commercial invoice and used in the primary stability batches for this application. The batch S012102005 (Cefotaxime Sodium) was not used in any stability studies for Ceftriaxone Sodium Injection, as it is a different API
Please upload USP monograph of drug substance manufacturer.	Drug manufacturer specification only says “>84%”, that is not sufficient by itself because: The USP lower limit is 90%, so “>84%” would be below the required minimum for injection grade. The finished product specification always has both a lower and upper limit (e.g., 90–115%), not just a single limit.

Decision

Deferred

The Board rejected the submitted stability study data, as the drug substance manufacturer’s specification stating assay limit “>84%” is not acceptable. This specification does not comply with USP requirements, which set a lower limit of 90% for ceftriaxone for injection (ready to fill powder). Furthermore, ceftriaxone for injection’s specifications must include both lower and upper acceptance limits (e.g., 90–115%), rather than a single limit. Moreover, submitted assay limit is of ceftriaxone sodium(API) not ceftriaxone for injection (ready to fill powder).

The applicant is therefore advised to submit complete product development data and stability studies using appropriate and pharmacopeia-compliant specifications with ceftriaxone for Injection, including defined lower and upper acceptance criteria in line with USP requirements.

124	Case Category	Routine (Haleema Sharif)
	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	(H4Q-HUG-3666, 2024-04-17)
	Detail of Fee Submitted	30000.0, 2023-12-13,
	The proposed proprietary name / brand name	Empazin Tablet 25 mg
	Label Claim	Each Film-coated Tablet Contains: Empagliflozin.....25 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree C
	For generic drugs (me-too Status)	Truglif Tablets 25mg, M/s AGP Limited, Reg. No. 104200.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03.
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical Co., Ltd. (Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China).
Detail of stability batches of drug product	Provided
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 mentioning 1kg of Empagliflozin and Form 6 is also attested by DRAP Karachi, dated 04-11-2021. Firm has also submitted copy of commercial invoice No. HN20211009-A dated 22-10-2021 mentioning 1kg of Empagliflozin, B. No. 20060201 and is also attested by DRAP Karachi, dHE-20210605-D01-E06-02 and invoice is also attested by DRAP, Karachi dated 04-11-2021.
Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP & PE studies are performed against comparator product i.e. Xenglu 25mg Tablet, B. No. 144134, Mfg. date 06-2022 manufactured by M/s Hilton Pharma and both comparator and applied formulation have shown similar release pattern and values of F2 is in acceptable range in all the three mediums of CDP i.e. 0.1N HCl, Acetate buffer and Phosphate buffer.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability study data of 3 batches of drug substance as per Zone IV-A is submitted. Accelerated 06 months and real time for 24 months.
The status in reference regulatory authorities	Jardiance 25mg Tablets, Approved in USFDA.
GMP status of the firm	GMP certificate issued to the firm based on GMP inspection conducted on 27 December 2023.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. 2-10/93-Lic (Vol-I) dated 07-06-2022 mentioning tablet (General) section.
Evaluation Remarks	
Registration Board in its 352nd meeting deferred the case of Empazin tablet 25mg by M/s Nawan Laboratories Pvt. Ltd. Karachi for Product Specific Inspection for verification of authenticity of submitted stability data especially with reference to the following points: The stability studies must be performed using a valid reference standard. In the initial submission, the Certificate of Analysis (COA) of the working standard indicated an expiry date of 17 04 2018. Verification is required to ensure that valid reference standards were used during the studies. The comparative dissolution profile was initially submitted using 6 tablets instead of the required 12. Upon query, the firm submitted the comparative dissolution profile with 12 tablets performed in 2022. Verification is required to confirm the accuracy of the submitted data. The submitted chromatograms do not indicate any processing date. The inspection will verify proper documentation and traceability of the analytical data. A justification is required for selecting a dissolution method that differs from the innovator product. The inspection will assess the appropriateness of the method. Following panel was constituted by Chairman Registration Board, 1.Hafiz Muhammad Tayyab, Additional Director, 2.Mr. Zubair Masood, DD The letter was issued to panel members and forwarded to M/s Nawan Laboratories Pvt. Ltd as well through eAPP. & M/s. Nawan was communicated a tentative date 09-12-2025 for inspection and firm vide tracking ID: VNS-M1G-RQG4 has submitted for postponement of inspection due to non-availability of technical person and maintenances of facility. The case is hereby submitted for consideration of the Board Please.	
Decision	
Deferred	

	The Registration Board agreed to the firm's request to postpone the inspection.	
125	Case Category	New Section (Haleema Sharif)
	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	(ZS6-NAQ-6UWU, 2024-12-31)
	Detail of Fee Submitted	75000.0, 2024-10-18,
	The proposed proprietary name / brand name	Invital D K2 180/25mcg soft gelatin capsule
	Label Claim	Each soft gelatin capsule contains: Menaquinone-7 (Vitamin K2) 180mcg Cholecalciferol ----- --25mcg Equiv.to Vitamin D3.....1000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO,30's-As per SRO,60'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)	Vitamin K2 with vitamin D
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anthem Biosciences Pvt. Ltd, Unit-IV. Address:Plot No. 276-P, 277-P, Sy No. 20, Bannikuppe Road Harohalli Industrial area, phase-II, Kanakapura Taluk, Ramanagara District.,M/s Fermenta Biotech Ltd.Address:Plot NOs. Z109 B&C, Dahej SEZ II, Village- Dahej, Taluka-Vagara, Dist-Bharuch 392130, Gujarat, India
	Detail of stability batches of drug product	3 batches: 600 capsule
	Documents for the procurement of API with approval from DRAP (in case of Import)	Cholecalciferol: Drug Import License dated 14-10-2022 Menaquine: Drug Import License dated 14-04-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Caruso's Vitamin K2 + D3: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per zone IV-A
	The status in reference regulatory authorities	Vitamin K2 + D3 Therapeutic Goods Administration (TGA) approved as listed medicine
	GMP status of the firm	03-01-2023: GMP certifiante issuance date
	Evidence of approval of manufacturing facility	18-05-2021: New section Soft gelatin capsule (General) section
Evaluation Remarks		
Previous Decision of Registration Board: Registration Board in its 347th meeting deferred the case for evidence of approval of applied formulation as a pharmaceutical drug product in reference regulatory authorities which were adopted by Registration Board in its 275th meeting. Reply of the Firm The firm has stated that the Vitamin K2 and Vitamin D3 product is listed (AUST L) on the Australian Register of Therapeutic Goods. They explained that listed medicines in Australia are not individually evaluated by the Therapeutic Goods Administration (TGA) for quality, safety, and efficacy prior to marketing, and that such listing is based on sponsor self-certification of compliance with regulatory requirements. Evaluation by PEC: It is clarified for the Registration Board that TGA has not approved this product as a pharmaceutical medicine. The product is only listed (AUST L), which does not involve pre-market		

evaluation for safety, quality, or efficacy. Only TGA registered medicines (AUST R) are approved as pharmaceutical products.

Decision

Rejected

Registration Board rejected the firm's application, as the submitted evidence does not indicate that applied formulation is approved by reference regulatory authority as a pharmaceutical drug product.

126	Case Category	New License (Haleema Sharif)
	Name, address of Applicant.	Fast Pharmaceuticals (Pvt) Ltd. Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (000954)
	Application Form Dy. No / Tracking ID & date of submission	(JG7-DNP-BU2B, 2024-12-10)
	Detail of Fee Submitted	37000.0, 2024-11-15,
	The proposed proprietary name / brand name	Cefas 200mg/5ml Suspension
	Label Claim	Each 5ml of Reconstituted Suspension Contains:- Cefixime (As Trihydrate) 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C.
	For generic drugs (me-too Status)	Cefspan D.S Suspension by Barret Hodgson
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited 5-A Zafar Ali Rd, Gulberg V, Lahore, Punjab.
	Detail of stability batches of drug product	3 batches: 666 bottles
	Documents for the procurement of API with approval from DRAP (in case of Import)	06-03-2024: Invoice submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefspan DS suspension: PE studies performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml (USFDA Approved)
	GMP status of the firm	28-04-2022: New DML issued
	Evidence of approval of manufacturing facility	29-04-2022: Issuance of DML letter with dry powder suspension (Cephalosporin) section
	Evaluation Remarks	
	Previous Decision of Registration Board: Registration Board in its 344th meeting deferred the case for following: Submit API specifications and analytical method from API manufacturer. Submit complete HPLC chromatograms for stability studies. Submit compatibility studies Submit in-use stability studies Submit preservative effectiveness studies. Evaluation by PEC: Firm has submitted following: API specifications and analytical method from API manufacturer. HPLC chromatograms for stability studies. Compatibility studies of drug with excipients (There was no loss of assay observed with the selected excipients and no interaction found with Drug substance after preparing and analyzing the binary mixtures of drug substance with excipients). In-use stability studies (stable for 8 days at room temperature 15-30oC after reconstitution) Preservative effectiveness studies.	
	Decision	

	Approved	
127	Case Category	New License (Haleema Sharif)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)
	Application Form Dy. No / Tracking ID & date of submission	(WSY-XBX-54JR, 2024-03-01)
	Detail of Fee Submitted	30000.0, 2024-01-25,
	The proposed proprietary name / brand name	Novidol Forte
	Label Claim	Each tablet contains Paracetamol 650mg and Orphenadrine Citrate 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Nuberol forte tablets by Searle Pharma
	Pharmacotherapeutic Group of (API)	Non-opioid analgesic and antipyretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Harika Drugs Private Limited,Pharmagen Limited
	Detail of stability batches of drug product	----
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted license to import for Orphenadrine Citrate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	----
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	----
	The status in reference regulatory authorities	Could not be confirmed.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	CLB letter No. 17th September 2021 indicate Tablet (General) section.
Evaluation Remarks		
Previous Decision: The Board in its 344 RB meeting deferred the case for submission of valid RRA reference of applied product OR submission of following as per decision of 179th meeting of the Authority, Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Evaluation by PEC: Firm has submitted a link of RRA i.e. TGA, Australia as an evidence of approval of applied combination in Australia, however it is of different strength (for 450mg and 35mg strength).		
Decision		
Deferred		
Registration Board deferred the case for provision of evidence of approval of applied formulation in RRA in applied strength i.e. Paracetamol 650mg and Orphenadrine Citrate 50mg.		

128	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(12U-TVM-DMB1, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-06,
	The proposed proprietary name / brand name	Dextone Capsule 30mg
	Label Claim	Each capsule contains; Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole 30 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Razodex Capsule 30mg by (Getz Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	PPI
	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 (Dexilant 30mg Tablets)
	Detail of previous approval	344 Meetings of Registration Board held on 31th Dec,2024 to 2nd Jan 2025.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
129	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(1A6-GMX-RN48, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Lestiva 4gm Sachet
	Label Claim	Each sachet contains Anhydrous Cholestyramine.....4gm (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)	Questran 4gm Sachet

	Pharmacotherapeutic Group of (API)	Bile Acid Sequestrant
	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 (Teve North america)
	Detail of previous approval	350 minutes of Meeting of Reg. Board Held on 29th to 30th July 2025 (Lyster 4gm Sachet)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
130	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(1EG-BTY-8261, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-07,
	The proposed proprietary name / brand name	Calopra Tablet 2mg
	Label Claim	Each Film Coated Tablet contains: Prucalopride Succinate Equivalent to Prucalopride.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Manufacturer Name: SEARLE PAKISTAN LIMITED Brand Name & Strength: PRU-CIC 2m g Ta blet Approved in 322nd Minutes of Meeting
	Pharmacotherapeutic Group of (API)	Prucalopride is in a class of medications called serotonin receptor agonists. (Reference; Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Manufacturer Name: axunio Pharma GmbH Brand Name & Strength: Prucalopride 2mg film-coated tablets Composition: Each film-coated tablet contains Prucalopride succinate equivalent to 2mg prucalopride Marketing Authorization number :PL 47848/0024 Dosage Form: oral tablet Reference Regulatory Authority: MHRA approved
	Detail of previous approval	Prucalopride Succinate 2mg Tablet in 343rd Meeting
	Evaluation Remarks	

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

131	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(1HS-PPW-XBW6, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	MIROLIN 2.5MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	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)	Wimits Pharmaceuticals Pvt. LTD 344TH MEETINGMirogab 2.5mg Tablet
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds $\alpha 2\delta$ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca^{2+}) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets 2.5mg Composition: Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin..... 2.5mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	344th

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
132	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(1U2-3DN-8WAG, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Carimax 4.5mg Capsule
	Label Claim	Each Capsule contains Cariprazine(as cariprazine hydrochloride) 4.5mg
	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)	Manufacturer Name: GENIX PHARMA PRIVATE LIMITED44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan. Brand Name & Strength: Caripz 4.5mg Capsule Composition: Each Capsule contains Cariprazine(as car
	Pharmacotherapeutic Group of (API)	Cariprazine is also used along with other medications to treat depressive symptoms in adults with major depressive disorder (MDD). Cariprazine is in a class of medications called atypical antipsychotics. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhpura Road Lahore-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
133	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

	Application Form Dy. No / Tracking ID & date of submission	(25J-H1U-1RGR, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	ELAGIX-200MG Tablet
	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	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Eladiol 150mg Tablet of M/s Nabiqasim Industries (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Elagolix is in a class of medications called gonadotropin-releasing hormone (GnRH) receptor antagonists.
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	ORILISSA 150mg Tablets of M/s AbbVie USFDA approved.
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
134	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(27B-4W2-2E58, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-11,
	The proposed proprietary name / brand name	Venoferra 50mg/ml Injection
	Label Claim	Each ml Contains:- Iron as Ferric Carboxymaltose.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml vial x 1's-As per SRO,10ml vial x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30
	For generic drugs (me-too Status)	FCM Injection of M/s Genix Pharma – Karachi
	Pharmacotherapeutic Group of (API)	Haematinics
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd. -Plot No. 145, Industrial Triangle Kahuta Road Islamabad.-

	The status in reference regulatory authorities	Injectafer Solution IV (USFDA Approved)
	Detail of previous approval	MaltEvo 50mg/ml Solution for Injection, product is approved in 331st DRB meeting for M/s PharmEvo Pr
	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.	
135	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Evolution Pharmaceuticals (Pvt.) Ltd. Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867)
	Application Form Dy. No / Tracking ID & date of submission	(2ZZ-Z87-7UP6, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-06,
	The proposed proprietary name / brand name	KOMET
	Label Claim	Each vial contains: 2 Million International Units (I.U) is approximately equivalent to 160mg of sterile Colistimethate sodium
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool, dry place, protected from light. Maintain at the specified temperature range. Do not freeze.
	For generic drugs (me-too Status)	Brand Name: Colistimethate Inj 2 MIU Manufacturer Name: Mukhtar Enterprises Registration No.: 094757
	Pharmacotherapeutic Group of (API)	Polymyxins are a group of lipopeptide antibiotics
	Name, address of Manufacturing site:	Name: M/s Biogen Life Sciences Address:8-km, Chak- Address:8-km, Chakbeli Road, Rawat, Rawalpindi Telephone: + 92 51 4493471 Fax: ---- E-mail: bls.qcd@gmail.com-
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection (MHRA Approved).
	Detail of previous approval	Applied product is approved for Biogen Life Sciences in Minutes of M-297 meeting of Registration Boa
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
136	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(39U-1RA-XBLU, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-08,
	The proposed proprietary name / brand name	Aculax 30mg/ml Injection
	Label Claim	Each 1ml ampoule contains Ketorolac Tromethamine 30mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Toradol 30mg /1ml Reg. NO.108584
	Pharmacotherapeutic Group of (API)	ANTI-INFLAMMATORY, NON-STEROID
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Ketocar 30mg/ml Injection Reg.NO 123812 , Meeting NO,333
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
137	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(4DM-8X6-7GPW, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Carimax 6mg Capsule
	Label Claim	Each Capsule contains Cariprazine(as cariprazine hydrochloride) 6mg

	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)	GENIX PHARMA PRIVATE LIMITED44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan. Brand Name & Strength: Caripz 6mg Capsule Composition: Each Capsule contains Cariprazine(as cariprazine hydrochloride
	Pharmacotherapeutic Group of (API)	Cariprazine is also used along with other medications to treat depressive symptoms in adults with major depressive disorder (MDD). Cariprazine is in a class of medications called atypical antipsychotics. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Skywin Pharmaceutical,-Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhpura Road Lahore-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
138	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(4G3-E2Q-ARX4, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-06,
	The proposed proprietary name / brand name	XEnole Tablet 500mg/20mg
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Glomov tablet by Global Pharmaceuticals Pvt LTd
	Pharmacotherapeutic Group of (API)	Esomeprazole (PPI) and Naproxen (NSAID)

	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	Vimovo Tablets 500mg/20mg by AstraZeneca Pharmaceutical industry company
	Detail of previous approval	343 MINUTES OF MEETING held on 3rd to 5th Dec 2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
139	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(4Y5-EXB-M935, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	Upafix 15mg PR Tablet
	Label Claim	Each Film Coated Extended-Release Tablet contains: Upadacitinib Hemihydrate equivalent to Upadacitinib.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals approved product 344th
	Pharmacotherapeutic Group of (API)	Upadacitinib is in a class of medications called Janus kinase (JAK) inhibitors (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore(-
	The status in reference regulatory authorities	Manufacturer Name: AbbVie Inc. Product of Ireland Brand Name & Strength: Rinvoq (upadacitinib) 15mg Extended-release Tablet Composition: Each tablet contains 15.4mg Upadacitinib hemihydrate equivalent to upadacitinib.....15mg NDC 0074-2306-30 Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: USFDA Approved
	Detail of previous approval	344th
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
140	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(5NV-QUS-ZZM2, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	LASLID 100MG TABLETS
	Label Claim	Each Film Coated Tablet contains Lasmiditan hemisuccinate equivalent to Lasmiditan.....100mg
	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)	Wimits PharmaceuticalsLasmiditanHemisuccinate equivalent toLasmiditan.....100mg
	Pharmacotherapeutic Group of (API)	Selective serotonin (5HT1) agonistsN02CC08
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-SunderIndustrial Estate, Lahore-
	The status in reference regulatory authorities	REYVOW(lasmiditan) tablet 100mgM/sElilillyand Company(USFDA approved) NDC 0002-4491-08
	Detail of previous approval	348th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
141	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(5WP-ME7-7Z9A, 2025-12-04)

	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Fireno Tablet 20mg
	Label Claim	Each Tablet contains: Finerenone 20mg (Innovator Spec's.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Kerendia tablet 20mg by Bayer healthcare
	Pharmacotherapeutic Group of (API)	mineralocorticoid receptor antagonist.
	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
	Detail of previous approval	348 Meetings of Registration Board held on 1st and 2nd July 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	
142	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	ISIS Pharmaceuticals & Chemical Works 25/1-3, Sector 12-C, North Karachi Industrial Area (000126)
	Application Form Dy. No / Tracking ID & date of submission	(6BA-VQD-RW8Y, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	CEFZYN INJECTION 2G
	Label Claim	Each Vial Contains: Cefoperazone as Sodium...1000mg Sulbactam as Sodium.....1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2g-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 C
	For generic drugs (me-too Status)	Cebac Injection 2g (M/s Bosch Pharma)
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins
	Name, address of Manufacturing site:	NICHOLAS PHARMACEUTICALS-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 2g Pfizer PMDA Japan

	Detail of previous approval	Wincef 2gm Injection (333 rd 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	
143	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(6GJ-PGB-QW2B, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Carimax 1.5mg Capsule
	Label Claim	Each Capsule contains Cariprazine(as cariprazine hydrochloride) 1.5mg
	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)	Manufacturer Name: GENIX PHARMA PRIVATE LIMITED44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan. Brand Name & Strength: Caripz 1.5mg Capsule Composition: Each Capsule contains Cariprazine(as car
	Pharmacotherapeutic Group of (API)	Cariprazine is also used along with other medications to treat depressive symptoms in adults with major depressive disorder (MDD). Cariprazine is in a class of medications called atypical antipsychotics. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS -Plot # 01, Al Badar Industrial Estate, Phase II Sheikhpura Road Lahore.-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
144	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(6QN-D34-8759, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Artecent-60 IM/IV Injection
	Label Claim	Each vial contains: Artesunate. 60mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from light. The reconstituted solution should be stored below 30°C and should be used within 1 hour. 6.5
	For generic drugs (me-too Status)	Gen-M Injection Each vial contains:- Artesunate 60 mg Manufactured by: Genix Pharma (Pvt) Ltd., 44-45/B Korangi Creek Raod Karachi , Karachi
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	Artesunate 60 mg Injection By Amivas LLC, 600 Capability Green, Luton,LU1 3LU, USA WHO & FDA Approved
	Detail of previous approval	331st 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.	
145	Decision	
	Approved	
	Case Category	Contract Manufacturing (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	(71S-P7X-EGP5, 2025-12-04)
	Detail of Fee Submitted	93000.0, 2024-10-15,
	The proposed proprietary name / brand name	PTI

	Label Claim	Each Film Coated Tablet contains: EMPAGLIFLOZIN 25mg LINAGLIPTIN (USP).....5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	14's , 28's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Empaa-L Tablet (Weather Folds Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals -Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK Pakistan-
	The status in reference regulatory authorities	EMPAGLIFLOZIN + LINAGLIPTIN 25mg+5mg TABLET (Boehringer Ingelheim International GmbH Binger Str. 173 55216 Ingelheim am Rhein Germany.) https://www.medicines.org.uk/emc/product/10316/s
	Detail of previous approval	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	
146	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(8GU-9VQ-4LVJ, 2025-12-04)
	Detail of Fee Submitted	93000.0, 4200 2025-07-15, 2025-08-12
	The proposed proprietary name / brand name	Neucillin 125mg/5ml dry suspension
	Label Claim	Each 5ml of reconstituted suspension contains: Amoxicillin trihydrate eq. to Amoxicillin.....125mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	90ml-As per SRO
	Shelf Life (Unit)	2 Yearstore at 25c
	For generic drugs (me-too Status)	AMOXIL 125mg/5ml Dry suspension
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Approved
	Detail of previous approval	-

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
147	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neomedix Plot #5, N-5, National Industrial Zone, Rawat (000539)
	Application Form Dy. No / Tracking ID & date of submission	(8SX-SSN-N8J3, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-08,
	The proposed proprietary name / brand name	Neo-D injection
	Label Claim	Each ml contains: Cholecalciferol 5mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	D DROP Inj by Ipram Pharmaceuticals Reg No 052799
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	ANSM
	Detail of previous approval	Cara D3 326
	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.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(8V9-LSB-188N, 2025-11-17)
	Detail of Fee Submitted	97200, 2025-11-06,

	The proposed proprietary name / brand name	Silflo Capsule 8mg
	Label Claim	Each capsule contains: Silodosin.....8mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Silorap 8mg Capsule BY Getz Pharma
	Pharmacotherapeutic Group of (API)	Alpha blockers
	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 (METOLAZONE TABLETS) Rapaflo capsule 8mg
	Detail of previous approval	344 Meetings of Registration Board held on 31th Dec,2024 to 2nd Jan 2025.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(99Q-V89-HPHU, 2025-12-11)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Fungikil Injection
	Label Claim	Each vial contains: Voriconazole lyophilized powder.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-Controlled
	Shelf Life (Unit)	2 YearThe unreconstituted vial does not require any special temperature storage conditions.
	For generic drugs (me-too Status)	Product Name: V.Zde 200mg/vial Injection Reg. No.: 097657 Composition: Each vial contains: Voriconazole.....200mg Manufacturer: Neutro Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-

	The status in reference regulatory authorities	VFEND 200mg lyophilized powder for injection, New Drug Application (NDA): 021464 Company: PFIZER USFDA approved
	Detail of previous approval	331st 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	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(9M5-GWA-EJ4B, 2025-11-10)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Riaxone Inj 2g IM/IV
	Label Claim	Each Vial contains: Ceftriaxone sodium equivalent to ceftriaxone....2g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Biotroxone Biogen Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Telecef Inj 2g 343 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision Approved	
151	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)

Application Form Dy. No / Tracking ID & date of submission	(9W2-2QR-TLJJ, 2025-11-17)
Detail of Fee Submitted	97200, 2025-11-06,
The proposed proprietary name / brand name	Dextone Capsule 60mg
Label Claim	Each capsule contains; Delayed release pellets of Dexlansoprazole eq. to Dexlansoprazole.....60mg (Innovator Specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO -Controlled
Shelf Life (Unit)	2 Year30C+-
For generic drugs (me-too Status)	Razodex Capsule 60mg by (Getz Pharmaceuticals)
Pharmacotherapeutic Group of (API)	PPI
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	Dexilant 60mg delayed release capsules, Manufacturer: Takeda Pharmaceutical USA; Inc. (USFDA Approved)
Detail of previous approval	Sopradex Capsule 60mg which is approved Minutes of 344 Meetings of Registration Board held on 31thDe

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.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(A23-LDD-YS2D, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Drozan-10mg Tablets
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE 10 MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Brand Name: Dydrogest 10mg Tablet. Registration holder: OBS Pakistan (Pvt) Ltd., C-14 Mangopir

		Road SITE Karachi. , Karachi. Status in regulatory authorities Dydrogest 10mg Tablet is DRAP Approved.
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES.
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICAL-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE, PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	Brand Name Duphaston 10 mg film-coated tablets. Marketing Authorization holder: Mylan IRE Healthcare Limited. Regulatory Authority: Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	347th
	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.	Roryan Pharmaceutical Industries Private Limited Plot No. 85-B Industrial Estate Hayatabad (000566)
	Application Form Dy. No / Tracking ID & date of submission	(A28-DYH-T2J8, 2025-12-04)
	Detail of Fee Submitted	93000.0, 4200 2025-08-07, 2025-09-23
	The proposed proprietary name / brand name	Ronem 500mg
	Label Claim	Each Vial Contains: Meropenem (as Trihydrate) 500mg (Blended with Sodium Carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Controlled
	For generic drugs (me-too Status)	PENRO IV 1000mg Injection M/s, Bosch Pharma
	Pharmacotherapeutic Group of (API)	Shenzhen Haibin Pharmaceutical Co., Ltd. Add: No. 2003, Shenyang Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
	Name, address of Manufacturing site:	Medicraft Pharmaceuticals (Pvt) Ltd.-126-B, Industrial Estate, Hayatabad, Peshawar.-
	The status in reference regulatory authorities	Approved in FDA (MERREM 1000mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 1000mg Injection M/s. Pfizer UK)
	Detail of previous approval	Medipenem 500mg, Meeting no: 336th

	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.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(B2X-WQJ-2VD8, 2025-11-10)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	R-Xime 200mg susp
	Label Claim	Each 5ml contains: Cefixime (as Trihydrate) 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml 60ml-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Maxgard Dry Suspension
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Varicef Susp 200mg 327 DR 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	
155	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(B9J-RV3-UJB3, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Carimax 3mg Capsule

Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg
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)	anufacturer Name: GENIX PHARMA PRIVATE LIMITED44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan. Brand Name & Strength: Caripz 3mg Capsule Composition: Each Capsule contains Cariprazine(as caripr
Pharmacotherapeutic Group of (API)	Cariprazine is also used along with other medications to treat depressive symptoms in adults with major depressive disorder (MDD). Cariprazine is in a class of medications called atypical antipsychotics. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
Name, address of Manufacturing site:	Skywin Pharmaceutical,-Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhpura Road, Lahore.-
The status in reference regulatory authorities	USFDA approved
Detail of previous approval	343rd meeting
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
156	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission
	(D5P-TSZ-HUM8, 2025-11-10)
	Detail of Fee Submitted
	97200, 2025-11-03,
	The proposed proprietary name / brand name
	Riaxone Inj 500mg IV
	Label Claim
	Each Vial contains: Ceftriaxone sodium equivalent to ceftriaxone....500mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1 vial-Controlled
	Shelf Life (Unit)
	2 YearStore below 30C
	For generic drugs (me-too Status)
	Ceftriaxone Inj Mehran International
	Pharmacotherapeutic Group of (API)
	Cephalosporins
	Name, address of Manufacturing site:
	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities
	USFDA

	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
157	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(EM4-XQX-6A39, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Tofix-10mg Tablets
	Label Claim	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib...10mg
	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)	Actinib tablet of M/s Searle
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Xeljanz tablet approved by US FDA
	Detail of previous approval	343rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
158	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nutrabiobiotics Pharmaceuticals PLOT NO 89- K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR (001008)
	Application Form Dy. No / Tracking ID & date of submission	(ENG-L32-1B1Q, 2025-12-02)

	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	Luton 2mg/0.5mg Tablet
	Label Claim	Luton 2mg/0.5mg Tablet Each of the 11 white tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown tablets contains: Estradiol Valerate.....2mg and Norgestrel... 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 21's , 3x21's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	PROGYLUTON BY Bayer
	Pharmacotherapeutic Group of (API)	Estradiol estrogen hormones , Norgestrel synthetic progestogen,
	Name, address of Manufacturing site:	M/S Skywin Pharmaceuticals-Plot No, 01 Al Badar Industrial Estate, Phase II Skeikhupura Road Lahore-
	The status in reference regulatory authorities	PROGYLUTON BY Bayer
	Detail of previous approval	Estragest 2/0.5mg Tablet approved in 347 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	
159	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(G2Z-7V8-B3R8, 2025-11-10)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	R-Xime 100mg Susp
	Label Claim	Each 5ml contains: Cefixime (as Trihydrate) 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Maxgard Dry Suspension
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	USFDA

	Detail of previous approval	Varicef Susp 100mg 327 DR 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	
160	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	OBS Pharma (Pvt) Ltd 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan (000243)
	Application Form Dy. No / Tracking ID & date of submission	(G9B-UXU-6U6M, 2025-12-11)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	Ferric Maltol 30mg Capsule
	Label Claim	Each capsule contains: Iron (as Ferric Maltol).....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 10's-As per SRO, 1 x 10's-As per SRO, 1x6's-As per SRO, 2x7's-As per SRO, 3 x 10's-As per SRO, 6 x 10's-As per SRO
	Shelf Life (Unit)	2 Year Store below 30°C.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Iron Preparations; Iron trivalent oral preparations
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan.-
	The status in reference regulatory authorities	ACCRUFeR (Ferric Maltol) 30mg capsules of M/s Shield Therapeutics Inc. (USFDA Approved)
	Detail of previous approval	Maltofer 30mg Capsule, 343rd meeting of Registration Board (3rd-5th December, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
161	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan

		(000614)
	Application Form Dy. No / Tracking ID & date of submission	(GY5-4B1-RM4V, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-28,
	The proposed proprietary name / brand name	HY-KOR 100MG Injection
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	For generic drugs (me-too Status)	Brand Name of Approved Medicines CORTISONE 100MG INJECTION Manufacturer VISION PHARMACEUTICALS Strength 100MG, 250MG, 500MG Composition Each vial contains:- Hydrocortisone sodium succinate as ready to
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals, -Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	HY?KOR 100MG Sterile powder for INJECTION Minutes for 339th meeting of Registration Board (6th Aug
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
162	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(HDG-Z5V-L1YG, 2025-12-11)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Fctose IV Injection
	Label Claim	Each ml contains: Iron as Ferric Carboxymaltose.....50mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1-Controlled
	Shelf Life (Unit)	2 YearStore in the original package. Do not store above 30 °C. Do not refrigerate or freeze
	For generic drugs (me-too Status)	FCM Injection Each 10ml vial contains: Ferric Carboxymaltose 500mg Manufactured by: Genix Pharma – KarachiFCM Injection Each 10ml vial contains: Ferric Carboxymaltose 500mg Manufactured by: Genix Phar
	Pharmacotherapeutic Group of (API)	Haematinics
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	VFEND 200mg lyophilized powder for injection, New Drug Application (NDA): 021464 Company: PFIZER USFDA approved
	Detail of previous approval	331st 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	
163	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(J42-1Q6-5BX3, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	MIROLIN 5MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	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)	Wimits Pharmaceuticals Pvt. LtMirogab 5mg Tablet 344th
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds $\alpha 2\delta$ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca^{2+})

		influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. (Reference; Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets 5mg Composition: Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin..... 5mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	344th
	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.	Winthrox Laboratories Pvt. Ltd K-219-A, SITE, Super Highway Phase II, Karachi (000807)
	Application Form Dy. No / Tracking ID & date of submission	(JE4-ESU-2WTM, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-07,
	The proposed proprietary name / brand name	Calopra Tablet 1mg
	Label Claim	Each Film Coated Tablet contains: Prucalopride Succinate Equivalent to Prucalopride.....1 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 25 Degree Centi Grade
	For generic drugs (me-too Status)	Manufacturer Name: Searle PAKISTAN LIMITED Brand Name & Strength: Pru-cic 1m g Tablet (Prucalopride) Approved in 322nd minutes of meeting
	Pharmacotherapeutic Group of (API)	Prucalopride is in a class of medications called serotonin receptor agonists. (Reference; Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Manufacturer Name: axunio Pharma GmbH Brand Name & Strength: Prucalopride 1 mg film-coated tablets Composition: Each film-coated tablet

		contains Prucalopride succinate equivalent to 1 mg prucalopride Marketing authorization number: PL 47848/0023 Dosage Form: oral tablet Reference Regulatory Authority: MHRA approved
	Detail of previous approval	Prucalopride Succinate 1mg Tablet in 343rd Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
165	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Linta Pharmaceuticals Private Limited Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. Islamabad. (000810)
	Application Form Dy. No / Tracking ID & date of submission	(L5Q-6TR-2TYA, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-15,
	The proposed proprietary name / brand name	Sritam 100mg/ml Oral Solution
	Label Claim	Each ml contains: Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Epian 100mg/ml Oral Solution Pharmasol (Pvt) Ltd Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan
	Pharmacotherapeutic Group of (API)	Antiepileptics
	Name, address of Manufacturing site:	M/s SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	KEPPRA 100mg/ml Oral Solution UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, approved in FDA.
	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	
166	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(LBU-ZLB-QMDB, 2025-11-25)
	Detail of Fee Submitted	97200, 2025-09-08,
	The proposed proprietary name / brand name	Siprix-30mg IM/IV Injection
	Label Claim	Each 1ml Ampoule contains: Ketorolac Tromethamine...30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -De-Controlled
	Shelf Life (Unit)	2 YearKeep ampoules in the original package to protect from light. This medicinal product does not require any special storage conditions. Do not refrigerate or freeze. Do not use if particulate matter is p
	For generic drugs (me-too Status)	Ketomal 30 mg Injection Reg. No. 074193
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	Already Approved in 343rdmeeting of Registration Board
	Detail of previous approval	343rd
	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.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(LWP-WP6-PMZ3, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Para D 500/25mg Tab
	Label Claim	Each Film Coated tablet contains: Paracetamol.....500mg Diphenhydramine Hydrochloride.....25mg

	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufactured by : Haleon Pakistan Limited, Petro road, Jamshoro Brand Name & Strength: PANADOL NIGHT TABLET Composition: Each tablet contains Paracetamol 500 mg Diphenhydramine hydrochlori
	Pharmacotherapeutic Group of (API)	Paracetamol (central analgesic effect that is mediated through activation of descending serotonergic pathways) Diphenhydramine Hydrochloride (Antihistamines)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.-Plot No129, Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Market authorization : Haleon LLC Distributed by GSKconsumer Healthcare Brand Name & Strength: PANADOL PM, Acetaminophen and diphenhydramine hydrochloride Film coated tablet Composition: Each tablet contains Paracetamol 500 mg Diphenhydramine hydrochloride 25 mg NDC 0135-7021-03
	Detail of previous approval	343rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
168	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(N3W-8Z4-UWGV, 2025-11-10)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Riaxone Inj 1g IV
	Label Claim	Each Vial contains: Ceftriaxone sodium equivalent to ceftriaxone....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Biotroxone Biogen Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporins

	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Celine Inj 1g 316 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
169	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(N53-H6E-HUYZ, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-24,
	The proposed proprietary name / brand name	Palnet - M 5MG Tablet
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDon Not store above 30
	For generic drugs (me-too Status)	Primolut N (Norethisterone) 5mg Tablet of M/s OBS
	Pharmacotherapeutic Group of (API)	synthetic progestational hormones
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS -Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Primolut N Tablet 5mg,Bayer plc Address: 400 South Oak Way, Reading, Berkshire, RG2 6AD
	Detail of previous approval	Just-N 5 MG Tablet approved in 347 meeting in 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	

170	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(NMR-L48-8X6J, 2025-11-10)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Lumisol D3 Inj
	Label Claim	Each Ampoule contains: cholecalciferol.....5mg(eq to 200000 IU of Vitamin D3
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's x 1ml-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Sunny D Scotmann
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	France
	Detail of previous approval	Suray Injection 323 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
171	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Schazoo Zaka (Pvt) Ltd 20 Km Lahore-Jaranwala Road Distt: Sheikhpura (000636)
	Application Form Dy. No / Tracking ID & date of submission	(NR4-MJL-7S2Z, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Metsone
	Label Claim	Each spray contains: Mometasone Furoate USP ... 50mcg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30 degree centigrade
	For generic drugs (me-too Status)	Nasomet manufactured by Sante, Rinelon manufactured by OBS
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Saffron Pharmaceutical (Pvt.) Ltd.-19 Km Sheikhpura road, Faisalabad, Pakistan-

	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	Hivate nasal spray, DRAP meeting # : 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	
172	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(PWE-R85-VR9W, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-04,
	The proposed proprietary name / brand name	Ketoley 30mg/ml Injection
	Label Claim	Each ml contains: Ketorolac tromethamine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Toradol 30mg/ml injection of M/s Barrett Hodgson
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drug
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Toradol 30mg /ml injection of M/s Roche Ltd. (MHRA Approved) (USFDA Approved)
	Detail of previous approval	Vintera Injection approved in 320th Meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
173	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	RSK Pharmaceuticals Plot#13-A Street #N-5 (000998)
	Application Form Dy. No / Tracking ID & date of submission	(QXX-GN6-SEAY, 2025-11-10)

	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Riaxone Inj 250mg IM
	Label Claim	Each Vial contains: Ceftriaxone sodium equivalent to ceftriaxone....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 vial-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Biotroxone Biogen Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporins
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Cefexo 250mg IM Inj 316 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
174	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neomedix Plot #5, N-5, National Industrial Zone, Rawat (000539)
	Application Form Dy. No / Tracking ID & date of submission	(R1Q-NYW-WEG6, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-08,
	The proposed proprietary name / brand name	Feboxy injection
	Label Claim	Each Ampoule of 10 mL contains: Ferric carboxymaltose corresponding to iron. 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Ferinject Injection (Each 10ml vial contains: Iron as Ferric carboxymaltose 500mg) of M/s. RG Pharmaceutical Reg.no. 072548.
	Pharmacotherapeutic Group of (API)	Anti-Anemic
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	333
	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.	Focus & Rulz Pharmaceuticals (Pvt) Ltd 44 - Industrial Triangle, Kahuta Road (000628)
	Application Form Dy. No / Tracking ID & date of submission	(S56-5PX-UB12, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-11,
	The proposed proprietary name / brand name	Ruzone 2g Injection
	Label Claim	Each vial Contains:- Ceftriaxone Sodium equivalent to ceftriaxone 2gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30
	For generic drugs (me-too Status)	Oxidil 2g injection M/s Sami
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic (3rd Generation)
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd. -Plot No. 145, Industrial Triangle Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Telecef 2g IV Injection,Product is approved in 343rd 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	
176	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(STZ-Z75-LWPL, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	MIROLIN 15MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to

		Mirogabalin.....15mg
	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)	Wimits Pharmaceuticals Pvt. Ltd.344th meeting Mirogab 15mg Tablet
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds $\alpha 2\delta$ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca^{2+}) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-Sunder Industrial Estate, Lahore-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets15mg Composition: Each Film coated tablet contains Mirogabalin besilate equivalent to Mirogabalin.....15mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	344th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
177	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(TST-D2P-R61J, 2025-12-11)
	Detail of Fee Submitted	97200, 2025-11-06,
	The proposed proprietary name / brand name	Fos-T 3g Sachet
	Label Claim	Fos-T 3g Sachet Each sachet contains: Fosmomycin Trometamol eq. to. Fosfomycin.....3g (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-

	For generic drugs (me-too Status)	Focin ultra Sachet 3g by Tabros Pharma
	Pharmacotherapeutic Group of (API)	Phosphonic antibiotics
	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	Monurol 3g Sachet (Zambon Switzerland Ltd.)
	Detail of previous approval	347 Meetings of Registration Board held on 28th to 30th April 2025
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
178	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Metro Pharmaceutical Plot no 14 street no ss-2 industrial zone rawat Islamabad (000772)
	Application Form Dy. No / Tracking ID & date of submission	(UJP-8SX-LSBA, 2025-11-17)
	Detail of Fee Submitted	97200.0, 2025-08-18,
	The proposed proprietary name / brand name	Metovan 20mg Tablet
	Label Claim	20mg per tablet
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Vonozan 10mg tablet
	Pharmacotherapeutic Group of (API)	inhibits gastric acid secretion by acting as a potassium-competitive acid blocker (P-CAB)
	Name, address of Manufacturing site:	M/S Linta Pharmaceuticals Pvt. Ltd.- Plot #3, Street S-5, National Industrial Zone, Rawat Islamabad.-
	The status in reference regulatory authorities	TAKECAB TAB by Takeda Pharmaceutical Company Limited JAPAN
	Detail of previous approval	Vonopraz 10mg Tablet , M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
179	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(V1H-R4B-VY7Y, 2025-11-17)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Artecent-30 IM/IV Injection
	Label Claim	Each Vial contains: Artesunate 30 mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	36 MonthStore below 30°C. Protect from light. The reconstituted solution should be stored below 30°C and should be used within 1 hour. 6.5
	For generic drugs (me-too Status)	Gen-M Injection Each vial contains:- Artesunate 30 mg Manufactured by: Genix Pharma (Pvt) Ltd., 44-45/B Korangi Creek Raod Karachi , Karachi
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs(Pvt).Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-
	The status in reference regulatory authorities	Artesunate 60 mg Injection By Amivas LLC, 600 Capability Green, Luton,LU1 3LU, USA WHO & FDA Approved
	Detail of previous approval	331st
180	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	
180	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Mediate Pharmaceutical Pvt Ltd Plot # 150-151 Sector 24, Korangi Industrial Area (000167)
	Application Form Dy. No / Tracking ID & date of submission	(V8M-MHZ-P9MG, 2025-10-23)
	Detail of Fee Submitted	97200, 2025-08-19,
	The proposed proprietary name / brand name	CPEM 1gm Injection
	Label Claim	Each vial contains: Meropenem (as trihydrate) 1g (Blended with sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO

	Shelf Life (Unit)	2 Year30°C
	For generic drugs (me-too Status)	Cili-Penem Injection 1g
	Pharmacotherapeutic Group of (API)	carbapenem antibiotics.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Meronem IV 1g Powder for solution for injection or infusion byMedicines and Healthcare products Regulatory Agency (MHRA) of UK
	Detail of previous approval	Ronem 1g Injection, 307th meeting minutes (87)
	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.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(VQ1-2NL-PP9H, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	MIROLIN 10MG TABLETS
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	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)	Wimits Pharmaceuticals Pvt. LtdMirogab 10mg Tablet 344th
	Pharmacotherapeutic Group of (API)	Mirogabalin belongs to the class of gamma amino acids and its derivatives. Mirogabalin selectively binds $\alpha 2\delta$ subunits of voltage-gated calcium channels (VGCCs). It reduces calcium (Ca^{2+}) influx and neurotransmission which inhibits neurotransmitter release in presynaptic neuron endings. (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan.-
	The status in reference regulatory authorities	Manufacturer Name: Daiichi Sankyo Co., Ltd Brand Name & Strength: Tarlige Tablets10mg Composition: Each Film coated tablet contains

		Mirogabalin besilate equivalent to Mirogabalin.....10mg Dosage Form: Oral Solid Dosage Form Reference Regulatory Authority: PMDA Approved
	Detail of previous approval	344th
	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.	Skywin Pharmaceuticals Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(VU1-999-DURB, 2025-10-23)
	Detail of Fee Submitted	97200, 2025-10-01,
	The proposed proprietary name / brand name	Urosky 25mg Tablet
	Label Claim	Each Tablet contains: Bethanechol Chloride.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's, 5x10's, 10x10-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	To manage postoperative and postpartum urinary retention, as well as overflow incontinence due to neurogenic bladder atony, and belongs to the parasympathomimetic drug class
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Bethanechol Chloride Tablet, USP 25mg of M/s Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Urotone 25mg 1x10's, 2x7's, 2x10's, 4x7's, 3x10's, 5x10's, 10x10's As per SROTablet approved in 344th
	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.	Nutrabiotech Pharmaceuticals PLOT NO 89- K/3 INDUSTRIAL ESTATE , HAYATABAD, PESHAWAR (001008)
	Application Form Dy. No / Tracking ID & date of submission	(VXL-1LD-5JST, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	Estra N 5mg Tablet
	Label Claim	Estra N 5mg Tablet Each Tablet Contains: Norethisterone..... 5 mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x 10's, 2 x 10's, 2x7's, 3 x 10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30
	For generic drugs (me-too Status)	Primolut N 5mg by OBS Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	19-nortestosterone-derived class of progestins
	Name, address of Manufacturing site:	M/S Skywin Pharmaceuticals-Plot No, 01 Al Badar Industrial Estate, Phase II Skeikhupura-faisalabad Road Lahore-
	The status in reference regulatory authorities	Primolut N 5mg by MHRA approved
	Detail of previous approval	Just-N 5mg Tablet, approved in 347th 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	
184	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(VYQ-PD5-QDN5, 2025-11-25)
	Detail of Fee Submitted	97200, 2025-09-08,
	The proposed proprietary name / brand name	Menem IV Injection 500mg
	Label Claim	Each vial contains: Meropenem (as trihydrate).....500mg (blended with sodium carbonate)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C. Do not freeze the reconstituted solution.
	For generic drugs (me-too Status)	Meropam 500mg Injection IV Reg No. 107175 M/s Munawar Pharma (Pvt) Ltd Lahore .
	Pharmacotherapeutic Group of (API)	Carbapenem Antibacterial Agent
	Name, address of Manufacturing site:	M/s Bio-Next Pharmaceuticals- Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	333rd
	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.	Roryan Pharmaceutical Industries Private Limited Plot No. 85-B Industrial Estate Hayatabad (000566)
	Application Form Dy. No / Tracking ID & date of submission	(W19-5B6-P9ZH, 2025-12-04)
	Detail of Fee Submitted	93000.0, 4200 2025-08-07, 2025-09-23
	The proposed proprietary name / brand name	Ronem
	Label Claim	Each vial contains: Meropenem (as trihydrate) 1000mg (blended with sodium carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Controlled
	For generic drugs (me-too Status)	PENRO IV 1000mg Injection M/s, Bosch Pharma
	Pharmacotherapeutic Group of (API)	Shenzhen Haibin Pharmaceutical Co., Ltd. Add: No. 2003, Shenyang Road, Yantian Distric, Shenzhen City, Guangdong Province, People's Republic of China.
	Name, address of Manufacturing site:	Medicraft Pharmaceuticals (Pvt) Ltd.-126-B, Industrial Estate, Hayatabad, Peshawar.-
	The status in reference regulatory authorities	Approved in FDA (MERREM 1000mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 1000mg Injection M/s. Pfizer UK)
	Detail of previous approval	Medipenem 1gm, Meeting no: 336th
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
186	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(W4L-G71-V727, 2025-12-11)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	Feribo Injection 500mg/10ml
	Label Claim	Each Ampoule contains Iron as Ferric Carboxymaltose 500mg (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 Year30C+-
	For generic drugs (me-too Status)	Feri inject injection 500mg/100ml by RG Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anti-anemic
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries - Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Injectafer Injection 500mg Iron /10ml (USFDA Approved)
	Detail of previous approval	Minutes of 333rd meeting of Registration Board (19th To 20th December, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
187	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(W59-PNJ-852V, 2025-12-04)

	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Artecent-120 IM/IV Injection
	Label Claim	Each vial contains: Artesunate. 120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	36 MonthStore below 30°C. Protect from light. The reconstituted solution should be stored below 30°C and should be used within 1 hour. 6.5
	For generic drugs (me-too Status)	Gen-M Injection Each vial contains:- Artesunate 120 mg Manufactured by: Genix Pharma (Pvt) Ltd., 44-45/B Korangi Creek Raod Karachi , Karachi
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	Artesunate 120 mg Injection By Amivas LLC, 600 Capability Green, Luton,LU1 3LU, USA WHO & FDA Approved
	Detail of previous approval	331st Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
188	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(WUU-BNV-XT6J, 2025-11-25)
	Detail of Fee Submitted	97200, 2025-09-08,
	The proposed proprietary name / brand name	Menem IV Injection 1g
	Label Claim	Each vial contains: Meropenem (as trihydrate) Ig ... 1000mg blended with sodium carbonate ... 90.2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C. Do not freeze the reconstituted solution.
	For generic drugs (me-too Status)	Meropam 1000mg Injection IV Reg No.107176 M/s Munawar Pharma (Pvt) Ltd Lahore
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic

	Name, address of Manufacturing site:	M/S Bio-Next Pharmaceuticals-Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	333rd
	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.	
189	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Skywin Pharmaceuticals Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpora road (000971)
	Application Form Dy. No / Tracking ID & date of submission	(WYZ-QNR-6S6Y, 2025-10-23)
	Detail of Fee Submitted	97200, 2025-10-01,
	The proposed proprietary name / brand name	Tofanib 10mg Tablet
	Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate Equivalent to Tofacitinib 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 X 10's, 2 X 10's, 4x7's, 3 X 10's, 10x10's As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Tofacitinib is in a class of medications called Janus kinase (JAK) inhibitors. It works by decreasing the activity of the immune system.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Xeljanz (Tofacitinib) 10mg Tablet of M/s Pfizer Labs Division of Pfizer Inc., (USFDA Approved)
	Detail of previous approval	Tofamit 10mg Tablet Approved in 343rd meeting of DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
190	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(XSH-TPV-6GS6, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Estramed 2mg/0.5mg Tablets
	Label Claim	Each of the 11 white tablets contains: Estradiol Valerate.....2mg Each of the 10 light brown tablets contains: Estradiol Valerate.....2mg Norgestrel.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Manufacture Name: Bayer Weimar GmbH und Co., KG, Weimar, Germany. Marketed by: Bayer Pakistan (Pvt.) Limited, Plot No. 23, Sector No. 22, Korangi industrial Area, 74900, Karachi-Pakistan. Brand Name
	Pharmacotherapeutic Group of (API)	Estrogen hormone / synthetic prostaglandin
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Industrial Estate, Phase-II, 18-KM, Sheikhpuraroad-
	The status in reference regulatory authorities	Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702. Manufacturer's name and address: Bayer Weimar GmbH und Co. KG, Weimar, Germany. Composition: Each of the 10 light brown tablets contains: estradiol valerate 2 mg norgestrel 0.5 mg Each of the 11 white tablets contains: estradiol valerate 2 mg Registration number of the medicine in the National Drug Registry of the Ministry of Health: 032 90 22502 00 Dosage Form: coated oral tablet Reference Regula
	Detail of previous approval	347th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
191	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
	Application Form Dy. No / Tracking ID & date of submission	(XUV-AHS-MTGE, 2025-11-27)
	Detail of Fee Submitted	97200, 2025-11-05,
	The proposed proprietary name / brand name	Tedilox Tablet 200mg
	Label Claim	Each film-coated tablet contains: Tedizolid phosphate.....200mg (Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Packed in Alu alu blister pack of 7's, 10's, 14's, 20's tablets.-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30°C
	For generic drugs (me-too Status)	Tezlid 200mg Tablet
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use.
	Name, address of Manufacturing site:	Nabiqasim industries pvt. Ltd.-17 / 24, Korangi Industrial Area, Karachi.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Tedivex Tablet 200mg (DRB-351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
192	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(XVT-Y25-DP98, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-28,
	The proposed proprietary name / brand name	HY-KOR 250mg Injection
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....250mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

	For generic drugs (me-too Status)	Brand Name of Approved Medicines CORTISONE 250mg INJECTION Manufacturer VISION PHARMACEUTICALS Strength 100MG, 250MG, 500MG Composition Each vial contains:- Hydrocortisone sodium succinate as ready to
	Pharmacotherapeutic Group of (API)	Applied as Cross Refer Product against Already Approved CTD
	Name, address of Manufacturing site:	M/S Wenovo Pharmaceuticals, -Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	HY?KOR 250MG Sterile powder for INJECTION Minutes for 339th meeting of Registration Board (6th Aug
	Evaluation Remarks In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision		
Approved		
193	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(YX1-VRG-TTB2, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	DeTig IV Injection
	Label Claim	Each Vial Contains: Tigecycline (Lyophilized powder) 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C.
	For generic drugs (me-too Status)	Product Name:: Tygacil 50mg Injection Registration No: 045642 Company Name: Wyeth Pakistan Limited
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	FDA-Approved Drugs TIGECYCLINE 50MG/VIAL Abbreviated New Drug Application (ANDA): 091620 Company: SANDOZ INC
	Detail of previous approval	330th Meeting of Registration Board

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
194	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(YZE-J86-VEA7, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-24,
	The proposed proprietary name / brand name	DUPHAPEX 10MG TABLET
	Label Claim	Each film coated tablet contains Dydrogestrone 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDon Not store above 30
	For generic drugs (me-too Status)	DYDROGEST 10MG TABLET
	Pharmacotherapeutic Group of (API)	natural hormone progesterone.
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS -Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Duphaston 10mg film coated tablet by MYLAN IRE Health care Limited
	Detail of previous approval	D- GEST 10MG TABLET , 336th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
195	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(Z52-DLY-LYW5, 2025-11-17)

	Detail of Fee Submitted	97200, 2025-11-06,
	The proposed proprietary name / brand name	Kionex Sachet 15gm
	Label Claim	Each sachet contains: Calcium polystyrene sulfonate.....15g (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	K-Styrene Sachet 15gm by Genome Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Hyperkalaemia and hyperphosphatemia
	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	MHRA approved UK
	Detail of previous approval	350 Meetings of Registration Board held on 29th to 30th July 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	
196	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Carer Pharmaceuticals industries Plot no.27, Main Road Rawat Industrial Estate, Rawat (000925)
	Application Form Dy. No / Tracking ID & date of submission	(Z8V-SQ7-SQX5, 2025-11-13)
	Detail of Fee Submitted	97200, 2025-11-07,
	The proposed proprietary name / brand name	Acneviz 20 mg Soft Gel Capsule
	Label Claim	Each soft gel capsule Contains: Isotretinoin... 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Oratane Capsule by Crystolite
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	BIOTAN 20mg Capsule,312th meeting of Registration Board

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
197	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(Z9J-AXA-YBW1, 2025-12-10)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	T-PANAD
	Label Claim	Each film coated tablet contains: Tapentadol as hydrochloride.....75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Welmark Pharmaceuticals,-plot # 122, Block B, Phase V, Industrial Estate Hattar, Haripur, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Minutes of 324th meeting of Registration Board p# 73 Tapentawel
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
198	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(ZJD-BWH-2MNL, 2025-12-04)
	Detail of Fee Submitted	93000.0, 4200 2025-07-23, 2025-10-27

	The proposed proprietary name / brand name	Bilust 2.5mg/ml oral solution
	Label Claim	Each ml contains: Bilastine..... 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Bilast 2.5mg/ml Oral Solution, Manufacturer: M/s. Seraph Pharmaceuticals Pvt. Ltd. Approved in 344th DRB Meeting
	Pharmacotherapeutic Group of (API)	Antihistamine, H1 receptor Antagonist
	Name, address of Manufacturing site:	M/s Seraph Pharmaceuticals Pvt. Ltd,-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	Brand Name: Pr JAMP BILASTINE ORAL SOLUTION., Manufacturer: JAMP Pharma Corporation, Suite 201 Brossard, Quebec J4Y 0E3
	Detail of previous approval	Bilast 2.5mg/ml Oral Solution, Approved in Minutes of 344th meeting of Registration Board (31st Dece
	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.	
199	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	VENUS PHARMA 23-KM MULTAN ROAD, LAHORE (000300)
	Application Form Dy. No / Tracking ID & date of submission	(ZPR-MGZ-TTS2, 2025-12-04)
	Detail of Fee Submitted	97200, 2025-10-23,
	The proposed proprietary name / brand name	NESTAR OPHTHALMIC SOLUTION 0.02%
	Label Claim	Each ml Ophthalmic Solution containing: Netarsudil (as Dimesylate).....0.2 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2.5ml -As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Attached Module I P1.5.8
	Pharmacotherapeutic Group of (API)	Rho Kinase inhibitor
	Name, address of Manufacturing site:	M/s Cunningham Pharmaceuticals (Pvt.) Ltd-81-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Attached Module I P 1.5.9
	Detail of previous approval	Netsudil 0.2mg/ml Ophthalmic solution, 335

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
200	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akhai Pharmaceuticals Private Limited A-248, A256 to A-259, HITE Lasbella Baluchistan (000640)
	Application Form Dy. No / Tracking ID & date of submission	(3TU-PDL-TT45, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Dexdot
	Label Claim	Each mL contains Dexmedetomidine Hydrochloride Eq. to Dexmedetomidine.....100mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2ml x 2's-De-Controlled, 2ml x 25's-De-Controlled, 2ml x 5's-De-Controlled
	Shelf Life (Unit)	2 Year 2-8 °C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Miscellaneous anxiolytics, sedatives and hypnotics
	Name, address of Manufacturing site:	Caraway Pharmaceuticals- Plot # 12, Street N-3, National Industrial Zone Rawat, Islamabad. Pakistan -
	The status in reference regulatory authorities	US FDA Approved Attached in Module 1
	Detail of previous approval	Dexmed 200mcg/2ml Injection , M-345 of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
201	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)

	Application Form Dy. No / Tracking ID & date of submission	(H47-PQ4-Y66V, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	Rop-D Injection 5mg/ml
	Label Claim	Each ml contains: Cholecalciferol 5mg (As per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	D-Drop Injection by Ipram Pharmeceuticals
	Pharmacotherapeutic Group of (API)	Vitamin-D3 analog
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot # 27, Main Road, Rawat Industries Estate, Rawat -
	The status in reference regulatory authorities	VITAMIN D3 GOOD INJECTION Doucharl-Recodrati-ANSM (France) approved.
	Detail of previous approval	346 Meetings of Registration Board held on 14th to 16 March,2023
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
202	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akhai Pharmaceuticals Private Limited A-248, A256 to A-259, HITE Lasbella Baluchistan (000640)
	Application Form Dy. No / Tracking ID & date of submission	(MHX-UGT-LQZJ, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Cis-Tracur
	Label Claim	Each mL contains Cisatracurium Besylate eq. to Cisatracurium.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5s x 5 mL-De-Controlled
	Shelf Life (Unit)	2 Year2-8 °C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Non-depolarizing skeletal Muscle relaxant of bezyliisoquinolinium
	Name, address of Manufacturing site:	Caraway Pharmaceuticals-Plot # 12, Street N-3, National Industrial Zone Rawat, Islamabad. Pakistan -

	The status in reference regulatory authorities	US FDA Approved Attached in Module 1
	Detail of previous approval	Cisatracar 10mg/5ml , M-321 of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
203	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(Q25-AUM-V2BT, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	Stron Injection 4mg/2ml
	Label Claim	Each 2ml ampoule contains: Ondansetron Hydrochloride Dihydrate equivalent to Ondansetron 4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Zofran Injection by GSK
	Pharmacotherapeutic Group of (API)	Serotonin Antagonist
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot #27,Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Minutes for 339th meeting of Registration Board (6th August to 8th August, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
204	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	fozan pharmaceuticals Industries (Pvt) Ltd 36-A hayatabad Industrial estate, Peshawar (000567)

	Application Form Dy. No / Tracking ID & date of submission	(DPJ-RY5-3T67, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	Artem 60mg
	Label Claim	Each Vial Contains: Artesunate.....60mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Gen-M Injection by Genix Pharma
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd-Plot # 145, Industrial Triangle, Kahuta Road. Islamabad.-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	BIOART 60MG IV INJECTION, 331 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	
205	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	fozan pharmaceuticals Industries (Pvt) Ltd 36-A hayatabad Industrial estate, Peshawar (000567)
	Application Form Dy. No / Tracking ID & date of submission	(HNB-Y4H-S11M, 2025-12-29)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	Artem 30mg
	Label Claim	Each Vial Contains: Artesunate.....30mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Gen-M Injection by Genix Pharma
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd-Plot # 145, Industrial Triangle, Kahuta Road. Islamabad.-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	BIOART 30MG IV INJECTION, 331 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	
206	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(E3E-SS1-JQ28, 2025-12-30)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	MYTHCO INJECTION 500mcg/ml
	Label Claim	Each 1 ml ampoule contains: Mecobalamin.....500mcg BP Specs
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Methycobal 500mcg/ml inj by Hilton Pharma
	Pharmacotherapeutic Group of (API)	Vitamin 12
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot #27,Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Methycobal Injection PMDA (Japan) approved
	Detail of previous approval	Minutes of 326th meeting of Registration Board (14th to 16th March, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
207	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Surge Laboratories (Pvt.) Ltd. 10th KM, Faisalabad Road, Bikhi District, Sheikhpura. (000484)
	Application Form Dy. No / Tracking ID & date of submission	(RYN-MGJ-GYVX, 2025-12-30)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Delzoid Tablet 450mg
	Label Claim	Each tablet contains: Delafloxacin Meglumine 649mg eq. to Delafloxacin.....450mg (Innovator's Specs.)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Packed in Alu-Alu Blister Pack of 7's, 10's, 14's, 20's, 28's, & 30's,-De-Controlled
	Shelf Life (Unit)	2 YearStored at 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Name, address of Manufacturing site:	Nabiqasim Industries (Pvt.) Ltd.-17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan-
	The status in reference regulatory authorities	FDA APPROVED
	Detail of previous approval	Nabdela (Now Delzof), Approved in meeting no: 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
208	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	(41D-RPU-BAJQ, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	FRITOLEV 100mg/ml Injection
	Label Claim	Each ml contains: Levetiracetam 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25°C
	For generic drugs (me-too Status)	Lerace 100mg/ml injection
	Pharmacotherapeutic Group of (API)	VENKATA NARAYANA ACTIVE INGREDIENTS PVT LTD
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	KEPPRA Injection 100mg/ml
	Detail of previous approval	Pritam 100mg/ml Injection, M351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned	

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
209	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	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	(4LZ-93V-83D7, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Tadalafil 5mg Tablet
	Label Claim	Each film-coated tablet contains: Tadalafil..... 5mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 inhibitors Urologicals, Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Cialis 5mg Tablet by Lilly del Caribe Inc (USFDA Approved)
	Detail of previous approval	Culis 5mg Tablet , Approved in DRB M-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	
210	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(5DS-N5A-ZQJX, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Atomex Oral Solution 4 mg/ml
	Label Claim	Each ml of Oral Solution contains: Atomoxetine Hydrochloride eq. to Atomoxetine... 4 mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Atten Oral Solution 4 mg/ ml
	Pharmacotherapeutic Group of (API)	SNRI
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited -Plot # 129, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Strattera 4 mg/ml Oral Solution
	Detail of previous approval	Atten 4 mg/ml Oral Solution, M-350
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
211	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(5G8-GUA-MJH3, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-09-08,
	The proposed proprietary name / brand name	Omecent-40 Lyophilized Injection
	Label Claim	Each vial contains: Omeprazole (as sodium) Lyophilized Powder...40mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's -Controlled
	Shelf Life (Unit)	2 YearDo not store above 25 ° C. Store in the original package in order to protect from light. Vials can however be stored exposed to normal indoor light outside the box for up to 24 hours.
	For generic drugs (me-too Status)	Acicheck 40 mg Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd-Plot # 145 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan.-
	The status in reference regulatory authorities	Omeprazole 40 mg powder for solution for infusion, PL DMRC Reference No. DMRC 32786665 Viatrix UK
	Detail of previous approval	333rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

	declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
212	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	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	(96A-1YV-N35V, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Apocent 12.5mg tablet
	Label Claim	Each film-coated tablet contains: Aprocitentan.....12.5mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	Endothelin receptor antagonist (ETRA)
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	TRYVIO 12.5mg tablets by Idorsia Pharmaceuticals US Inc (USFDA Approved)
	Detail of previous approval	Solvio 12.5mg Tablet, approved in DRB M-345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
213	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(97S-4A6-DL36, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-17,
	The proposed proprietary name / brand name	PROGESTEL 10MG TABLETS

	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE.....10MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-Free of Cost
	Shelf Life (Unit)	2 YearDo not store above 25°C.
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet by Aspin Pharma
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals- Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	HPRA APPROVED
	Detail of previous approval	TABLET D-GEST 10 MG, DRB-336th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
214	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9WP-B74-T84X, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	ELAGIX-150MG Tablet
	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	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Eladiol 150mg Tablet of M/s Nabiqasim Industries (Pvt) Ltd.,
	Pharmacotherapeutic Group of (API)	Elagolix is in a class of medications called gonadotropin-releasing hormone (GnRH) receptor antagonists.
	Name, address of Manufacturing site:	Wimits Pharmaceutical Pvt Ltd-Plot # 129,Sunder Industrial Estate Lahore, Pakistan-
	The status in reference regulatory authorities	Manufacturer Name: AbbVie Inc. North Chicago, IL 60064 03-B517 Brand Name & Strength: Orilissa(Elagolix) 150mg tablet Composition: Orilissa (Elagolix) Tablet Contains: 150mg

		Equivalent to 155.2mg Elagolix Sodium NDC0074-0038-28 Dosage Form: oral solid tablet Reference Regulatory Authority: USFDA approved.
	Detail of previous approval	343rd
	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.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(B5W-7ML-9BMR, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-10-02,
	The proposed proprietary name / brand name	WINZAGO 200mg tablet
	Label Claim	Each film coated tablet contains: linzagolix as choline 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	medizan laboratory
	Pharmacotherapeutic Group of (API)	Linzagolix is a selective gonadotropin-releasing hormone (GnRH) receptor antagonist
	Name, address of Manufacturing site:	medizan laboratroy-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA APPROVED
	Detail of previous approval	M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
216	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)

	Application Form Dy. No / Tracking ID & date of submission	(BRW-S7Q-RVN4, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Setron IM/IV Injection
	Label Claim	Each 2ml Contains:- Ondansetron (as Hydrochloride Dihydrate).....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2ml x 1's 2ml x 5's-Controlled
	Shelf Life (Unit)	2 YearThis medicinal product does not require any special temperature storage conditions. Keep ampoules in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Product Name: Serenety 4mg/2ml Injection Registration No: 121755 Company Name: BF Biosciences Limited Company Address: 5-KM Sundar Raiwind Road, Raiwind, Lahore Route of Admin: IM/IV
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	FDA-Approved Drugs ONDANSETRON 4mg Abbreviated New Drug Application (ANDA): 077406 Company: CHARTWELL MOLECULES
	Detail of previous approval	336th
217	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	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(DU8-W81-B4G1, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-19,
	The proposed proprietary name / brand name	Dysin 10mg tablet
	Label Claim	Each Film Coated Tablet Contains; Dydrogesterone 10mg (USP Spec's)

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's, 20's, 28's-As per SRO
Shelf Life (Unit)	2 YearStore below 30 Centigrade
For generic drugs (me-too Status)	Dydrogest 10mg Table by OBS Pharma Pakistan
Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones
Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot #01,Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-
The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets ® Approved in HPRA of Ireland
Detail of previous approval	Tablet D-Gest 10mg, M-336
Evaluation Remarks	
In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
Case Category	Contract Manufacturing (Incharge Evaluation Cell)
Name, address of Applicant.	Linta Pharmaceuticals Private Limited Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. Islamabad. (000810)
Application Form Dy. No / Tracking ID & date of submission	(EXS-6BU-9L88, 2025-12-31)
Detail of Fee Submitted	97200, 2025-10-27,
The proposed proprietary name / brand name	Tofanib 5mg Tablet
Label Claim	Each Film Coated Tablet contains: Tofacitinib Citrate eq, to Tofacitinib.....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 YearControlled room temperature blow 30 degree celsius
For generic drugs (me-too Status)	Tofajak 5mg Tablets by Hirani’s Pharmaceuticals Reg. No. 110057
Pharmacotherapeutic Group of (API)	Pharmacologic classification: Janus kinase (JAK) inhibitors Therapeutic classification: Immunosuppressant
Name, address of Manufacturing site:	M/S Wnsfeild Pharmaceuticals-Plot #122, Block-A, Phase-V, Industrial Estate, Hattar, Haripur, KPK -
The status in reference regulatory authorities	TOFACITINIB 5mg TABLET by Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium. Registered by UK MHRA
Detail of previous approval	Tofocib 5mg Tablet, M-343rd

	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.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(GD7-7PA-JBXH, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Myfin 1 % Cream (Iuliconazole 10 mg)
	Label Claim	Each gm Cream Contains: Luliconazole..... 10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore at a temperature not exceeding 30°C.
	For generic drugs (me-too Status)	Lunaz 1% Cream approved for Winbrains Research Labs in DRB meeting 331
	Pharmacotherapeutic Group of (API)	Imidazole & Triazole Derivatives (Antifungal)
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot #69/1, Phase I-II, Industrial Estate, Hattar, Haripur, KPK -
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/lab
	Detail of previous approval	Lunaz 1% Cream approved in 331st 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	
220	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(GTP-NJD-ZXNX, 2025-12-31)

	Detail of Fee Submitted	97200, 2025-11-12,
	The proposed proprietary name / brand name	Setron DS IM/IV Injection
	Label Claim	Each 4ml Ampoule contains: Ondansetron (HCl Dihydrate) eq. to Ondansetron...8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5x4ml 1x 4ml -Controlled
	Shelf Life (Unit)	2 YearThis medicinal product does not require any special temperature storage conditions. Keep ampoules in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Product Name:: Ondansetron Normon 8Mg Injection Registration No: 081802 Company Name: Merixil Pharma Company Address: Office 28, 2nd Floor, Rose Plaza , I-8 Markaz
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145 Industrial Triangle, kahuta Road,Islamabad-25000, Pakistan.+92-51-4491742- 3, +92-51-4492745-6+92-51-4491714info@bio-labs.net-
	The status in reference regulatory authorities	Ondansetron Accord 2mg/ml EFG solution for Injection Registration Number: 72117 Company name: Accord Healthcare S.L.U Country: SPAIN
	Detail of previous approval	336th
	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.	jupiter Pharma Plot No 25 Street S-6 RCCI Rawat Rawalpindi (000838)
	Application Form Dy. No / Tracking ID & date of submission	(GTR-BHW-Z1SR, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-08-22,
	The proposed proprietary name / brand name	Vismalt Injection
	Label Claim	Each Ampoule contains Iron as Ferric Carboxymaltose 500mg/10ml (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearStore between 15 to 25C
	For generic drugs (me-too Status)	Bioferin Injection 500mg/10ml By Bosch Pharma

	Pharmacotherapeutic Group of (API)	Anti-anaemic
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat -
	The status in reference regulatory authorities	Ferinject ® Dispersion for Injection/Infusion is approved in USFDA.
	Detail of previous approval	Feronyl Injection 333 Reg 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	
222	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(GWN-SE1-SNJL, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Resmit 100mg tablet
	Label Claim	Each film coated tablet contains: Resmetirom 100mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	thyroid hormone receptor (THR)-beta agonist
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Rezdiffra 100mg Tablets by Madrigal (USFDA Approved)
	Detail of previous approval	Resmet 100mg Tablet, Approved in DRB M-345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

223	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CRYSTOLITE PHARMACEUTICALS Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (000778)
	Application Form Dy. No / Tracking ID & date of submission	(LHD-GSD-BA39, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	NORTRIN 5MG TABLETS
	Label Claim	EACH TABLET CONTAINS: NORETHISTERONE.....5MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO, 20's-As per SRO, 30's-As per SRO
	Shelf Life (Unit)	2 Year Do not store above 25°C.
	For generic drugs (me-too Status)	PRIMOLUT-N TABLETS BY OBS PHARMA (PVT) LTD
	Pharmacotherapeutic Group of (API)	19-nortestosterone-derived class of progestins
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Just-N 5mg Tablet, DRB-M 347th
224	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	
224	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(Q8V-VVM-V99T, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Resmit 60mg Tablet
	Label Claim	Each film coated tablet contains: Resmetirom 60mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's, As per SRO-As per SRO
	Shelf Life (Unit)	2 Year Store between 15 to 30C
	For generic drugs (me-too Status)	New molecule

	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor (THR)-beta agonist
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Rezdiffra 60mg Tablets by Madrigal (USFDA Approved)
	Detail of previous approval	Resmet 60mg Tablet, Approved in DRB-M 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
225	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(SLG-9GS-BEL9, 2025-12-31)
	Detail of Fee Submitted	93000, 4200 2025-05-27, 2025-12-02
	The proposed proprietary name / brand name	Opza 40mg Injection
	Label Claim	Each vial contains: Omeprazole as sodium....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearCool & Dry Place
	For generic drugs (me-too Status)	Risek injection of Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Biogen Life Sciences-8Km, Chakbeli Road Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	REFLEX Injection 40mg IV- DRB- 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	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
226		

	Name, address of Applicant.	CCL Pharmaceuticals (Pvt.) Ltd. 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat (000052)
	Application Form Dy. No / Tracking ID & date of submission	(WUS-D5T-TLYL, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	Isotret Capsule 20mg
	Label Claim	Each Soft Gel Capsule Contain: Isotretinoin 20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,5's-De-Controlled,50's-De-Controlled,6's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	BIOTAN 20mg Capsule
	Pharmacotherapeutic Group of (API)	Chongqing Huapont Shengchem Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Isotretinoin 20mg soft capsules
	Detail of previous approval	BIOTAN 20mg Capsule, 312th 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	
227	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Palpex Pharmaceuticals pvt ltd FD-46 A8 , ST 1 SECTOR 38 , KORANGI CREEK INDUSTRIAL PARK (000858)
	Application Form Dy. No / Tracking ID & date of submission	(Y19-2RN-8AMG, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-10-24,
	The proposed proprietary name / brand name	PALOGYLUT 2/0.5MG Tablet
	Label Claim	11 White tablets, Each Containing Estradiol Valerate U.S.P.....2mg 10 Light Brown tablets, Each Containing Estradiol U.S.P.....2mg Norgestral U.S.P.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearDon Not store above 30
	For generic drugs (me-too Status)	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet by Bayer Pakistan (Pvt.) Limited,
	Pharmacotherapeutic Group of (API)	hormone replacement therapy (HRT) combined oral contraceptives (COCs)
	Name, address of Manufacturing site:	Skywin Pharmaceuticals,-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhpura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	PROGYLUTON (Estradiol Valerate-Norgestral) Tablet,Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.
	Detail of previous approval	Estragest 2mg/0.5mg tablet , 347th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
228	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(ZQA-MDY-76VZ, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Resmit 80mg Tablet
	Label Claim	Each film coated tablet contains: Resmetirom 80mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's, 2*10's, 3*10's, As per SRO -As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	thyroid hormone receptor (THR)-beta agonist
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Rezdiffra 80mg Tablets by madrigal (USFDA Approved)
	Detail of previous approval	Resmet 80mg Tablet, Approved in DRB-M 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

	declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
229	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	(ZTJ-JDL-RSDJ, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-11-28,
	The proposed proprietary name / brand name	Combrain 400mcg + 12mcg Rota Capsule
	Label Claim	Each Rotacap Rota Capsule contains: Budesonide (USP).....400Mcg Formoterol Fumarate (USP) 12Mcg (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)	Venticort Rotacaps 400mg + 12mcg Highnoon Labs (Reg#089365)
	Pharmacotherapeutic Group of (API)	Long-Acting Beta Agonists
	Name, address of Manufacturing site:	M/s Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Combrain 400/12mcg DPI Capsule Minutes for 339th 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	
230	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(AAY-SQR-NAVP, 2026-01-01)
	Detail of Fee Submitted	97200, 2025-11-28,

	The proposed proprietary name / brand name	BILTEX 20mg Tablet
	Label Claim	Each Uncoated Tablet contains: Bilastine.....20MG (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 YearBelow 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Orodispersible Tablet Bilix 10 mg Bilaxten 20mg Tablet Manufacturer M/s AGP Limited. / Searle Pharma Strength 10mg tablet / 20mg Tablet Composition Each Orodispersible
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	M/S Wezen Pharmaceuticals, -Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Biltex Tablet Approved in DRB 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	
231	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(Q8N-ZYQ-GRLA, 2026-01-01)
	Detail of Fee Submitted	97200, 2025-11-28,
	The proposed proprietary name / brand name	BILTEX 10mg Tablet
	Label Claim	Each Orodispersible Tablet contains: Bilastine 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 YearBelow 25 C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Orodispersible Tablet Bilix 10 mg Manufacturer M/s AGP Limited Strength 10mg tablet Composition Each Orodispersible tablet contains:
	Pharmacotherapeutic Group of (API)	Benzimidazoles
	Name, address of Manufacturing site:	M/S Wezen Pharmaceuticals, -Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat-

	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Biltex Tablet Approved in DRB 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	
232	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(UZZ-PHR-X8YH, 2026-01-01)
	Detail of Fee Submitted	97200, 2025-10-02,
	The proposed proprietary name / brand name	WINZAGO 100mg tablet
	Label Claim	Each film coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	medizan laboratory
	Pharmacotherapeutic Group of (API)	non-peptide, selective antagonist of the gonadotropin-releasing hormone (GnRH) receptor
	Name, address of Manufacturing site:	medizan laboratroy-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA APPROVED
	Detail of previous approval	M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
233	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

Application Form Dy. No / Tracking ID & date of submission	(ZQR-EDV-W651, 2026-01-01)
Detail of Fee Submitted	97200, 2025-11-10,
The proposed proprietary name / brand name	Acotia - 100mg Tablets
Label Claim	Each Film Coated Tablet contains Acotiamide HCl Hydrate.....100mg
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)	Kaizen Pharma Pvt Ltd. Approved in minutes of Meeting 333
Pharmacotherapeutic Group of (API)	ACOTIAMIDE belongs to a class of drugs called 'gastroprokinetics'. It is primarily used in the treatment of functional dyspepsia (indigestion). (Reference;Basic and Clinical Pharmacology By Bertram G. Katzung)
Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhpura Road Lahore-
The status in reference regulatory authorities	Axcount Generika Gmbh Max-Planck-Street 36 D 61381 Friedrichsdorf Germany Marketing authorization holder Brillpharma (Ireland) Limited Inniscarra, Main Street, Rathcoole, Co. Dublin, Ireland E-mail: info@brillpharma.co.uk
Detail of previous approval	344th meeting

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

234	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(LPR-GET-TQHW, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Tadalafil 20mg Tablet
	Label Claim	Each film-coated tablet contains: Tadalafil..... 20mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2's, 10's, As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore below 30 Centigrade
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Cialis 20mg Tablet by Lilly del Caribe Inc (USFDA Approved)
	Detail of previous approval	Culis 20mg tablet, Approved in DRB M-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	
235	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Akson Pharmaceuticals (Pvt) Ltd Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir (000486)
	Application Form Dy. No / Tracking ID & date of submission	(MBH-LG5-X93M, 2025-12-31)
	Detail of Fee Submitted	97200, 2025-12-22,
	The proposed proprietary name / brand name	Veric 20mg Tablet
	Label Claim	Every film-coated tablet contains: Vardenafil (as hydrochloride trihydrate)..... 20mg. (USP Spec's.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's Alu PVC blister, As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore between 15 to 30C
	For generic drugs (me-too Status)	New molecule
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Levitra 20mg Tablet by BAYER HLTHCARE (FDA Approved)
	Detail of previous approval	Velif 20mg tablet , Approved in DRB M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
236	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(11X-GEX-WW4H, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-18,
	The proposed proprietary name / brand name	Tramed-D 75mg/25mgTablet
	Label Claim	Each Film Coated tablet contains: Tramadol HCl 75mg Dexketoprofen trometamol Equivalent to Dexketoprofen 25mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Tramadol HCl (is a synthetic analgesic drug exhibiting opioid and non-opioid properties, acting mainly on the central nervous system) Dexketoprofen trometamol (nonsteroidal anti- inflammatory drug (NSAID))
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Manufactured by: Menarini – Von Heyden GmbH Leipziger Strasse 7-13 01097 Dresden Germany Brand Name & Strength: Skudexa 75 mg/25 mg film-coated tablets Composition: Each tablet contains: 75 mg of Tramadol hydrochloride 25 mg Dexketoprofen
	Detail of previous approval	351st
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
237	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Semos Pharmaceuticals PVT LTD Plot No.11, Sector 12-A North Karachi, Industrial Area, Karachi, Pakistan (000335)

Application Form Dy. No / Tracking ID & date of submission	(13Y-MD8-EB1N, 2026-01-05)
Detail of Fee Submitted	97200, 2025-12-10,
The proposed proprietary name / brand name	Sonion 40mg Soft Gel Capsule
Label Claim	Each Soft Gel Capsule contains: Isotretinoin.....40mg (BP Specifications)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	2x10's, 3x10's, 5x10's-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Maxinoin 40mg Capsule (Reg # 108920) By MAXITECH PHARMA (PVT.) LTD.
Pharmacotherapeutic Group of (API)	API Name: Isotretinoin (Manufacturer name: Chongqing Huapont Shengchem Pharmaceuticals Co. Ltd. China)
Name, address of Manufacturing site:	Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	USFDA Approved, Brand name: Isotretinoin 40mg Soft Capsule (Isotretinoin)
Detail of previous approval	Meeting No: Minutes of 335th 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

238	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(1LS-2YH-47EU, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Dewferric 500mg/10ml Injection
	Label Claim	Each m lContains: Ferric carboxy maltose Equivalent to ElementalIron..... 50mg Filledvolume:10mL
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1X10ml-As per SRO,1x20ml-As per SRO,1x2ml- 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:	Skywin Pharmaceutical-Plot No.01 A1 Badar Industrial Estate Phase II Sheikhpura Road Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
239	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Global Pharmaceuticals Pvt Ltd Plot Number 204-205 Industrial Triangle Kahuta Road (000417)
	Application Form Dy. No / Tracking ID & date of submission	(1S3-DEQ-MHPP, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-17,
	The proposed proprietary name / brand name	Paraliv IV Infusion
	Label Claim	Each 100ml contains: Paracetamol.....1000mg Ibuprofen (as sodium dihydrate) 300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 centigrade
	For generic drugs (me-too Status)	Bofalgan plus1000mg/300mg IV Infusion
	Pharmacotherapeutic Group of (API)	Paracetamol, combinations excl. psycholeptics
	Name, address of Manufacturing site:	Vision Pharmaceuticals (Pvt) Ltd.-Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Maxigesic IV (TGA) https://www.ebs.tga.gov.au/ebs/picmi/picmirepositor/OpenForm&t=PI&q=maxigesic&r=/
	Detail of previous approval	Co-Acetamol 1000mg/300mg IV Infusion (343rd meeting of DRB)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
240	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

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	(4Z3-6ND-H8VS, 2026-01-05)
Detail of Fee Submitted	97200, 2025-12-11,
The proposed proprietary name / brand name	DOLKETO-T
Label Claim	Each film coated tablet contains: Dexketoprofen Trometamol eq. to Dexketoprofen 25 mg Tramadol Hydrochloride 75mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7's, 10's, 14's, 20's, 28's, 30's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C
For generic drugs (me-too Status)	Genix Pharma (Pvt) Ltd (DEXKET-T)
Pharmacotherapeutic Group of (API)	DEXKETOPROFEN TROMETAMOL (Metrochem API Private Limited) and TRAMADOL HCl (Supriya Lifesciences Limited)
Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
The status in reference regulatory authorities	Menarini Laboratories S.A (Enanplus)
Detail of previous approval	TOPFEN-T Tablet 25mg/75mg(Dexketoprofen/ Tramadol), 345 meeting minutes
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
241	Case Category
Name, address of Applicant.	Contract Manufacturing (Incharge Evaluation Cell) Global Pharmaceuticals Pakistan Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (000724)
Application Form Dy. No / Tracking ID & date of submission	(8SN-35A-6865, 2026-01-05)
Detail of Fee Submitted	97200, 2025-12-17,
The proposed proprietary name / brand name	Calmigyl IV Infusion
Label Claim	Each 100ml contains: Paracetamol.....1000mg Ibuprofen (as sodium dihydrate) 300mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-De-Controlled
Shelf Life (Unit)	2 YearStore below 30 centigrade
For generic drugs (me-too Status)	Bofalgan plus1000mg/300mg IV Infusion

	Pharmacotherapeutic Group of (API)	Paracetamol, combinations excl. psycholeptics
	Name, address of Manufacturing site:	Vision Pharmaceuticals (Pvt) Ltd.-Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Maxigesic IV (TGA) https://www.ebs.tga.gov.au/ebs/picmi/picmirepositor/OpenForm&t=PI&q=maxigesic&r=/
	Detail of previous approval	Co-Acetamol 1000mg/300mg IV Infusion (343rd meeting of DRB)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
242	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(9RY-EX3-9RSN, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-10-31,
	The proposed proprietary name / brand name	Laslid 50mg Tablet
	Label Claim	Each Film Coated Tablet contains Lasmiditan hemisuccinate equivalent to Lasmiditan.....50mg
	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)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	ANTIMIGRAINE PREPARATIONSSelectiveserotonin (5HT1) agonists N02CC08
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-129-SunderIndustrial Estate, Lahore-
	The status in reference regulatory authorities	Eli lilly and Company Address: Lilly USA, LLC Indianapolis, IN46285, USA Product of ireland Brand Name & Strength: REYVOW (lasmiditan) tablet 50mg Composition: Each tablet contains 50mg Lasmiditan(equivalent to 57.824mg Lasmiditan hemisuccinate) NDC 0002-4312-08 Dosage Form: oral tablet Reference Regulatory Authority: USFDA approved
	Detail of previous approval	348th
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
243	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(A7G-X6S-S7B6, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Dapostat 2mg TABLETS
	Label Claim	Each film coated tablet contains; Daprodustat..... 2mg
	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)	genome 350th meeting approved
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor WHO ATC Code: B03XA07
	Name, address of Manufacturing site:	GENOME PHARMACEUTICALS (PVT.) LTD.-16/I, Phase IV , Industrial Estate Hattar Pakistan, -
	The status in reference regulatory authorities	SRA Registration Status: Japan Name: Duvroq 2mg Tablet Manufacturer: GSK Enclosed on page number 17(a)
	Detail of previous approval	350th
	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	
244	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(ATV-GAB-2TZ8, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	TADAF
	Label Claim	Each Film Coated Tablet contains: Tadalafil 20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's,7's, 10's, 14's, 20's, 28's,30's & 60's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 20'C-25'C
	For generic drugs (me-too Status)	Nabiqasim Industries Pvt Ltd(Tadalis)
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-
	The status in reference regulatory authorities	Lilly USA, LLC Indianapolis, IN 46285, USA(CIALIS)
	Detail of previous approval	Tadlif Tablet 20mg (352 meeting No)
	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.	
245	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(B6T-HXB-TB94, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	TADAF
	Label Claim	Each Film Coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's,7's, 10's, 14's, 20's, 28's,30's & 60's-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C
	For generic drugs (me-too Status)	Highnoon Laboratories Ltd. (Fildil)
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-

	The status in reference regulatory authorities	Lilly USA, LLC Indianapolis, IN 46285, USA (CIALIS)
	Detail of previous approval	TADLIF TABLET 2.5mg, 352 meeting minutes
	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	
246	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(BGU-AZ5-89N8, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-12,
	The proposed proprietary name / brand name	Til-X 50 mg Tablet
	Label Claim	Each Film coated Tablet contains: Sildenafil Citrate.....50mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Senigra Tablet
	Pharmacotherapeutic Group of (API)	phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Shrooq Pharmaceuticals Pvt.Ltd-21-KM, Ferozepur Road, Lahore.-
	The status in reference regulatory authorities	Provided in Module 1
	Detail of previous approval	Vcra 50mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
247	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(E15-A8Q-NEW7, 2026-01-05)

	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Imeglizon 500mg
	Label Claim	Each Film coated Tablet Contains: Imeglimin Hydrochloride.....500mg (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 at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Cadchem laboratories limited. Address: 1060, Industrial Area, Phase- II Chandigarh - 160002, 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	329M
	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	
248	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(G8B-A17-ANGT, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Cardano 0.5 mg Tablets
	Label Claim	Each uncoated Tablet Contains; Cabergoline 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Genome pharma
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Prolactine inhibitors WHO ATC Code: G02CB03
	Name, address of Manufacturing site:	Genome Pharmaceuticals (Pvt. Ltd)-Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Registered in UK Brand Name: Dostinex Tablets 0.5mg Manufacturer:

		Pfizer Limited Address: Ramsgate Road, Sandwich, Kent, CT13 9NJ
	Detail of previous approval	321st 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	
249	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(GDZ-115-2BZ1, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	TADAF
	Label Claim	Each Film Coated Tablet contains: Tadalafil 5 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 7's, 10's, 14's, 20's, 28's, 30's & 60's-As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C
	For generic drugs (me-too Status)	Highnoon Laboratories Ltd. (Fildil)
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
	The status in reference regulatory authorities	Lilly USA, LLC Indianapolis, IN 46285, USA (CIALIS)
	Detail of previous approval	TADLIF TABLET 5mg, 352 meeting minutes
	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	
250	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	(H1B-2WN-GUXY, 2026-01-05)
Detail of Fee Submitted	97200, 2025-12-10,
The proposed proprietary name / brand name	Esoren 375mg/20mg Tablet
Label Claim	Each modified release tablet contains : Naproxen..... 375mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate... 20mg (immediate release Coat)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Yearstore below 30 centigrade
For generic drugs (me-too Status)	Glomov 375/20mg tablet by M/s Global Pharmaceuticals Pvt Ltd. Reg.no 109339
Pharmacotherapeutic Group of (API)	Nonsteroidal Antiinflammatory drug and proton pump inhibitor
Name, address of Manufacturing site:	Solaris life Sciences (PVT) Ltd.-Plot No.08, Street no S-1 RCCI industrial Estate, Rawat Pakistan -
The status in reference regulatory authorities	Vimovo 375/20mg tablet M/s by Astrazeneca Pharmaceutical industry biomedical campus Cambridge CB2 0AA UK
Detail of previous approval	343 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	
251	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission
	(HQ4-L7E-JTQV, 2026-01-05)
	Detail of Fee Submitted
	97200, 2025-12-11,
	The proposed proprietary name / brand name
	Ezocid 500/20mg Tablet
	Label Claim
	Each film coated delayed release tablet contains: Naproxen (enteric coated core) ...500mg Esomeprazole as magnesium trihydrate (immediate release coat)...20mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	2x7's-As per SRO,3x10's-As per SRO
	Shelf Life (Unit)
	2 YearBetween 25c to 30c
	For generic drugs (me-too Status)
	Glomov Tablet By Global Pharma

	Pharmacotherapeutic Group of (API)	Propionic acid derivatives & Proton pump inhibitors.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	US-FDA
	Detail of previous approval	NASPEC 500/20MG Tablet-340-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	
252	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(LNL-X51-78BG, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-10-27,
	The proposed proprietary name / brand name	Levoma 12.5mg/ml Injection
	Label Claim	Each ml contains: Levosulpiride..... 12.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Levopraid 25mg/2ml injection
	Pharmacotherapeutic Group of (API)	Prokinetic agent
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	DISLEP solution for injection/infusion
	Detail of previous approval	M-340
	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	
253	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(MHG-VTR-S9QQ, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Esta-Duo
	Label Claim	Each Film Coated Tablet Contains: Paracetamol 500mg Ibuprofen 200mg (As per Innovator specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Provas - Duo Tablets Manufacturer Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Citi Pharma Limited. Pakistan Address: 3km, Head Balloki Road, Bhai Pheru, Distt K and ZENITH CHEMICAL INDUSTRIES (PVT.) LTD 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore – Pakistanasur - Pakistan Tel: +92-49-4510872/ 4513192
	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	336M
	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	
254	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Himedic Pharmaceuticals Pvt Ltd 19 KM link Multan Road Lahore (000824)
	Application Form Dy. No / Tracking ID & date of submission	(MQU-HPU-JB8L, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-12,
	The proposed proprietary name / brand name	Til-X 100 mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Sildenafil as Citrate.....100mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temprature

	For generic drugs (me-too Status)	Senigra Tablet
	Pharmacotherapeutic Group of (API)	phosphodiesterase type 5 (PDE5) inhibitor
	Name, address of Manufacturing site:	Shrooq Pharmaceuticals Pvt.Ltd-21-KM, Ferozepur Road, Lahore.-
	The status in reference regulatory authorities	Provided in Module 1
	Detail of previous approval	Vcra 100mg Tablet, M-351 DRB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
255	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(NXS-1GX-7XGA, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Elgozon 150mg
	Label Claim	Each Film Coated Tablets Contains: Elagolix Sodium e.q to Elagolix....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Shandong Loncom Pharmaceutical Co., Ltd. No, 127, Qizhong Avenue, QiheCounty, Dezhou, Shandong province, China
	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	335M
	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	

256	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(RD6-H1X-PM1G, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Dapostat 1mg TABLETS
	Label Claim	Each film coated tablet contains; Daprodustat..... 1mg
	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)	Genome Pharma 350th meeting
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor WHO ATC Code: B03XA07
	Name, address of Manufacturing site:	GENOME PHARMACEUTICALS (PVT.) LTD.-16/I, Phase IV , Industrial Estate Hattar -
	The status in reference regulatory authorities	SRA Registration Status: Japan Name: Duvroq 1mg Tablet Manufacturer: GSK Enclosed on page number 17(a)
	Detail of previous approval	350th
257	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	
257	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(TLD-L14-LSW5, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-11-10,
	The proposed proprietary name / brand name	Norezan 5mg Tablets
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C

	For generic drugs (me-too Status)	Manufacture Name: OBS Pharma (Pvt.) Ltd. Manufacturer Address: 108, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore Brand Name & Strength: Primolut N (Norethisterone) 5mg Tablet Composition: Each
	Pharmacotherapeutic Group of (API)	Norethisterone, also known as norethindrone, is a synthetic progestational hormone belonging to the 19-nortestosterone-derived class of progestins. (Reference; Basic and Clinical Pharmacology By Bertram G. Katzung)
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01, Al-Badar Industrial Estate, Phase II, 18-Km, Sheikhpura Road Lahore-
	The status in reference regulatory authorities	Manufacture Name: Bayer plc Address: 400 South Oak Way, Reading, Berkshire, RG2 6AD Brand Name & Strength: Primolut N Tablet 5mg Composition: Each tablet contains: Norethisterone.....5mg Market Authorization Number: PL 00010/0553 Dosage Form: oral tablet Reference Regulatory Authority: MHRA Approved
	Detail of previous approval	347th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
258	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(VEV-BUA-JPJ9, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	TADAF
	Label Claim	Each Film Coated Tablet contains: Tadalafil 10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's, 7's, 10's, 14's, 20's, 28's, 30's & 60's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 20'C-25'C
	For generic drugs (me-too Status)	Nabiqasim Industries Pvt Ltd(Tadalafil)
	Pharmacotherapeutic Group of (API)	Century Pharmaceuticals Limited

	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-
	The status in reference regulatory authorities	Lilly USA, LLC Indianapolis, IN 46285, USA(CIALIS)
	Detail of previous approval	Tadlif Tablet 10mg (352 meeting No)
	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	
259	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Davis Pharmaceutical Laboratories Plot No. 121, Industrial Triangle Area, Kahuta Road (000432)
	Application Form Dy. No / Tracking ID & date of submission	(WEQ-AX7-2GNN, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	Ezocid 375/20mg Tablet
	Label Claim	Each film coated delayed release tablet contains: Naproxen (enteric coated core)...375mg Esomeprazole as magnesium trihydrate (immediate release coat).....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's-As per SRO,3x10's-As per SRO
	Shelf Life (Unit)	2 YearBetween 25c to 30c
	For generic drugs (me-too Status)	Glomov Tablets By Global Pharma
	Pharmacotherapeutic Group of (API)	Propionic acid derivatives & Proton pump inhibitors
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	US-FDA
	Detail of previous approval	NASPEC 375/20MG Tablet-340-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	

260	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(WHX-5YY-44SW, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Elgozon 200mg
	Label Claim	Each Film Coated Tablet Contains: Elagolix Sodium eq to Elagolix 200mg (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)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	Shandong Loncom Pharmaceutical Co., Ltd. No, 127, Qizhong Avenue, QiheCounty, Dezhou, Shandong province, China
	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	335M
261	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	
261	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	(1N2-NRD-5WZ3, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-26,
	The proposed proprietary name / brand name	BFR 40 mg powder for solution for injection/infusion.
	Label Claim	Each vial contains: Esomeprazole sodium eq. to esomeprazole.....40mg (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 30°C in a cool and dry place.
	For generic drugs (me-too Status)	Novoteph by sami Pharma

	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	VARIANT PHARMACEUTICALS (PVT.) LTD- PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	Minutes of 312th meeting of Registration Board ESOVAR 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	
262	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(5EG-RAS-37HQ, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	Zoblin XR 165MG
	Label Claim	Each Extended-Release Film Coated Tablet 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 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi Taluka Mahad, District Raigad 402302 Maharashtra, 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	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	
263	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(977-BUL-PE4S, 2026-01-07)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	PENURIK 500mg INJECTION
	Label Claim	Each Vial contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Cili-Penem Injection 500mg by M/s Ipram Pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 307 MoM, Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Meronem IV 500mg Powder for solution for injection or infusion, MHRA UK
	Detail of previous approval	Ronem 500mg Injection in 307 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
264	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(EZW-WPS-BJRM, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	Zoblin XR 82.5MG
	Label Claim	Each Extended Release Film Coated Tablet 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 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar

	Pharmacotherapeutic Group of (API)	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi Taluka Mahad, District Raigad 402302 Maharashtra, 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	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	
265	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(NSR-9E4-2DQR, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-18,
	The proposed proprietary name / brand name	Toysn Injection 2.25gm
	Label Claim	Each vial contains: Piperacillin (as Sodium) 2g + Tazobactam (as Sodium) 0.25g USP Specs
	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)	Pipral-T 2.25gm 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 2.25gm))
	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	
266	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(QB2-79W-PSEW, 2026-01-07)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	PENURIK 1g INJECTION
	Label Claim	Each Vial contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Cili-Penem Injection 1g by M/s Ipram Pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 307 MoM, Please see attached.
	Name, address of Manufacturing site:	Nicholas Pharmaceuticals.-Plot # 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.-
	The status in reference regulatory authorities	Meronem IV 1g Powder for solution for injection or infusion, MHRA UK
	Detail of previous approval	Ronem 1g Injection in 307 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
267	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(SHR-RNG-ATGV, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	Bempex-Z
	Label Claim	Each Film coated Tablet Contains: Bempedoic acid 180mg Ezetimibe 10mg (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)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar

	Pharmacotherapeutic Group of (API)	Metrochem API Private Limited, Unit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).
	Name, address of Manufacturing site:	Horizon healthcare (Pvt)Ltd. Sundar-plot no 33 sundar industrial estate Lahore-
	The status in reference regulatory authorities	complies
	Detail of previous approval	322
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
268	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Horizon Healthcare (pvt.) ltd. 35-A Small Industrial Estate - Taxila (000856)
	Application Form Dy. No / Tracking ID & date of submission	(V63-PYH-M937, 2026-01-07)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	Zoblin XR 330MG
	Label Claim	Each Film Coated Tablet contains: Pregabalin.....330mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd Sundar
	Pharmacotherapeutic Group of (API)	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi Taluka Mahad, District Raigad 402302 Maharashtra, 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	336M
	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	
269	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(S1Z-BRG-PA3Z, 2026-01-08)
	Detail of Fee Submitted	93000, 2024-10-22,
	The proposed proprietary name / brand name	onsoft
	Label Claim	Each 2ml Ampoule 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 YearBelow 30 °C
	For generic drugs (me-too Status)	ondaren injection
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Name, address of Manufacturing site:	bio-labs pvt ltd-plot no 145 industrial triangle kahuta road islamabad -
	The status in reference regulatory authorities	MHRA APPROVED
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
270	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	(944-W7U-1MYA, 2025-01-23)
	Detail of Fee Submitted	93000.0, 4200 2024-12-10, 2026-01-08
	The proposed proprietary name / brand name	Viridio Tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100-As per SRO,20's-As per SRO,30's-As per SRO,32's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Not Applicable

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt) Ltd-Plot No.129, Sunder Industrial Estate, Raiwind Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Viagra Tablet (US-FDA)
	Detail of previous approval	Limpa-Met XR 25/5/1000 mg Tablet (340th DRB)
	Evaluation Remarks	
	Initially the applicant mentioned wrong cross-referred product. Later on, they sent General Request Form TID YH4-9TN-A49M for consideration of this application under cross-referencing for Wimits' registered product. They were advised to attach following: Contract agreement Undertakings including Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification F.No.1-2/2022-DMC dated 13th June, 2023 Covering letter for considering for cross-referencing differential fee as per current fee SRO In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
271	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	(TWP-BS8-A745, 2025-01-23)
	Detail of Fee Submitted	93000.0, 4200 2024-12-10, 2026-01-08
	The proposed proprietary name / brand name	Viridio Tablet
	Label Claim	Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,20's-As per SRO,30's-As per SRO,32's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt) Ltd-Plot No.129, Sunder Industrial Estate, Raiwind Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Viagra Tablet (US-FDA)
	Detail of previous approval	Limpa-Met XR 25/5/1000 mg Tablet (340th DRB)
	Evaluation Remarks	
	Initially the applicant mentioned wrong cross-referred product. Later on, they sent General Request Form TID YH4-9TN-A49M for consideration of this application under cross-referencing for Wimits'	

registered product. They were advised to attach following: Contract agreement Undertakings including Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification F.No.1-2/2022-DMC dated 13th June, 2023 Covering letter for considering for cross-referencing differential fee as per current fee SRO In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

272	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	(JP2-124-DQ59, 2025-01-23)
	Detail of Fee Submitted	93000.0, 4200 2024-12-10, 2026-01-08
	The proposed proprietary name / brand name	Tadivra Tablet
	Label Claim	Each film coated tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,14's-As per SRO,20's-As per SRO,30's-As per SRO,32's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt) Ltd-Plot No.129, Sunder Inudustrial Estate, Raiwind Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Cialis Tablet by US-FDA
	Detail of previous approval	Limpa-Met XR 25/5/1000 mg Tablet (340th DRB)

Evaluation Remarks

Initially the applicant mentioned wrong cross-referred product. Later on, they sent General Request Form TID YH4-9TN-A49M for consideration of this application under cross-referencing for Wimits' registered product. They were advised to attach following: Contract agreement Undertakings including Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification F.No.1-2/2022-DMC dated 13th June, 2023 Covering letter for considering for cross-referencing differential fee as per current fee SRO In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
273	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	(TW2-Z4Y-EJ6R, 2025-04-18)
	Detail of Fee Submitted	93000.0, 4200 2024-12-10, 2026-01-08
	The proposed proprietary name / brand name	Tadivra Tablet
	Label Claim	Each film coated tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO, 100's-As per SRO, 14's-As per SRO, 20's-As per SRO, 30's-As per SRO, 32's-As per SRO, 5's-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical (Pvt) Ltd-Plot No.129, Sunder Industrial Estate, Raiwind Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Adcirca Tablet by US-FDA
	Detail of previous approval	
	Evaluation Remarks	
	Initially the applicant did not mention cross-referred product. Later on, they sent General Request Form TID YH4-9TN-A49M for consideration of this application under cross-referencing for Wimits' registered product. They were advised to attach following: Contract agreement Undertakings including Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification F.No.1-2/2022-DMC dated 13th June, 2023 Covering letter for considering for cross-referencing differential fee as per current fee SRO In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
274	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)

Application Form Dy. No / Tracking ID & date of submission	(76D-TYM-A7BU, 2026-01-10)
Detail of Fee Submitted	97200, 2025-10-31,
The proposed proprietary name / brand name	RABAFIX-100 Tablet
Label Claim	Each Tablet Contains: Rebamipide.....100mg
Reference to Finished product specifications	Any Other
Proposed Pack Size	as per sro-As per SRO
Shelf Life (Unit)	2 Year30C
For generic drugs (me-too Status)	Brand Name: Mucosta 100mg Tablet Manufacturer Name/Registration holder: Otsuka Pharmaceutical co., Ltd, JapanMarketed By:Otsuka Pakistan Limited
Pharmacotherapeutic Group of (API)	Antacids or anti-reflux agent
Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd-29- SunderIndustrial Estate, Lahore-
The status in reference regulatory authorities	REBAMIPIDE TAB100mgof M/sOHARAPharmaceutical Co., Ltd (PMDA Approved)
Detail of previous approval	348th
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	
275	Case Category
	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.
	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission
	(JV1-U2Q-YDYX, 2026-01-10)
	Detail of Fee Submitted
	97200, 2025-11-10,
	The proposed proprietary name / brand name
	Daprotab6mg TABLETS
	Label Claim
	Each film coated tablet contains; Daprodustat 6mg
	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)
	geneome Pharma meeting 350th
	Pharmacotherapeutic Group of (API)
	Pharmacotherapeutic Group: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor WHO ATC Code: B03XA07

	Name, address of Manufacturing site:	GENOME PHARMACEUTICALS (PVT.) LTD.-16/I, Phase IV , Industrial Estate Hattar Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Japan Name: Duvroq 6mg Tablet Manufacturer: GSK Enclosed on page number 17(a)
	Detail of previous approval	350th
	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	
276	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(UW4-WNQ-A4MU, 2026-01-10)
	Detail of Fee Submitted	97200, 2025-12-18,
	The proposed proprietary name / brand name	Rupaix-10 Tablet
	Label Claim	Each Tablet contains: Rupatadine Fumarate eq. to Rupatadine.....10mg
	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)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Rupatadine is a second generation antihistamine and platelet-activating factor antagonist used to treat allergies.
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd,-Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Manufactured by: Menarini – Von Heyden GmbH Leipziger Strasse 7-13 01097 Dresden Germany Brand Name & Strength: Skudexa 75 mg/25 mg film-coated tablets Composition: Each tablet contains: 75 mg of Tramadol hydrochloride 25 mg Dexketoprofen. Dosage Form:Film coated oral solid tablet Reference Regulatory Authority: HPRA Approved.
	Detail of previous approval	352th
	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	
277	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(ZMH-VEL-RTGH, 2026-01-10)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	DEUMAX 6mg TABLETS
	Label Claim	Each film coated tablet contains; Deucravacitinib 6mg
	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)	Brand Name: Dvanib 6mg Tablets Manufacturer Name: Hamaz Pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Immunosuppressants, selective immunosuppressants
	Name, address of Manufacturing site:	GENOME PHARMACEUTICALS (PVT.) LTD.-16/I, Phase IV , Industrial Estate Hattar Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Japan Brand Name: SOTYKTU 6 mg film-coated tablets Manufacturer Name: Bristol-Myers Squibb Pharma Enclosed on page number 17(a)
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
278	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	May and Baker (Pvt.) Ltd 23-Ghouri Block, Bahria Town, Lahore (000953)
	Application Form Dy. No / Tracking ID & date of submission	(G2A-9WE-HN99, 2026-01-09)

	Detail of Fee Submitted	93000.0, 1 2025-07-21, 2025-09-30
	The proposed proprietary name / brand name	Tazocillin 2.25g
	Label Claim	Each vial contains: Piperacillin as sodium.....2g Tazobactam as sodium 0.25g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year25C
	For generic drugs (me-too Status)	Tazop Injection of Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals (Pvt.) Ltd.,-Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Piperacillin and tazobactam Injection (USFDA Approved)
	Detail of previous approval	TALBACT Injection 2.25g Injection , DRB Meeting No.316
	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	
279	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(7RX-971-83TD, 2026-01-09)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	Acugolix 100mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's; 2x7's; 2x10's; 3x10's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin-releasing hormones
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA & EMA Approved
	Detail of previous approval	Lingolix 100mg Tablets (351)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
280	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(4SL-XPS-YHBJ, 2026-01-09)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	Acugolix 200mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's; 2x7's; 2x10's; 3x10's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Anti-gonadotropin-releasing hormones
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA & EMA Approved
	Detail of previous approval	Lingolix 200mg Tablets (351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
281	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(31N-U66-Y9TS, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Vildena 20mg Tablet

	Label Claim	Each film-coated tablet contains: Vardenafil (as hydrochloride trihydrate)..... 20mg. (USP Spec's.)
	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)	Velif 20mg Tablets by Solaris life Sciences
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	Velif 20mg Tablet , 351st 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	
282	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(314-TSE-9ZYD, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Tadil 5mg Tablet
	Label Claim	Each film-coated tablet contains: Tadalafil..... 5mg (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 30C
	For generic drugs (me-too Status)	Culis 5mg Tablet by Solaris Life Sciences
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	Culis 5mg Tablet , 352nd 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	
283	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(2A5-M8J-AQM7, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	E-Dewplus 20/500mg Tablet
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO,28s-As per SRO,30s-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-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	
284	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(265-Y2P-R5DV, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Sildew 8mg Capsule
	Label Claim	Each capsule contains: Silodosin.....8mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
285	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(21R-YW1-A4Y4, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	ESOXEN TABLET 500MG/20MG
	Label Claim	Each modified release tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Proxen-ES DR 500mg/20mg Tablet by Martin Dow Limited.
	Pharmacotherapeutic Group of (API)	Data already approved in 340 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	VIMOVO 500mg/20mg Tablet, USFDA Approved
	Detail of previous approval	Naspec 500/20mg Tablet, 340 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	
286	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	(1RN-YEQ-MWE3, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Mamti 10mg-5ml Oral solution
	Label Claim	Mamti 10mg-5ml Oral solution Each 5ml contains: Memantine hydrochloride eq.to Memantine 10mg (Innovator,s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Afdol 10mg/5ml Oral solution by AGP Limited
	Pharmacotherapeutic Group of (API)	NMDA receptor antagonist
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan.-
	The status in reference regulatory authorities	Approved by U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)
	Detail of previous approval	336th meeting of Registration Board (4th to 6th June ,2024)
Evaluation Remarks		
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.		
Decision		
Approved		
287	Case Category	Routine (Muhammad Sarfraz Nawaz)
	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	(7H7-B1X-U4AV, 2025-06-27)
	Detail of Fee Submitted	300000.0, 2025-06-18,
	The proposed proprietary name / brand name	HP-Fipronil Spot-on-solution
	Label Claim	Each ml contains: Fipronil.....100mg/ml The active ingredient is Fipronil 0.5ml:50mg/tube, 0.67ml:67mg/tube, 1.34ml:134mg/tube, 2.68ml:268mg/tube, 5.36ml:536mg/tube
	Reference to Finished product specifications	Manufacturers Specification

	Proposed Pack Size	0.5 ml-De-Controlled,0.67 ml-De-Controlled,1.34 ml-De-Controlled,2.68 ml -De-Controlled,5.36 ml-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Fipronil Spray , Reg:22176 , Saadat International.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Hebei Hope Harmony Pharmaceutica Co., LTD.- Industry Development Area, Yuanshi County, Shijiazhuang City, Hebei Province , China -China
	Name, address of Marketing Authorization Holder:	Hebei Hope Harmony Pharmaceutica Co., LTD., Industry Development Area, Yuanshi County, Shijiazhuang City, Hebei Province , China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
288	Case Category	Routine (Muhammad Sarfraz Nawaz)
	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	(68X-1LJ-69N9, 2025-07-01)
	Detail of Fee Submitted	300000.0, 2025-06-30,
	The proposed proprietary name / brand name	OxyTc Spray-HP
	Label Claim	Per Bottle 140g Contains: Oxytetracycline hydrochloride 5g (equal to 3.58% w/w)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	140g/bottle-De-Controlled
	Shelf Life (Unit)	3 YearRoom Temperature
	For generic drugs (me-too Status)	ToxyMac Spray , (Nawan Laboratories PVT, LTD.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Hebei Hope Harmony Pharmaceutica Co., LTD.- Industry Development Area, Yuanshi County, Shijiazhuang City, Hebei Province , China -China
	Name, address of Marketing Authorization Holder:	Hebei Hope Harmony Pharmaceutica Co., LTD., Industry Development Area, Yuanshi County, Shijiazhuang City, Hebei Province , China , China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

	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	
289	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
	Application Form Dy. No / Tracking ID & date of submission	(B9D-V45-BUS7, 2025-07-04)
	Detail of Fee Submitted	300000.0, 2025-06-03,
	The proposed proprietary name / brand name	Diluent LBP
	Label Claim	Each ml contains: Phosphate buffer pH 7 (KCl 0.19 mg/ml, NaCl 5.86 mg/ml, KH ₂ PO ₄ 6.81mg/ml and NaOH 1.16 mg/ml)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100 ml (1,000 doses)-De-Controlled,200 ml (2,000 doses)-De-Controlled,300 ml (3,000 doses)-De-Controlled,50 ml (500 doses)-De-Controlled,500 ml (5,000 doses)-De-Controlled
	Shelf Life (Unit)	24 MonthDiluent is stored on temperature of 2–8°C and do not freeze, include temperature on its distribution. Diluent is protected from heat and direct sunlight
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	PT MEDION FARMA JAYA-Office Address: Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Plant Address: Jl. Raya Batujajar No. 29, Cimareme, Ngamprah, Bandung Barat – Indonesia-Indonesia
	Name, address of Marketing Authorization Holder:	Hilton Pharma (Pvt) Ltd, Plot No. 13, 14 & 43 Sector-15, Korangi Industrial Area 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		
Firm has applied for vaccine diluent registration in pharmaceutical division without mentioning the detail of vaccine, we may refer the case to relevant division.		
Decision		
Deferred		

	Referred to Biological Drug Division.	
290	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(V6S-4BD-Q33L, 2025-03-21)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	Butapho
	Label Claim	Each ml Contains: Butaphosphan 100mg Vitamin B12 0.05mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	Carasil Pak Reg No. 058816, Mfg by, Dae Sung Microbiological Lab, Korea, Imported by Selmor Agencies
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
291	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
291	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(S1H-ZEM-5W45, 2025-03-21)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	TIMOX 15 LA
	Label Claim	Each ml contains: Amoxicillin Trihydrate 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature

	For generic drugs (me-too Status)	Trioxyl LA (Pak Reg No. 021275) Mfg by Unived Ireland, Imported by orient animal health
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
292	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(89P-JV3-8EA5, 2025-03-21)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	KETO 10
	Label Claim	Each ml contains: Ketoprofen 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	Profenol Pak Reg No. 057057, Mfg by Leads Pharma, Islamabad, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
293	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(UNN-UUX-1Y9Z, 2025-03-21)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	TIMO- G
	Label Claim	Each ml contains Amoxicillin Trihydrate 150mg Gentamycin Sulphate 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	GENMOX LA, PAK REG NO. 118468, Mfg by Sakan, Vietnam, Imported by Atzan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
294	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(E92-USJ-S3M4, 2025-03-21)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	ENROTI
	Label Claim	Each ml contains Enrofloxacin 100mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	Encure 10 (Pak Reg. No. 020803 Mfg. By: Nawan Labortories Karachi)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
295	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	RIVER PHARMA 669-B, Peoples Colony No. 1, (06-331-0168-120180D)
	Application Form Dy. No / Tracking ID & date of submission	(6PX-D83-Y2QP, 2025-03-22)
	Detail of Fee Submitted	300000.0, 2025-03-20,
	The proposed proprietary name / brand name	TIGENTA
	Label Claim	Each ml contains: Gentamycin Sulphate 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	GENTAWAN 10%, Pak Reg No. 021304, Mfg by Nawan Laboratories, Karachi.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Tigervet UKA, PHARMA COM.PANY LIMITED-Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province-Vietnam
	Name, address of Marketing Authorization Holder:	Tigervet UKA, PHARMA COM.PANY LIMITED, Road D1, Yen My II Industrial Park, Yen My Town, Yen My District, Hung Yen Province, Vietnam
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	

	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	
296	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(HPW-X7N-37AV, 2025-03-12)
	Detail of Fee Submitted	300000.0, 2025-03-12,
	The proposed proprietary name / brand name	Ceftimed
	Label Claim	Each ml contains: Ceftiofur HCL 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 YearStore at room temprature
	For generic drugs (me-too Status)	Clinexin 5% Suspension For Injection, (Pak Reg no. 085728, Mfg. by Centrovat Laboratories, Chile, Imported by Mustafa Brothers
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
297	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(WDW-RAX-GYWL, 2025-03-13)
	Detail of Fee Submitted	300000.0, 2025-03-12,
	The proposed proprietary name / brand name	Amoximed LA
	Label Claim	Each ml contains: Amoxicillin (trihydrate) 150mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled

	Shelf Life (Unit)	3 YearStore at room temprature
	For generic drugs (me-too Status)	Trioxyl LA(Pak Reg No. 021275) Mfg by Unived Ireland, Imported by orient animal health
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
298	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(P7U-H4M-YTLQ, 2025-03-13)
	Detail of Fee Submitted	300000.0, 2025-03-12,
	The proposed proprietary name / brand name	Mediprofen
	Label Claim	Each ml Contains: Ketoprofen 100mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 YearStore at room temprature
	For generic drugs (me-too Status)	Profenol Pak Reg No. 057057, Mfg by Leads Pharma, Islamabad, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	

299	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(459-7VU-9NVQ, 2025-03-13)
	Detail of Fee Submitted	300000.0, 2025-03-12,
	The proposed proprietary name / brand name	Mediflox 10%
	Label Claim	Each ml contains: Enrofloxacin 100mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 YearStore at room temprature
	For generic drugs (me-too Status)	Encure 10 (Pak Reg. No. 020803 Mfg. By: Nawan Labortories Karachi)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	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	
300	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad (06-331-0168-031770D)
	Application Form Dy. No / Tracking ID & date of submission	(XAN-1NT-9DL4, 2025-03-18)
	Detail of Fee Submitted	75000.0, 2025-03-17,
	The proposed proprietary name / brand name	Dairymed Intramammary Suspension
	Label Claim	1 intramammary Syringe (5.4g of intramammary suspension) contains: Cloxacillin (as Cloxacillin benzathine) 600mg Ampicillin (as Ampicillin trihydrate) 300mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	5.4g -De-Controlled
	Shelf Life (Unit)	2 YearStore at room temprature
	For generic drugs (me-too Status)	New Molecule
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Ave & Vetmedic doo-Bregalnička32, Vršac-Serbia
	Name, address of Marketing Authorization Holder:	Ave & Vetmedic doo, Belgrade, Serbia

	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
301	Decision	
	Approved	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy	
	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Fizi Pharmaceuticals & Laboratories 8Km raiwind road lahore (000732)
	Application Form Dy. No / Tracking ID & date of submission	(JUG-YEN-7W63, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-08,
	The proposed proprietary name / brand name	Fizopine or Fizotop-V or Tropinex -Vet Injection 50ml
	Label Claim	Each ml Contains: Atropine Sulphate 1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml De-controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 Degree Celsius
	For generic drugs (me-too Status)	ATROFAR INJECTION. M/S Izfaar Pharmaceuticals Pvt Ltd 542 A&B Sundar Industrial Estate Lahore Registration No: 074751
	Pharmacotherapeutic Group of (API)	Anticholinergic drug
302	Name, address of Manufacturing site:	--
	GMP status of the firm	attached
	Evidence of approval of manufacturing facility	Liquid Injectable SVP- Vet (General) section approval letter submitted
	Evaluation Remarks	
	Decision	
	Approved	
	Case Category	New Section (Najia Saleem)
	Name, address of Applicant.	Fizi Pharmaceuticals & Laboratories 8Km raiwind road lahore (000732)
	Application Form Dy. No / Tracking ID & date of submission	(MZ8-1QL-59ZR, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-08,
	The proposed proprietary name / brand name	Fizimectin Plus or Fizovectin or Fiziolor Injection 100ml

	Label Claim	Each 100ml contains: Ivermectin...1gm Clorsulon...10gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree Celsius
	For generic drugs (me-too Status)	JFMEC-Super Injection of M/s Jfrin Pharmaceuticals, Hub Industrial Estate Balochistan. (Reg. No. 041211).
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Submitted Liquid Injectable SVP-vet General section approval
	Evaluation Remarks	
	Decision	
	Approved	
303	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Haarolds Pharmaceuticals (Pvt) Ltd. Plot No. 58C, 59C, 60C, 61C, 62C, 63C and 64C, Small Industrial Estate, Bhimber, Azad Jammu Kashmir (000921)
	Application Form Dy. No / Tracking ID & date of submission	(YQB-XDQ-5WEG, 2025-07-17)
	Detail of Fee Submitted	37000.0, 2025-07-16,
	The proposed proprietary name / brand name	TRIMECTIN DRENCH
	Label Claim	Each 100ml contains Triclabendazole 12gm Ivermectin..... 0.2gm Albendazole 10gm
	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)ROOM TEMPRATURE
	For generic drugs (me-too Status)	MECBEN DRENCH (121897)
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view in above facts detail visit of facility and supporting documents provided by the company, the panel unanimously Recommended M/S Harrolds pharmaceutical (PVT) LTD Plot No. 60C-64C, Small Industrial Estate,Bhimber AJ&K (By way of formulation
	Evidence of approval of manufacturing facility	Oral liquid- Veterinary section approval granted.
	Evaluation Remarks	
	Decision	

	Approved	
304	Case Category	New License (Najia Saleem)
	Name, address of Applicant.	Vetnicare Pharmaceutical Vetnicare Pharmaceutical, Khanna Labana, 8-Km Sheikhupura Road, Muridke-Pakistan (001003)
	Application Form Dy. No / Tracking ID & date of submission	(6SX-G6W-VSDM, 2025-03-13)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	Flor Care-23
	Label Claim	Each ml contains: Florfenicol.....230mg (As per innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 50 ml, 100ml, 1-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store at room temperature
	For generic drugs (me-too Status)	Poul Flor-23 Oral Solution of M/s. Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No.118544)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Conclusion: In view of inspection preceding and the facilities verifications, such as company profile, building, material management, production, in process controls, (Quality Control Testing, machinery equipment, Air handling, water treatment system, per
	Evidence of approval of manufacturing facility	Oral liquid section general veterinary granted.
305	Evaluation Remarks	
	The firm has demanded 120ml, 250ml, 500ml, 1Litre, 2.5 Litre, 5.0 Litre, 10.0 Litre, 25 Litre pack sizes in addition to the above-mentioned pack sizes.	
	Decision	
	Approved	
	upto 1 Litre pack size.	
305	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Vetnicare Pharmaceutical Vetnicare Pharmaceutical, Khanna Labana, 8-Km Sheikhupura Road, Muridke-Pakistan (001003)
	Application Form Dy. No / Tracking ID & date of submission	(X6T-ZB1-V23J, 2025-03-13)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	Alba-Vet
	Label Claim	Each ml contains Albendazole-----100mg BP-Vet, Specifications
	Reference to Finished product specifications	British Pharmacopeia

Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature
For generic drugs (me-too Status)	Albense-10 Drench Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043143)
Pharmacotherapeutic Group of (API)	Anthelmintics
Name, address of Manufacturing site:	--
GMP status of the firm	Conclusion: In view of inspection preceding and the facilities verifications, such as company profile, building, material management, production, in process controls, (Quality Control Testing, machinery equipment, Air handling, water treatment system, per
Evidence of approval of manufacturing facility	Oral liquid section (General)(Veterinary) approval granted
Evaluation Remarks	
150ml, 500ml, 1Litre, 2.5Litre pack sizes are also demanded by the firm.	
Decision	
Approved	
upto 1 litre pack size.	
306	Case Category
	New Section (Najia Saleem)
	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
	(WJY-TD6-GJUI, 2024-12-27)
	Detail of Fee Submitted
	75000.0, 2024-11-21,
	The proposed proprietary name / brand name
	Calcidiol plus 10mg/180 mcg soft gelatin Capsule
	Label Claim
	Each soft gelatin capsule contains: Menaquinone-7 (Vitamin K2) 180mcg Calcifediol Monohydrate 10mcg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	20's-As per SRO,30's-As per SRO,60'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)
	None
	Pharmacotherapeutic Group of (API)
	Vitamin K2 with Vitamin D analogs
	Name, address of Manufacturing site:
	Self Manufacturing
	Name & address of API manufacturer
	Anthem Biosciences Pvt. Ltd, Unit-IV. Plot No. 276-P, 277-P, Sy No. 20, Bannikuppe Road Harohalli Industrial area, phase-II, Kanakapura Taluk, Ramanagara District.,CARBOGEN AMCIS B.V Nieuweweg 2A Veenendaal 3901 BE Netherlands
	Detail of stability batches of drug product
	3 batches: 1000 capsule
	Documents for the procurement of API with approval from DRAP (in case of Import)
	Calcifediol: Drug Import License dated 02-09-2022 Menaquinone: Drug Import License dated 14-04-2023

Pharmaceutical Equivalence and Comparative Dissolution Profile	Opti Active D & K2 of Bioclinic Naturals: PE studies performed
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per zone IV-A
The status in reference regulatory authorities	Opti Active D & K2 Therapeutic Goods administration (TGA) approved as Listed Medicine
GMP status of the firm	03-01-2023: GMP certificate issuance date
Evidence of approval of manufacturing facility	18-05-2021: New section Soft gelatin capsule (General) section

Evaluation Remarks

Previous Decision of Registration Board: Registration Board in its 347th meeting deferred the case for evidence of approval of applied formulation as a pharmaceutical drug product in reference regulatory authorities which were adopted by Registration Board in its 275th meeting. Reply of the Firm: The firm has stated that the product is listed (AUST L) on the Australian Register of Therapeutic Goods. They explained that listed medicines in Australia are not individually evaluated by the Therapeutic Goods Administration (TGA) for quality, safety, and efficacy prior to marketing, and that such listing is based on sponsor self-certification of compliance with regulatory requirements. Calcifediol 10 µg per capsule, is well below EFSA's 100 µg/day UL and aligned with EC's new max daily dose for novel foods. Menaquinone-7 (180 µg): Meets long-term safety; no EU upper limit due to strong safety, supported by FDA GRAS. Regulatory recognition: EU, US, and Australia permit non-prescription use within these ranges; both ingredients listed in USP and BP. Australia listing: No pre-market TGA evaluation indicated, but overall regulatory status and literature support safety and global alignment. Evaluation by PEC: It is clarified for the Registration Board that TGA has not approved this product as a pharmaceutical medicine. The product is only listed (AUST L), which does not involve pre-market evaluation for safety, quality, or efficacy. Only TGA registered medicines (AUST R) are approved as pharmaceutical products.

Decision

Rejected

The Registration Board rejected the instant application because the approval status of the applied formulation as a pharmaceutical drug has not been confirmed in any Reference Regulatory Authority (RRA) declared by the Registration Board in its 275th meeting.

307	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(1TY-SZ9-3VNS, 2024-01-15)
	Detail of Fee Submitted	30000.0, 2023-09-12,
	The proposed proprietary name / brand name	D-LAN DDR CAPSULES 30mg
	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	14's & 30's-As per SRO
	Shelf Life (Unit)	2 Year(s) Store below 30°C
	For generic drugs (me-too Status)	Delanzo DDR Capsules 30mg
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Winbrains Research Laboratories
	Detail of stability batches of drug product	03 batches data as per zone IV-A, batch size 1000 capsules
	Documents for the procurement of API with approval from DRAP (in case of Import)	NA
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted data against Razodex 30mg
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted data of 3 batches for 2 years as per zone IV-A
	The status in reference regulatory authorities	Dexilant 30mg Capsule
	GMP status of the firm	GMP inspection report based on evaluation conducted 26-10-2023
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Sr. No.	Shortcomings as per decision of 347th RB meeting
	1	Validity status of DML of the applicant
	2	valid GMP certificate of Ms. Winbrains Research laboratories (pellets manufacturer)
	3	3.2.S.1.4 and 3.2.S.2.6: In contrary to reference product i.e. Dexilant capsules of M/s Takeda Pharms (USFDA approved) which are filled with two types of enteric coated granules exhibiting dual delayed release mechanism, the local manufacturer has used only one type of three layered enteric coated pellets. Submit evidence of reference/innovator product having same pellets as manufactured by M/s Winbrains Research Laboratories.
	Updated status	
	Submitted	
	Submitted GMP certificate based on evaluation conducted on 05-05-2021	
	The formulation developed by Winbrains is scientifically and functionally equivalent to the reference product Dexilant®: □ Dual delayed release is achieved via coating design instead of separate pellet populations. □ In-vitro data shows comparable dissolution at specified pH conditions. Moreover, DRAP has given approval to another company who took pellets from Winbrains.	
308	Decision	
	Approved	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(YMG-49M-583N, 2024-01-15)
	Detail of Fee Submitted	30000.0, 2023-09-12,
	The proposed proprietary name / brand name	D-LAN DDR CAPSULES 60mg

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	14's & 30's-Free of Cost
Shelf Life (Unit)	2 Year(s)Store below 30°C
For generic drugs (me-too Status)	Delanzo DDR Capsules 60mg
Pharmaceutical Group of (API)	PPI
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Winbrains Research Laboratories
Detail of stability batches of drug product	3 batches of 1000 capsules, as per zone IV-A conditions
Documents for the procurement of API with approval from DRAP (in case of Import)	NA
Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted data against Razodex 60mg capsules
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	As per zone IV-A
The status in reference regulatory authorities	Dexilant 60mg Capsule
GMP status of the firm	GMP inspection report based on evaluation conducted on 26-10-2023
Evidence of approval of manufacturing facility	submitted

Evaluation Remarks

Sr. No.	Shortcomings as per decision of 347th RB meeting	Updated status
1	Validity status of DML of the applicant	Submitted
2	valid GMP certificate of Ms. Winbrains Research laboratories (pellets manufacturer)	Submitted GMP certificate based on evaluation conducted on 05-05-2021
3	3.2.S.1.4 and 3.2.S.2.6: In contrary to reference product i.e. Dexilant capsules of M/s Takeda Pharms (USFDA approved) which are filled with two types of enteric coated granules exhibiting dual delayed release mechanism, the local manufacturer has used only one type of three layered enteric coated pellets. Submit evidence of reference/innovator product having same pellets as manufactured by M/s Winbrains Research Laboratories.	The formulation developed by Winbrains is scientifically and functionally equivalent to the reference product Dexilant®: Dual delayed release is achieved via coating design instead of separate pellet populations. In-vitro data shows comparable dissolution at specified pH conditions. Moreover, DRAP has given approval to another company who took pellets from Winbrains.

Decision

Approved

309	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhpura Road, Lahore (000576)
	Application Form Dy. No / Tracking ID & date of submission	(7NV-MGA-6AGR, 2024-06-20)

	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	NEUTERBIN 250MG TABLET
	Label Claim	Each Tablet contains: Terbinafine HCl equivalent to Terbinafine.....250mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	3 x 10's -As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25C
	For generic drugs (me-too Status)	Lamisil Tablet 250mg by Novartis Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted 6 months accelerated and real time stability studies data of three batches as per zone IV-A conditions
	Documents for the procurement of API with approval from DRAP (in case of Import)	ADC attested commercial invoice submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP submitted against Lamisil 250mg tablets of Ms Novartis Batch No. BAC550
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 36 month real time stability studies data of three batches submitted as per zone IV-A conditions
	The status in reference regulatory authorities	LAMISIL by FDA
	GMP status of the firm	GMP certificate based on evaluation conducted on 04-2022
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Decision	
	Approved	
310	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(U1U-N2X-DZA4, 2024-06-26)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	nefcon Eye drops
	Label Claim	Each mL Contains: Nepafenac 1mg (0.1%) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°C

	For generic drugs (me-too Status)	Neplo Ophthalmic Solution Alza Pharmaceuticals 081620
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Nefcon 1mg/ml eye drops of M/s Weather Folds approved in M-336 of RB.
	Evaluation Remarks	
	The firm initially selected No in data already approved however during evaluation they informed that their cross-referred application was approved in 336th meeting. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicant has also submitted a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification.	
	Decision	
	Approved	
311	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(8TX-4PT-VDHT, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-25,
	The proposed proprietary name / brand name	TRIBEN INJECTION (10ML)
	Label Claim	Each ml contains:Sulphadiazine 400mgTrimethoprim 80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ZINTRAN INJECTION. REG. NO. 063568 (ZAKFAS PHARMACEUTICALS (PVT.) LTD, MULTAN)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Deferred in M-351 till resumption of production in liquid injectable (General) section in compliance with GMP. Now the firm has submitted letter dated 29-12-2025 from DD (QA&LT) VIII for resumption of production activities in Liquid Injectable (General) section.	
	Decision	
	Approved	

312	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(455-LBG-TRTQ, 2024-10-26)
	Detail of Fee Submitted	37000.0, 9400.0 2024-10-22, 2025-08-06
	The proposed proprietary name / brand name	CYNO-1000 INJECTION
	Label Claim	Each ml contain :- Cynacobalamin 1000 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	CYANOZON EXTRA INJECTION Reg. No. 119706 (AMAZON PHARMACEUTICALS (PCT.)LTD,BHIMBER.AJ & K,)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
313	Evaluation Remarks	
	Deferred in M-351 till resumption of production in liquid injectable (General) section in compliance with GMP. Now the firm has submitted letter dated 29-12-2025 from DD (QA&LT) VIII for resumption of production activities in Liquid Injectable (General) section.	
	Decision	
	Approved	
	with USP specifications.	
313	Case Category	Routine (Najia Saleem)
	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	(AA1-NTT-PZY8, 2024-04-16)
	Detail of Fee Submitted	150000.0, 9000.0 2023-12-14, 2025-07-16
	The proposed proprietary name / brand name	Bovimate
	Label Claim	Each ml contains: Buserelin as acetate.....4µg (Chinese Veterinary Pharmacopoeia)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	5 Vials per Box -De-Controlled
	Shelf Life (Unit)	24 Month(s)Store at a cool and dark place
	For generic drugs (me-too Status)	Conceptual Injection by Star Labortries
	Pharmacotherapeutic Group of (API)	Synthetic Gonadotrophin releasing hormone.
	Name, address of Manufacturing site:	M/s Ningbo Sansheng Biological Technology Co., Ltd-No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China Country: China-China

Name, address of Marketing Authorization Holder:	M/s Ningbo Sansheng Biological Technology Co., Ltd, No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang Province, China, China
Details of Certificates (CoPP/FSC/cGMP):	Valid legalized CoPP & GMP has been submitted.
Details of Authorization Letter :	Scanned copy of distribution agreement with MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
Deferred in M-347 meeting, the Board was apprised by the Division of Biological evaluation & Research (BE&R) that the active substance in the product is synthetic in nature, the Board deferred the case and directed the Division of BE&R to forward the application to Division of PE&R for further evaluation and processing. Now the firm has submitted scanned copies of distribution agreement and FSC confirming free sale status and GMP status of the manufacturer, the firm shall also submit original legalized FSC, GMP and LOA and adjusted fee challan.	
Decision	
Approved	
with as per innovator's specifications, subject to compliance with current import policy for finished drugs. Moreover, the firm shall submit the following before issuance of registration letter:	
i. Original valid LOA notarized from country of origin	
ii. Original legalized valid FSC and GMP certificates	
iii. fee for registration adjusted fee challan	
Case Category	Routine (Najia Saleem)
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	(334-VQR-NHBP, 2024-02-06)
Detail of Fee Submitted	75000.0, 2023-11-14,
The proposed proprietary name / brand name	Colicalm
Label Claim	Each ml contains:Simethicone.....66.66mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	30ml Bottle-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)	Nil
Pharmacotherapeutic Group of (API)	Antiflatulance
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Sudeep Pharmaceuticals Private Limited, 129/1/A, 129/12, 13, 14, 15, G.I.D.C Estate, Nandesari- 391 340. Vadodara, Gujarat.
Detail of stability batches of drug product	3 batches of 1L each
Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested commercial invoice submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE data against Mylicolin of Ms Johnson & Johnson
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted as per zone IV conditions
	The status in reference regulatory authorities	Italian Medicine Agency (AIFA)
	GMP status of the firm	Kaizen: GMP certificate based on evaluation conducted on 03-01-2023
	Evidence of approval of manufacturing facility	Kaizen: GMP certificate based on evaluation conducted on 03-01-2023 confirms Oral liquids (syrup, solution, suspension) section
	Evaluation Remarks	
	Deferred in M-345 for clarification of applied dosage form whether the applied formulation is suspension/emulsion or solution. Firm's reply: The firm has submitted reference of approval of applied formulation Mylicon Children oral drops, as solution in AIFA, Italy.	
	Decision	
	Approved	
315	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(XNW-SAY-Z9L5, 2024-05-21)
	Detail of Fee Submitted	30000.0, 2024-05-06,
	The proposed proprietary name / brand name	Ivotek Forte Injection
	Label Claim	Each ml contains:- Ivermectin 3.15% (B.P Vet. Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15°C - 25°C in a cool and dry place.
	For generic drugs (me-too Status)	Actimec INJECTION 3.15%(114925) SELMORE PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D
	Evidence of approval of manufacturing facility	Liquid injectable (General) vial section confirmed from letter N0. F.1-27/85-Lic (Vol-III) dated 31-10-2023
	Evaluation Remarks	
	Decision	
	Approved	

316	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(ERY-YUJ-1ZQR, 2024-08-28)
	Detail of Fee Submitted	30000.0, 9400 2024-08-22, 2025-12-16
	The proposed proprietary name / brand name	ETER IVERMEC DRENCH
	Label Claim	Each 100ml Contains:- Ivermectin.....80mg(As per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	IVERSAN-ORAL SOLUTION. Reg. # 035023 (SANNA LABORATORIES, FAISALABAD)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has revised FPP specifications to USP along with submission of fee.	
	Decision	
317	Approved	
	with USP specifications.	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(LX6-XP1-T35E, 2024-07-13)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	ETER PRI ORAL SOLUTION
	Label Claim	Each 5ml Contains:- Cyanocobalamin 0.125mg Sodium Chloride 600mg Potassium Chloride 40mg Calcium Chloride hexahydrate 10mg Magnesium Chloride hexahydrate ...20mg Sodium lactate 213.5mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1 Liter-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PRION ORAL RE-HYDRATING SOLUTION. Reg. # 043294 M/s PRIX PHARMACEUTICA (PVT) LTD., LAHORE
	Pharmacotherapeutic Group of (API)	Restorative/anti-inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
318	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(MYA-D13-MQWW, 2024-08-26)
	Detail of Fee Submitted	30000.0, 9400.0 2024-08-20, 2025-08-06
	The proposed proprietary name / brand name	MECAM 20 INJECTION
	Label Claim	Each ml contains:- Meloxicam 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ELVOSOL STAR INJECTION Reg. No. 063733 (ELKO ORGANIZATION)
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
319	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(UU8-2B7-YMZQ, 2024-07-14)

Detail of Fee Submitted	30000.0, 2024-07-11,
The proposed proprietary name / brand name	ETER NSPB ORAL SOLUTION
Label Claim	Each 1000ml contains: - Norfloxacin.....50gm Sulfamethoxy pyridazine.....50gm Trimethoprim.....10gm Phenylbutazone.....12gm Bromhexine.....5gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 Liter-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	RAJUPT ENTERPRISES KARACHI (ANTI CRD/B ORAL SOLUTION REG. No. 018434)
Pharmacotherapeutic Group of (API)	Antibiotic/mucolytic/NSAID
Name, address of Manufacturing site:	--
GMP status of the firm	cGMP compliance (Satisfactory)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Target species: Poultry	
Decision	
Rejected	
since the Sub-committee on Veterinary Drugs recommended use of Phenylbutazone primarily in non-food-producing animals restricting its use to equine animals only while the firm has mentioned target species poultry.	
320	
Case Category	Routine (Najia Saleem)
Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
Application Form Dy. No / Tracking ID & date of submission	(X4L-WJ5-YUSN, 2024-06-19)
Detail of Fee Submitted	30000.0, 9400.0 2023-12-22, 2025-08-06
The proposed proprietary name / brand name	Ampro Forte Water Soluble Powder
Label Claim	Each 1000 gm Contains:- Amprolium 200 gm Ethopabate 10gm Sulphaquinoxaline 120gm Pyrimethamine 10gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm -De-Controlled,250gm-De-Controlled,500gm-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	M/S MY LAB PHARMA (NOXIN WATER SOLUBLE WATER REG. No. 105056)
Pharmacotherapeutic Group of (API)	Anticoccidal

	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	for submission of fee for the applied product since the attached fee challan No. 9845124329 is for another product Enramin powder.	
321	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(XQV-D53-54NH, 2024-08-26)
	Detail of Fee Submitted	30000.0, 9400.0 2024-08-21, 2025-08-06
	The proposed proprietary name / brand name	Mecam 20 Injection 10ML
	Label Claim	Each ml contains:- Meloxicam 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	MELOXTER 20 INJECTION Reg. No. 109921 (M/S AAMSTER LABORTORIES RAWAT ISLAMABAD)
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
322	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	(N67-1VH-MNY4, 2025-05-29)
	Detail of Fee Submitted	37000.0, 2025-05-22,
	The proposed proprietary name / brand name	Megapen-Strep Injection
	Label Claim	Each mL Contains: Procaine Penicillin G.....200mg Dihydrostreptomycin Sulphate eq. to Dihydrostreptomycin.....200mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not Store above 25°C
	For generic drugs (me-too Status)	112337 "DI STREP PROCAINE 400 INJECTION " "EACH ML CONTAINS:- PROCAINE PENICILLIN.....200MG DIHYDROSTREPTOMYCIN (AS SULPHATE).....200MG (USP SPECIFICATIONS) " LOCALLY MANUFACTURED "M/S. ETERNA P
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated conditions their current GMP compliance level is rated as good.
	Evidence of approval of manufacturing facility	Dry powder Injection (Penicillin) vet section approval submitted
	Evaluation Remarks	
	Decision	
	Approved	
323	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	

Deferred

for submission of target species.

324	Case Category	Routine (Najia Saleem)
	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	(M7A-UZJ-QDMU, 2024-01-03)
	Detail of Fee Submitted	75000.0, 2023-11-14,
	The proposed proprietary name / brand name	Colicalm
	Label Claim	Each ml contains:Simethicone.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25ml Bottle-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)	Nil
	Pharmacotherapeutic Group of (API)	Antiflatulance
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sudeep Pharmaceuticals Private Limited, 129/1/A, 129/12, 13, 14, 15, G.I.D.C Estate, Nandesari- 391 340. Vadodara, Gujarat.
	Detail of stability batches of drug product	3 batches of IL each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested commercial invoice
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted PE data against Aero-red 100mg/ml drops of Ms Uriach consumer healthcare batch No.903
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	6 months accelerated and 24 months real time stability data submitted as per zone IV conditions
	The status in reference regulatory authorities	Medicines and Healthcare Products Regulatory Agency
	GMP status of the firm	Kaizen: GMP certificate based on evaluation conducted on 03-01-2023
	Evidence of approval of manufacturing facility	Kaizen: GMP certificate based on evaluation conducted on 03-01-2023 confirms Oral liquids (syrup, solution, suspension) section
	Evaluation Remarks	
	Initially the firm has applied for formulation developed against Aero-Red Oral Solution in solution dosage form, which is revoked on 13-02-2025, without mentioning reasons for revocation. Now the firm has submitted evidence of approval in MHRA (Espumisan oral drops as emulsion). The composition of the applied product is also different from the reference product Espumisan approved in MHRA.	
	Decision	
	Deferred	

	for submission of evidence of approval of applied formulation in the same dosage form in Reference Regulatory Authorities declared by the Registration Board in its 275th meeting	
325	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	tab INTERNATIONAL Office No. 77-K, Phase-I, Defence, Commercial Market, Lahore, Nishter Town (05-352-0065-107628D)
	Application Form Dy. No / Tracking ID & date of submission	(LTL-199-PW3D, 2024-09-13)
	Detail of Fee Submitted	300000.0, 2024-09-12,
	The proposed proprietary name / brand name	Tilmosav
	Label Claim	Each ml contains: Tilmicosin (as phosphate) 250mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	120ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Room temperature
	For generic drugs (me-too Status)	Pulmotil AC (Elanco GmbH, LCI), Tilcosin Solution (Selmor), Hicos (Hilton),
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Saudi Pharmaceutical Industries-Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia.-Saudi Arabia
	Name, address of Marketing Authorization Holder:	Saudi Pharmaceutical Industries, Street No.248, Second Industrial City, Riyadh, Kingdom of Saudi Arabia., Saudi Arabia
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copies of FSC (valid upon submission but expired now) and valid GMP certificate submitted
	Details of Authorization Letter :	Scanned copy of LOA valid till 15-05-2027 submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 6 months accelerated data submitted as per zone IV-A conditions
326	Evaluation Remarks	
	Scanned copy of legalized COPP and power of attorney submitted. Firm shall submit original legalized documents and fee for revision of FPP specifications before issuance of registration letter.	
	Decision	
326	Approved	
	with as per innovator's specifications, subject to compliance of current Import Policy for finished drugs. The firm shall submit original valid legalized COPP and power of attorney and fee for revision of FPP specifications before issuance of registration letter.	
	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	HIPRA PAKISTAN PVT LTD. House no 86-88, J-1 Sunflower Society, M.A Johar Town, Lahore (05-352-0058-050528D)
	Application Form Dy. No / Tracking ID & date of submission	(VQD-SJN-9GZJ, 2025-04-09)
	Detail of Fee Submitted	300000.0, 2025-04-08,
326	The proposed proprietary name / brand name	Eficur
	Label Claim	Each ml contains: Ceftiofur as HCl.....50mg

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	250 ml-De-Controlled
Shelf Life (Unit)	24 Year(s)store below 25 degree C
For generic drugs (me-too Status)	Eficur 100 ml (080159)
Pharmacotherapeutic Group of (API)	Cephalosporin antibacterial
Name, address of Manufacturing site:	Laboratorios Hipra-Laboratorios Hipra, S.A.,Avda. la Selva, 1,17170 Amer (Girona), Spain-Spain
Name, address of Marketing Authorization Holder:	Laboratorios Hipra, Laboratorios Hipra, S.A., Avda.la Selva,135,17170 Amer (Girona), Spain, Spain
Details of Certificates (CoPP/FSC/cGMP):	submitted, could be verified online
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
The cephalosporin/penicillin are manufactured in the building named VIF1 (Manufacture of Inactivated Vaccines and Pharmacological Products for animal use). Inside this building other activities are carried out as:Manufacture of viral, bacterial and combined inactivated vaccines Manufacture of solvents for vaccines. Manufacture of β -lactam injectable suspensions Manufacture of Pharmacological Products Aseptic filling lines However, cephalosporin/penicillin are considered substance with special requirements. Therefore, penicillanic antibiotics are handled in dedicated rooms using dedicated equipment and operated by dedicated personnel to avoid any contamination.The firm has submitted scanned copies of LOA, GMP, FSC	
Decision	
Deferred	
for further deliberation.	
327	Case Category
	Routine (Najia Saleem)
	HIPRA PAKISTAN PVT LTD. House no 86-88, J-1 Sunflower Society, M.A Johar Town, Lahore (05-352-0058-050528D)
	Name, address of Applicant.
	Application Form Dy. No / Tracking ID & date of submission
	(AQW-NE9-3MTH, 2025-04-09)
	Detail of Fee Submitted
	300000.0, 2025-04-08,
	The proposed proprietary name / brand name
	Selectan
	Label Claim
	Each ml contains: Florfenicol.....300mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	250 ml-De-Controlled
	Shelf Life (Unit)
	24 Month(s)room temperature
	For generic drugs (me-too Status)
	Selectan 100ml (Reg. No. 080158)
	Pharmacotherapeutic Group of (API)
	Antibiotic
	Name, address of Manufacturing site:
	Laboratorios Hipra-Laboratorios Hipra, S.A.,Avda. la Selva, 1,17170 Amer (Girona), Spain-Spain
	Name, address of Marketing Authorization Holder:
	Laboratorios Hipra, Laboratorios Hipra, S.A., Avda.la Selva,135,17170 Amer (Girona), Spain, Spain
	Details of Certificates (CoPP/FSC/cGMP):

	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	The firm has submitted scanned copies of LOA, GMP, FSC	
	Decision	
	Approved	
	subject to compliance of current Import Policy for finished drugs. The firm shall submit original LOA, FSC and GMP before issuance of registration letter.	
328	Case Category	Import (Sabahat Zehra)
	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	(51Z-XG3-7H77, 2025-02-20)
	Detail of Fee Submitted	300000.0, 2025-01-31,
	The proposed proprietary name / brand name	Eagle Long-PS Inj
	Label Claim	Each ml contains Dihydrostreptomycin Sulfate 200mg(A) Penicillin G Benzathine Hydrate 100,000IU Penicillin G Procaine 150,000IU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store between 15-25 C in a cool and dry place
	For generic drugs (me-too Status)	BPS-LA injection Reg# 112154
	Pharmacotherapeutic Group of (API)	beta lactam antibiotics
	Name, address of Manufacturing site:	Eagle Vet. Tech Co., Ltd.-235-34, Chusa-ro, Shinam-myeon, Yesan-gun, Chungcheongnam-do, 32417 Korea-South Korea
	Name, address of Marketing Authorization Holder:	U.M. Enterprises, plot No.12 sector No.15 Korangi Industrial area , Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	Evaluation Remarks	
	As the product is imported from Korea, the Korean Authority doesn't issue any separate report for dedicated facility of pencillin production. However, declaration of separate area for pencillin production is provided by importer.	
	Decision	
	Approved	
	Approved, subject to dedicated facility.	
329	Case Category	Import (Sabahat Zehra)
	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	(YBJ-473-Q4WM, 2025-02-17)
Detail of Fee Submitted	300000.0, 2025-01-31,
The proposed proprietary name / brand name	Eagle Long-PS Inj
Label Claim	Each ml contains Dihydrostreptomycin Sulfate 200mg(A) Penicillin G Benzathine Hydrate 100,000IU Penicillin G Procaine 150,000IU
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100ml-De-Controlled
Shelf Life (Unit)	24 Year(s)Store in a dry and dark place
For generic drugs (me-too Status)	BPS LA injection
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	Eagle Vet. Tech Co., Ltd.-235-34, Chusa-ro, Shinam-myeon, Yesan-gun, Chungcheongnam-do, 32417 Korea-South Korea
Name, address of Marketing Authorization Holder:	U.M. Enterprises, plot No.12 sector No.15 Korangi Industrial area , Pakistan
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
As the product is imported from Korea, the Korean Authority doesn't issue any separate report for dedicated facility of penicillin production. However, declaration of separate area for penicillin production is provided by importer.	
Decision	
Approved	
Approved, subject to dedicated facility.	
330	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
	(TSE-RUW-92RR, 2025-09-13)
	Detail of Fee Submitted
	38700, 2025-09-11,
	The proposed proprietary name / brand name
	Tycostrep injection
	Label Claim
	Each ml contains Tylosin 100mg Colistin sulphate 20mg Dihydrostreptomycin 200mg (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 controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)
	TCS Injection (Leads pharma) Reg#058848
	Pharmacotherapeutic Group of (API)
	Antibiotics
	Name, address of Manufacturing site:
	--

	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
331	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(4UA-8E3-E874, 2025-04-23)
	Detail of Fee Submitted	37000.0, 9400 2025-04-22, 2025-11-19
	The proposed proprietary name / brand name	Power Booster Powder
	Label Claim	Each Kg Contains: Vitamin A .0.8 gm. Vitamin D3 0.16 gm. Vitamin E 0.38 gm. Vitamin B1 1.0 gm Vitamin B2 1.25 gm Vitamin B12 0.001 gm Vitamin B3 (Nicotinamide) 6.25 gm Copper Sulphate (Cu) 0.25 gm Magnesium Sulphate 25gm Calcium Chloride 0.023 gm Zinc Sulphate 2.17 gm Manganese Sulphate 120gm Potassium Iodide 0.5 gm Sodium Selenite 0.01gm D.C.P (P) (Phosphorous) 150 gm Sodium Chloride 120 gm Vitamin B6 4 gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,20Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	White Gold Powder (Reg no. 058842) Leads Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Multivitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

	Approved upto 1 kg pack size.	
332	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(M7Y-6M4-JZ1V, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-07-07,
	The proposed proprietary name / brand name	LINCOFAS-4400 POWDER
	Label Claim	Each 1000gm Contains: Lincomycin as Hydrochloride 44 gm.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at controlled temperature below 30°C, Keep away from sunlight.
	For generic drugs (me-too Status)	Licogrow-44 Oral Powder (Reg no. 080157) Ras Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
333	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
333	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(S8P-7BL-H8DE, 2025-05-03)
	Detail of Fee Submitted	37000.0, 9400 2025-04-30, 2025-11-19
	The proposed proprietary name / brand name	FACTOFAS-300 ORAL POWDER
	Label Claim	Each 100gm Contains: Fosfomycin Calcium (B.P) Tylosin as Tartrate (B.P) Fructose 1,6 Diphosphate (B.P) Sodium Phosphate (B.P) Magnesium sulphate (B.P) 10 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,200gm-De-

		Controlled,20Kg-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	Fosfotyl Powder (Reg no. 078240) Leads Pharma (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic + mineral supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted fee for Pre-registration variation i,e Rs 9400/-	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
334	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(MPV-ZBW-VD6S, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-07-07,
	The proposed proprietary name / brand name	N.T.C ORAL SOLUTION
	Label Claim	Each 100ml Contains: Norfloxacin (BP Vet) 10% Tylosin as Tartrate 5% Colistin Sulphate (BP) 250 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at controlled temperature below 30°C, Keep away from sunlight
	For generic drugs (me-too Status)	Norcotyl Oral Solution (Reg no. 071021) Biogen Pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
335	Approved	
	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(ZHW-18P-6Y7P, 2024-10-24)
	Detail of Fee Submitted	37000.0, 2024-10-18,
	The proposed proprietary name / brand name	IMMUNE BOSTER ORAL POWDER
	Label Claim	Each 1000gm contains:- Proteases 100,000IU Lipases 23000IU Amylases 125000IU Mannases 20000IU Bacillus subtilis (inactivated)..... 1000mg Levamisole 15gm Vitamin E 20gm Vitamin C 40gm (As Per Innovator's specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25 °C. Protect from light
	For generic drugs (me-too Status)	IMMUNO EBC ORAL POWDER. Reg.# 033237 (MEDI EXCEL PHARMACEUTICALS (PVT.) LTD.)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
336	Approved	
	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(R9P-7RN-ZAZ4, 2025-07-09)

	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Lintal 4.4% Oral Powder
	Label Claim	Each 100 gm. Contains:Lincomycin HCl.....4.4 %
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,15kg- De-Controlled,1kg-De-Controlled,20gm-De- Controlled,20kg-De-Controlled,250gm-De- Controlled,25kg-De-Controlled,500gm-De- Controlled,50gm-De-Controlled,5gm-De- Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	ACLINCO 4.4 %
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
337	Case Category	New License (Sabahat Zehra)
	Name, address of Applicant.	Pivotal pharmaceuticals (Pvt) Ltd. Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi (001006)
	Application Form Dy. No / Tracking ID & date of submission	(BM1-VSA-D973, 2025-07-10)
	Detail of Fee Submitted	37000.0, 2025-05-26,
	The proposed proprietary name / brand name	Trital Oral Powder
	Label Claim	Each gm contains Neomycin sulphate.....30mg. Furaltadone.....75mg. Chlortetracycline HCl.....100mg
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,1kg- De-Controlled,20kg-De-Controlled,250gm-De- Controlled,25kg-De-Controlled,500gm-De- Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	Trifle Water Soluble Powder (Reg. # 029615)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The formulation contains furaltadone as an ingredient.	

	Decision	
	Deferred	
	The instant case is deferred for review of formulation to Sub-committee on veterinary drugs.	
338	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(6J1-BVB-XM98, 2025-01-16)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	Senbro-T WSP
	Label Claim	Each Kg contains: Colistin Sulphate 4gm Neomycin Sulphate 70gm Chlortetracycline Hydrochloride 80gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good Level
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
339	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
	Application Form Dy. No / Tracking ID & date of submission	(P3M-ET1-5JVH, 2025-07-08)
	Detail of Fee Submitted	37000.0, 2025-07-07,
	The proposed proprietary name / brand name	TYLOFAS-200 POWDER
	Label Claim	Each 1000gm Contains: Tylosin as Tartrate (B.P) 200gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled, 10gm-De-Controlled, 1Kg-De-Controlled, 250gm-De-Controlled, 25Kg-De-Controlled, 500gm-De-Controlled, 5Kg-De-Controlled

Shelf Life (Unit)	2 Year(s)Store at controlled temperature 30°C, Keep away from sunlight.
For generic drugs (me-too Status)	Tylox Oral Power (Reg no. 027465) Rotass Universal Trading Co.
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Approved upto 1 kg pack size.	
Case Category	Routine (Sabahat Zehra)
Name, address of Applicant.	INTERVAC (PVT) LTD 18KM SHEIKHUPURA ROAD (000623)
Application Form Dy. No / Tracking ID & date of submission	(HVB-EWL-6Q9S, 2025-07-08)
Detail of Fee Submitted	37000.0, 2025-07-07,
The proposed proprietary name / brand name	TYLOFAS-100 POWDER
Label Claim	Each 1000gm Contains: Tylosin as Tartrate (B.P) 100gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,1Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
Shelf Life (Unit)	2 Year(s)30C degree centigrade
For generic drugs (me-too Status)	Tylolina 100% Powder (Reg no. 069624)
Pharmacotherapeutic Group of (API)	Antibiotics
Name, address of Manufacturing site:	--
GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhpura Road, Sheikhpura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	

	Approved Approved upto 1 kg pack size.	
341	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(D8P-HLR-W7BH, 2025-07-31)
	Detail of Fee Submitted	37000.0, 2025-07-31,
	The proposed proprietary name / brand name	MAJI LINCO FORTE-40 ORAL WATER SOLUBLE POWDER
	Label Claim	Each gm contains: Lincomycin as HCl 400 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,25000gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	POUL LINK-40 Oral Powder (118503)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
342	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(WBL-PXD-BD3V, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-17,
	The proposed proprietary name / brand name	TOXIMAJ-B ORAL POWDER
	Label Claim	Each gm contains: Sodium Benzoate.....500 mg Ethanol Beta Amino Phosphoric Acid..... 100 mg Vitamin A..... 10,000 IU Vitamin E..... 2.5 mg Vitamin K3..... 1 mg Vitamin C..... 2.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,25 Kg-De-

		Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Benzo Tox Powder (118525)
	Pharmacotherapeutic Group of (API)	Multivitamins/ Growth promoter
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
343	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(DMN-RB4-D8SW, 2025-07-18)
	Detail of Fee Submitted	37000.0, 2025-07-17,
	The proposed proprietary name / brand name	NORAMAG-AG ORAL LIQUID
	Label Claim	Each 100ml contains: Norfloxacin ----- 20 gm Guaifenesin ----- 20 gm Aminophylline ----- 8 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Noramin-G Liquid (044976)
	Pharmacotherapeutic Group of (API)	Antibiotic/Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 litre pack size.	
344	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)

Application Form Dy. No / Tracking ID & date of submission	(UHB-6SY-TEAV, 2025-07-10)
Detail of Fee Submitted	37000.0, 2025-07-09,
The proposed proprietary name / brand name	FLORIMAJ-23 ORAL LIQUID
Label Claim	Each 100ml contains: Florfenicol ----- --- 23 gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10 lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
For generic drugs (me-too Status)	Floro Forte Oral Liquid (074073)
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	Satisfactory level of GMP Compliance
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Approved upto 1 litre pack size.	
345	Case Category
	Routine (Sabahat Zehra)
	Name, address of Applicant.
	M/s. Salford Laboratories (Pvt) Ltd Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir (001009)
	Application Form Dy. No / Tracking ID & date of submission
	(UXX-QAE-YUDB, 2025-07-15)
	Detail of Fee Submitted
	37000.0, 2025-07-15,
	The proposed proprietary name / brand name
	NOR-AG ORAL LIQUID
	Label Claim
	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20% Guaifenesin USP..... 20% Aminophylline USP..... 8%
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	100ml-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)
	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)
	NOR+AG SOLUTION (058968) BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)
	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:
	--
	GMP status of the firm
	The panel recommends grant of DML
	Evidence of approval of manufacturing facility

	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 litre pack size.	
346	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	M/s. Salford Laboratories (Pvt) Ltd Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir (001009)
	Application Form Dy. No / Tracking ID & date of submission	(5ME-TGA-68VS, 2025-07-15)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	NOR-C ORAL LIQUID
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20g Colistin sulphate BP..... 60MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,2.5Lit-De-Controlled,250ml- De-Controlled,500ml-De-Controlled,Lit-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	NOR-C MAARSON ORAL LIQUID (071056) ATTABAK PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 litre pack size.	
347	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	M/s. Salford Laboratories (Pvt) Ltd Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir (001009)
	Application Form Dy. No / Tracking ID & date of submission	(STP-7J5-JJ7B, 2025-07-15)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	NORSTER ORAL LIQUID
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin HCl 25g
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	NORMAK ORAL LIQUID (058943) A&K PHARMA FAISLABAD
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 litre pack size.	
348	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	M/s. Salford Laboratories (Pvt) Ltd Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir (001009)
	Application Form Dy. No / Tracking ID & date of submission	(LS2-QNL-ZBG2, 2025-07-15)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	TRISTER ORAL LIQUID
	Label Claim	Each ml contains (As Per Innovator Spec.) Norfloxacin BP..... 50mg Sulphamethoxypyridazine 50mg Trimethoprim 10mg Phenylbutazone 12mg Bromhexine 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	MEGA BIOTIC SOLUTION (057006) SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Target species are sheep, goats, camelids and horses.	
	Decision	
	Approved	

	Approved upto 1 litre pack size in light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to equines only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in these animals, should also be shown clearly.	
349	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Majestic Pharma plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad (000873)
	Application Form Dy. No / Tracking ID & date of submission	(UDE-94P-5V4M, 2025-07-31)
	Detail of Fee Submitted	37000.0, 9400 2025-07-31, 2025-12-31
	The proposed proprietary name / brand name	MAJIFON 98% POWDER
	Label Claim	Each gm contains: Trichlorfon..... 980 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,12gm-De-Controlled,250gm-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature and avoid from heat and sunlight.
	For generic drugs (me-too Status)	Trichlovet 98% Powder (080768)
	Pharmacotherapeutic Group of (API)	Antiparasitic
	Name, address of Manufacturing site:	--
	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	Not applicable
	GMP status of the firm	Satisfactory level of GMP Compliance
	Evidence of approval of manufacturing facility	.
	Evaluation Remarks	
	Decision	
	Approved	
350	Case Category	Routine (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	(NSJ-NYT-47XP, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	TLA INJECTION
	Label Claim	Each ml contains Tylosin Tartrate eq. to Tylosin 180mg (BP Vet Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 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)	Tylocare 180 (vetline pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
351	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	(GXR-31E-7TYE, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Colistin 60 injection
	Label Claim	Each 100ml contains Colistin sulphate (B.P VET) 60MIU (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 controlled room temperature.protect from heat,light and ,moisture
	For generic drugs (me-too Status)	Colistan Forte Injection (Leads pharma)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
352	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	(P5Q-EG2-HPD5, 2025-09-13)
	Detail of Fee Submitted	38700, 2025-09-12,
	The proposed proprietary name / brand name	Electro Ras Plus W/S Powder
	Label Claim	Each gm Contains Aspirin 200mg Vitamin C 600mg Sodium chloride 35mg Sodium citrate 7mg (Manufacturer's Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 kg-De-Controlled,100 gm-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)	Electrobar-c w/s Powder (Varrik pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Analgesic, antipyretic, antioxidant
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
353	Decision	
	Approved	
	Approved upto 1 kg pack size	
	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	(YQ6-8TJ-HTXM, 2025-09-12)
	Detail of Fee Submitted	38700, 2025-09-11,
	The proposed proprietary name / brand name	Norsultrim aqueous solution
	Label Claim	Each 1000ml contains :Norfloxacin HCl(USP) 7% Sulphamethoxypyridazine (B.P) 10% Trimethoprim (B.P).....2%
	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)	Nor-sul-tri Aquous Solution (Vetline pvt.)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
354	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Hi-Med Pharmaceuticals 208C Sundar industrial estate Raiwind Road Lahore (000884)
	Application Form Dy. No / Tracking ID & date of submission	(41V-D93-WW43, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-06-20,
	The proposed proprietary name / brand name	Acepan Injection 150mg/ml
	Label Claim	Each ml contains: Aceclofenac.....150mg (Product Specs: Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store Below 25 degree celcius
	For generic drugs (me-too Status)	Acenac Injection 150mg/ml (S.J. & G. FAZUL ELLAHIE (PVT.)LTD.)
	Pharmacotherapeutic Group of (API)	non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aarti Drugs Limited
	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	ACECLOFENAC INJECTION 150 MG/ML (THEMIS MEDICARE LIMITED)
	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 applied formulation has not been found in any approved reference regulatory agencies and firm in their response confirmed that The product (Aceclofenac 150mg/ml) is not available in RRA and they are submitting "Me Too" as a reference.	
	Decision	
	Deferred	

	Deferred for confirmation of approval status of applied formulation in the approved Reference Regulatory Agencies.	
355	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(553-HPD-WY6D, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	LIPAGLI
	Label Claim	Each film coated tablet contains: Linagliptin 5mg Empagliflozin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Brand Name: Xenglu-Lin 5mg/10mg Tablet Registration holder: Hilton Pharma
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	Name & address of API manufacturer	Name: Fuxin Long Rui Pharmaceutical Co. Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province, 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 GLYXAMBI ® Manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. Regulatory Authority: FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm submitted the GMP certificate of contract acceptor M/s. Seraph Pharmaceuticals dated 11th November,2022 mentioned that firm has tablet(general) section.
	Evaluation Remarks	
	Previous approval details: Registration Board in its 339th meeting already approved the data of applied formulation of M/s. Seraph Pharmaceuticals on Form-5F. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
356	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(5LZ-DYJ-MSGJ, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	LIPAGLI
	Label Claim	Each film coated tablet contains: Linagliptin 5mg Empagliflozin 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30°C
	For generic drugs (me-too Status)	Brand Name: Xenglu-Lin 5mg/25mg Tablet Registration holder: Hilton Pharma
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	Name & address of API manufacturer	Name: Fuxin Long Rui Pharmaceutical ,SY No. 10/G-1, Gaddapotharam (V), Jinnaram (M), Sangareddy (D), Telangana State, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Pincode 502319, Telan
	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 GLYXAMBI ® Manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. Regulatory Authority: FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm submitted the GMP certificate of contract acceptor M/s. Seraph Pharmaceuticals dated 11th November,2022 mentioned that firm has tablet(general) section.
Evaluation Remarks		
revious approval details: Registration Board in its 339th meeting already approved the data of applied formulation of M/s. Seraph Pharmaceuticals on Form-5F. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of		

already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

357	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Jenner Pharmaceuticals Pvt. Ltd Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura (000823)
	Application Form Dy. No / Tracking ID & date of submission	(X8Z-TPT-XH1Q, 2024-06-26)
	Detail of Fee Submitted	30000.0, 2024-05-30,
	The proposed proprietary name / brand name	Vorijen Tablets
	Label Claim	Each Film Coated Tablet Contains: Voriconazole 50mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10 s-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30C
	For generic drugs (me-too Status)	Dynazole Tablets 50mg 106533
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use, triazole derivatives
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hema Pharmaceuticals Pvt. Ltd. Plot No.6201/A&B, Opp: EWAC Alloys, Ltd. GIDC Estate, Ankleshwar- 393002 Dist. Bharuch, Gujarat, India
	Detail of stability batches of drug product	Stability data of batches VRJ-PB-043001 VRJ-PB-043002 VRJ-PB-043003 (batch size 800 tablets) is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken Loan from M/s. Dyson Pharmaceuticals and as an evidence firm submitted the Loan letter along with clearance certificate.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the comparator product Dynazole Tablet 50mg of M/s. Dyson Pharmaceuticals.
	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	MHRA/ Vfend 50mg film-coated tablets https://products.mhra.gov.uk/product/?product=VFEND%2050%20MG%20FILM-COATED%20TABLETS
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm submitted the GMP certificate dated 06-07-2022 mentioned that firm has tablet (general section)
	Evaluation Remarks	

	Decision	
	Approved	
358	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(6UM-YEY-JUPT, 2025-06-04)
	Detail of Fee Submitted	300000.0, 2025-03-14,
	The proposed proprietary name / brand name	Abenix 100mg Tablet
	Label Claim	Each film-coated tablet contains.... Abemaciclib 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03
	Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product VERZENIO 100 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 100 TABLET
	Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Firm submit GMP CERTIFICATE NO. DA/6- 110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data submitted
	The status in reference regulatory authorities	Verzenio 100mg Film-coated Tablet (USA)
Evaluation Remarks		
Firm submitted the BMR in which following variations has been observed: Weight per Tablet (Coated): 400.00 mg ±3 % (388 mg to 412 mg) mentioned in section 3.2.P.1 Weight per tablet (Coated): 412.00 mg ± 3% (3.99.64 mg to 424.36 mg) mentioned in process validation protocol Weight of tablet (Coated): 618.00 mg ± 4% (593.28 mg to 642.72 mg) mentioned in BMR of batch no. AB5921 In-process sheet of compression and coating mentioned the date of year 2024 Weight of tablet (Coated): 418mg ±4 % (493.28mg to 642.72 mg) mentioned in BMR of batch no. AB5922 Weight of tablet (Coated): 618.00 mg ± 4% (593.28 mg to 642.72 mg) mentioned in BMR of batch no. ABS923		

Composition	Quantity as section 3.2.P.1	Required total (mg)	Batch-1 AB5922 total (mg) Claimed batch size: 6666 tablets in stability datasheets	Batch-2 (AB5921) total (mg) Claimed batch size: 6666 tablets in stability datasheets	Batch-3 (ABS923) total (mg) Claimed batch size: 6666 tablets in stability datasheets
Abemaciclib (API)	100.000	666,600	666,600	1,000,000	666,600
Croscarmellose (CCS)	20.000	133,320	133,320	200,000	133,320
Lactose Monohydrate	120.000	799,920	799,220	1,200,000	799,920
Sodium Stearyl Fumarate (SSF)	8.000	53,328	53,328	80,000	53,328
Colloidal Silica (Aerosil)	5.000	33,330	33,330	50,000	33,330
Microcrystalline Cellulose (MCC PH102)	147.000	979,902	979,902	1,470,000	979,902

Decision

Rejected

The Registration Board decided to reject the instant application upon observing a variation in the weight of the coated tablet in all three BMRs compared to the drug product details submitted in the CTD section 3.2.P.1. Furthermore, the composition of all three stability batches also shows variations despite the same claimed batch size for each batch. Details of the observed variations are recorded in the evaluation remarks column.

359	Case Category	Priority As Per 257-M of RB (Saima Hussain)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(YSJ-68H-6VT4, 2025-05-12)
	Detail of Fee Submitted	300000.0, 2025-03-14,
	The proposed proprietary name / brand name	Abenix 200mg Tablet
	Label Claim	Each film coated tablet contains.....Abemaciclib 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03
	Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product VERZENIO 200 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 200 TABLET
	Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh
	Details of Certificates (CoPP/FSC/cGMP):	Firm submit GMP CERTIFICATE NO. DA/6-110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data submitted
	The status in reference regulatory authorities	Verzenio 200mg Film-coated Tablet (USA)
	Evaluation Remarks	
	Variations have been observed between the Batch Manufacturing Record (BMR) and the data submitted in the Drug Product section of Module-III. Moreover, overwriting and alteration of dates were identified on multiple pages of the BMR, specifically at two locations where the year “2025” appears to have been cut and changed to “2022,” raising concerns regarding data integrity. In addition, some pages of the BMR reflect that the manufacturing process was performed in the year 2025. Furthermore, firm submitted the BMR of only 2 stability batches. Weight per Tablet (Coated): 800.00 mg ± 5% (760 mg to 840 mg) mentioned in section 3.2.P.1 Weight per tablet (Coated): 815.00 mg ± 5% (774.25 mg to 855.8 mg) mentioned in process validation protocol Weight of tablet (Coated): 818.00 mg ± 4% (793.28 mg to 842.72 mg) mentioned in BMR of batch no. AB63128 In-process sheet of coating process Weight of tablet (Coated): 818.00 mg ± 4% (793.28 mg to 842.72 mg) mentioned in BMR of batch no. AB63129	
	Decision	
	Rejected	
	The Registration Board rejected the present application after noting a discrepancy between the coated tablet weight recorded in the Batch Manufacturing Record (BMR) and the drug product details submitted in the CTD section 3.2.P.1 of the dossier. In addition, overwriting and alteration of dates were observed on multiple pages of the BMR; specifically, at two locations the year “2025” appears to have been cut and changed to “2022,” raising serious concerns regarding data integrity. Moreover, several pages of the BMR indicate that the manufacturing process was carried out in the year 2025. Furthermore, the firm submitted BMRs for only two stability batches, which is insufficient to support the application.	
360	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	TABROS PHARMA (PVT). LTD. Plot No. L-20/B, Sector 22, F.B. Industrial Area (000106)
	Application Form Dy. No / Tracking ID & date of submission	(3AY-STN-LXWT, 2024-06-28)
	Detail of Fee Submitted	30000.0, 9400 2024-06-13, 2026-01-06
	The proposed proprietary name / brand name	DB6 Delayed Release 10/10mg Tablet
	Label Claim	Each delayed release tablet contains: Doxylamine Succinate 10mg Pyridoxine HCl.....10mg Innovator’s Specification
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30 Degree
	For generic drugs (me-too Status)	Xyquil DR Tablet, M/s Sami Pharmaceuticals (Pvt.) Ltd. Pakistan
	Pharmacotherapeutic Group of (API)	Antihistamine + Vitamin B6
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Huazhong Pharmaceutical Co., Ltd. Address: No 118 Xianshan Road, Xiangyang, Hubei Province, China,R L Fine Chem Pvt. Ltd. Plot No. IP 27-29, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chikkaballapura, Karnataka, India.
	Detail of stability batches of drug product	Stability data of batches Batch number STB001-1/DB6, STB002-1/DB6,STB003-1/DB6 of batch size 1500 tablet each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate of both API has submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence and comparative dissolution profile has performed against the comparator product Xyquil DR Tablet 10/10mg (Sami Pharmaceuticals Pvt. Ltd.)
	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	Diclegis Tablet, Duchesnay Inc. USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm submitted the GMP certificate dated 1st April,2024 in which mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	According to the innovator's product description, DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets are round, white, and film-coated. However, the applied product is described as a light-pink, round, biconvex, enteric-coated tablet, plain on both sides. Furthermore, the submitted manufacturing method indicates that the applied formulation is enteric-coated and that no film coating has been performed. In view of this discrepancy, the firm has to justify how the applied formulation can be considered similar to the innovator's product. Firm responded that The description difference regarding "film-coated" versus "enteric-coated" is terminology only. An enteric coat is a specific type of film coating designed to achieve delayed release, and therefore serves the same functional purpose as the innovator's delayed-release system. Comparative dissolution studies confirm that our enteric-coated tablet provides the same delayed-release profile as the innovator in both acidic and buffer media. As both the innovator and our product utilize a film-coating system, the difference in terminology does not affect dissolution, stability, or therapeutic outcome. Further ,firm amend the label claim/product description along with requisite fee as under: Each delayed release film coated tablet contains:Doxylamine Succinate... 10mgPyridoxine HCl ...10mg	
	Decision	
	Approved	
361	Case Category	Routine (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	(EW8-UYD-W83Q, 2025-05-08)	
Detail of Fee Submitted	37000.0, 2025-04-23,	
The proposed proprietary name / brand name	Mirica	
Label Claim	Each Capsule Contains: Pregabalin-----100mg	
Reference to Finished product specifications	British Pharmacopeia	
Proposed Pack Size	2x7's/2x10's/10x10's-As per SRO	
Shelf Life (Unit)	2 Year(s)15-30 Degree Centigrade	
For generic drugs (me-too Status)	Gablin 100mg Capsule by CCL Pharmaceuticals Pvt. Ltd. Lahore-Pakistan	
Pharmacotherapeutic Group of (API)	Anticonvulsants, Used in treatment of Epilepsy, Neuropathic pain, Fibromyalgia and as Anti-anxiety	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer		
Detail of stability batches of drug product	Batch Nos.: 1- TRD-100-001, 2- TRD-100-002, 3- TRD-100-003, Batch Size Each: 2000 Capsules	
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter submitted.	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PHARMACEUTICAL EQUIVALENCE(ATTACHED IN RELEVANT MODULE): Mirica(Misaq) & Gablin(CCL) are similar or comparable to each other in physical/chemical aspects as per BP. 2-COMPARATIVE DISSOLUTION PROFILE(ATTACHED IN RELEVANT MODULE): The dissolution profile of test product is similar to comparator product by more than factor 50% in the acidic medium and no response in the acetate buffer.	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Based on 6 months accelerated stability data and 12 months long term stability data of exhibit batches, retest period of 24 months is assigned.	
The status in reference regulatory authorities	US-FDA	
GMP status of the firm	Our Firm is Newly Licensed.	
Evidence of approval of manufacturing facility	Name: MISAQ PHARMACEUTICALS PVT. LTD. /DML # 000985/ Site Address: 7-B, Woven Garments Zone, Value Addition City, Khurrianwala-Sahianwala Road, Faisalabad-Pakistan.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Justify for not including the Enantiomeric Purity Test, Residue on	Enantiomeric Purity Test Justification for Omission: Enantiomeric purity typically

	Ignition, and Chloride and Sulfate tests in the batch analysis of the drug substance performed by the drug product manufacturer, despite these tests being recommended in the USP monograph of Pregabalin API. Justify how the drug product manufacturer ensures the compliance of drug substance complied USP specification, considering that said tests recommended by the USP have not been performed during the quality analysis of the drug substance by the drug product manufacturer.	controlled and validated by the API manufacturer, using chiral chromatography or equivalent validated methods. 2- Residue on Ignition (ROI): This test is performed and controlled by the API manufacturer, as part of their process validation and batch release testing. Chloride and Sulfate Tests :These are process-related impurities and should be adequately controlled and validated by the API supplier as part of their manufacturing process.
2.	Provide justification for using a 10 µL injection volume instead of the 100 µL recommended by BP in the dissolution test. As per the submitted raw data sheets, the dilution concentrations used for the dissolution test were 0.11% for the sample and 0.28% for the standard, whereas the BP recommends 0.0028% w/v for both. Similarly, for the assay, the concentrations used were 1.8 mg/mL (standard) and 5.84 mg/mL (sample), deviating from the BP-recommended concentration of 1.8 mg/mL for both.	Firm responded that “The deviations from BP-recommended concentrations in the dissolution (0.11% for sample, 0.28% for standard) and assay (5.84 mg/mL for sample vs. 1.8 mg/mL for standard) were necessary to ensure reliable analytical performance. The BP-recommended concentrations gave low absorbance, affecting sensitivity and reproducibility. Therefore, higher concentrations within the validated method range were used to achieve acceptable linearity, accuracy, and precision. The method remains scientifically justified and complies with guidelines, ensuring accurate and valid results. For deviation in injection volume, firm claimed that The dissolution test was performed in 2023 and 2024 following the BP 2023 and 2024 monographs for Pregabalin capsule, which specify an injection volume of 10 µL. Therefore, our method is fully compliant with the BP 2023, 2024 requirements, and no deviation has occurred regarding the injection volume.
3.	you are required to submit the API borrow letter on the official letterhead of the loan-giving company, clearly mentioning the date, reference number of the document, and the batch number/lot number of the API that has been borrowed.	Firm submitted the API loan letter from M/s. Quaper Pharmaceuticals along with clearance certificate of the borrowed API.

Decision

Deferred

Deferred for submission of following:

1. Submit the drug substance analysis report conducted by the drug product manufacturer, including all tests recommended in the relevant USP monograph. If any of the USP-recommended tests were not performed, provide a scientifically sound justification for their omission.
2. Submit the performance report of assay and dissolution tests of drug product conducted in accordance with the BP monograph for Pregabalin Capsules at the next scheduled stability study time

point. The submission should be accompanied by complete raw data sheets and corresponding chromatograms.

362	Case Category	Contract Manufacturing (Saima Hussain)
	Name, address of Applicant.	Winbrains Research Laboratories Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725)
	Application Form Dy. No / Tracking ID & date of submission	(7DV-PAB-N3D5, 2025-04-05)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-26, 2025-02-21
	The proposed proprietary name / brand name	Dypa-M 5mg/850mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Metformin Hydrochloride (USP) 850mg Dapagliflozin as Propanediol Monohydrate.....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 YearStore below 25°C.
	For generic drugs (me-too Status)	DAPLYZA TABLET 5/850mg by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Previous Approval details: Products already Approved on CTD format in 339the meeting of Registration Board for the proposed manufacturing site. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated13th June, 2023, the instant application is being presented for consideration of the Board as an application forcross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adoptthe same source of drug substance, drug product formulation, specifications and container closure and fulfill otherconditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of theDrugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

363	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	(G52-67Z-B7TH, 2025-05-26)
	Detail of Fee Submitted	37000.0, 2025-04-23,
	The proposed proprietary name / brand name	Mirica
	Label Claim	Each Capsule Contains: Pregabalin----- -75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's/10x7's/10x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)15-30 Degree Centigrade
	For generic drugs (me-too Status)	Gablin 75mg Capsule by CCL Pharmaceuticals Pvt. Ltd.-Lahore-Pakistan
	Pharmacotherapeutic Group of (API)	Used in treatment of Epilepsy, Neuropathic pain, Fibromyalgia and as Anti-anxiety
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of batches TRD-75-001 ,TRD-75-002,TRD-75-003 (batch size 2000 capsules) each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has taken loan from M/s. Quaper Pvt. Ltd. and as an evidence submitted the Loan letter.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the comparator product Gablin Capsule 75mg of M/s. Global Pharmaceuticals.
	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	US-FDA
	GMP status of the firm	Our Organization is Newly Licensed.
	Evidence of approval of manufacturing facility	Issuance of License letter dated 26-10-2023 mentioned that firm has capsule(general) section
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Justify for not including the Enantiomeric Purity Test, Residue on Ignition, and Chloride and Sulfate tests in the batch analysis of the drug substance performed by the drug product manufacturer, despite these tests being recommended in the USP monograph of Pregabalin API. Justify how the drug product manufacturer ensures the compliance of drug substance complied USP specification,	Enantiomeric Purity Test Justification for Omission: Enantiomeric purity typically controlled and validated by the API manufacturer, using chiral chromatography or equivalent validated methods. 2- Residue on Ignition (ROI): This test is performed and controlled by the API manufacturer, as part of their process validation and batch release testing. Chloride and Sulfate Tests :These are process-related impurities and should be adequately controlled and validated by

	considering that said tests recommended by the USP have not been performed during the quality analysis of the drug substance by the drug product manufacturer.	the API supplier as part of their manufacturing process.
2.	Provide justification for using a 10 µL injection volume instead of the 100 µL recommended by BP in the dissolution test. As per the submitted raw data sheets, the dilution concentrations used for the dissolution test were 0.11% for the sample and 0.28% for the standard, whereas the BP recommends 0.0028% w/v for both. Similarly, for the assay, the concentrations used were 1.8 mg/mL (standard) and 5.84 mg/mL (sample), deviating from the BP-recommended concentration of 1.8 mg/mL for both.	Firm responded that “The deviations from BP-recommended concentrations in the dissolution (0.11% for sample, 0.28% for standard) and assay (5.84 mg/mL for sample vs. 1.8 mg/mL for standard) were necessary to ensure reliable analytical performance. The BP-recommended concentrations gave low absorbance, affecting sensitivity and reproducibility. Therefore, higher concentrations within the validated method range were used to achieve acceptable linearity, accuracy, and precision. The method remains scientifically justified and complies with guidelines, ensuring accurate and valid results. For deviation in injection volume, firm claimed that The dissolution test was performed in 2023 and 2024 following the BP 2023 and 2024 monographs for Pregabalin capsule, which specify an injection volume of 10 µL. Therefore, our method is fully compliant with the BP 2023, 2024 requirements, and no deviation has occurred regarding the injection volume.
3.	you are required to submit the API borrow letter on the official letterhead of the loan-giving company, clearly mentioning the date, reference number of the document, and the batch number/lot number of the API that has been borrowed.	Firm submitted the API loan letter from M/s. Quaper Pharmaceuticals along with clearance certificate provided by the Loan giver.

Decision

Deferred

Deferred for submission of following:

1. Submit the drug substance analysis report conducted by the drug product manufacturer, including all tests recommended in the relevant USP monograph. If any of the USP-recommended tests were not performed, provide a scientifically sound justification for their omission.
2. Submit the performance report of assay and dissolution tests conducted in accordance with the BP monograph for Pregabalin Capsules at the next scheduled stability study time point. The submission should be accompanied by complete raw data sheets and corresponding chromatograms.

364	Case Category	Contract Manufacturing (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	(H7N-A5R-5JHT, 2025-05-26)
Detail of Fee Submitted	37000.0, 2025-04-23,
The proposed proprietary name / brand name	Mirica
Label Claim	Each Capsule Contains: Pregabalin-----50mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	2x7's/10x10's/3x10's-As per SRO
Shelf Life (Unit)	2 Year(s)15-30 Degree Centigrade
For generic drugs (me-too Status)	Gablin 50mg Capsule by CCL Pharmaceuticals, Lahore-Pakistan
Pharmacotherapeutic Group of (API)	Used in treatment of Epilepsy, Neuropathic pain, Fibromyalgia and as Anti-anxiety
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	Stability data of batches TRD-50-001, TRD-50-002, TRD-50-003 (2000 capsules) each is submitted by the firm
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted API Loan letter.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the comparator product Gablin Capsule 50mg of M/s. Global.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-iv is submitted
The status in reference regulatory authorities	US-FDA
GMP status of the firm	New Lincense
Evidence of approval of manufacturing facility	Issuance of License letter mentioned that firm has capsule (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Justify for not including the Enantiomeric Purity Test, Residue on Ignition, and Chloride and Sulfate tests in the batch analysis of the drug substance performed by the drug product manufacturer, despite these tests being recommended in the USP monograph of Pregabalin API. Justify how the drug product manufacturer ensures the compliance of drug substance complied USP specification, considering that said tests recommended by the USP have not been performed during the quality analysis of the drug substance by the drug product manufacturer.	Enantiomeric Purity Test Justification for Omission: Enantiomeric purity typically controlled and validated by the API manufacturer, using chiral chromatography or equivalent validated methods. 2- Residue on Ignition (ROI): This test is performed and controlled by the API manufacturer, as part of their process validation and batch release testing. Chloride and Sulfate Tests :These are process-related impurities and should be adequately controlled and validated by the API supplier as part of their manufacturing process.
2.	Provide justification for using a 10 µL injection volume instead of the 100 µL recommended by BP in the dissolution	Firm responded that "The deviations from BP-recommended concentrations in the dissolution (0.11% for sample, 0.28% for standard) and assay

	test. As per the submitted raw data sheets, the dilution concentrations used for the dissolution test were 0.11% for the sample and 0.28% for the standard, whereas the BP recommends 0.0028% w/v for both. Similarly, for the assay, the concentrations used were 1.8 mg/mL (standard) and 5.84 mg/mL (sample), deviating from the BP-recommended concentration of 1.8 mg/mL for both.	(5.84 mg/mL for sample vs. 1.8 mg/mL for standard) were necessary to ensure reliable analytical performance. The BP-recommended concentrations gave low absorbance, affecting sensitivity and reproducibility. Therefore, higher concentrations within the validated method range were used to achieve acceptable linearity, accuracy, and precision. The method remains scientifically justified and complies with guidelines, ensuring accurate and valid results. For deviation in injection volume, firm claimed that The dissolution test was performed in 2023 and 2024 following the BP 2023 and 2024 monographs for Pregabalin capsule, which specify an injection volume of 10 µL. Therefore, our method is fully compliant with the BP 2023, 2024 requirements, and no deviation has occurred regarding the injection volume.
3.	you are required to submit the API borrow letter on the official letterhead of the loan-giving company, clearly mentioning the date, reference number of the document, and the batch number/lot number of the API that has been borrowed.	Firm submitted the API loan letter from M/s. Quaper Pharmaceuticals along with clearance certificate.

Decision

Deferred

Deferred for submission of following:

1. Submit the drug substance analysis report conducted by the drug product manufacturer, including all tests recommended in the relevant USP monograph. If any of the USP-recommended tests were not performed, provide a scientifically sound justification for their omission.
2. Submit the performance report f assay and dissolution tests conducted in accordance with the BP monograph for Pregabalin Capsules at the next scheduled stability study time point. The submission should be accompanied by complete raw data sheets and corresponding chromatograms.

365	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
	Application Form Dy. No / Tracking ID & date of submission	(UZH-9SM-L1VX, 2025-02-17)
	Detail of Fee Submitted	300000.0, 2025-01-17,
	The proposed proprietary name / brand name	GUFISOME
	Label Claim	Each vial contains: Amphotericin B 50mg Excipients (Intercalated in to Liposomal membrane).....q.s
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	1's (Vial)-As per SRO
Shelf Life (Unit)	24 Year(s)Store below 25°C. Do not freeze. Protect from light and moisture.
For generic drugs (me-too Status)	Anfotericina FADA 50mg Injection Manufactured by: Medinet Pharmaceuticals, Pakistan
Pharmacotherapeutic Group of (API)	Antimycotics
Name, address of Manufacturing site:	Gufic Biosciences Limited -National Highway No. 8, Near Grid, Kabilpore, Navsari - 396424, Gujarat, INDIA-India
Name & address of API manufacturer	North China Pharmaceutical Huasheng Co., Ltd. No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei, China.
Detail of stability batches of drug product	stability data submitted
Documents for the procurement of API with approval from DRAP (in case of Import)	NA
Pharmaceutical Equivalence and Comparative Dissolution Profile	.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
The status in reference regulatory authorities	AmBisome 50mg Manufactured by: Gilead Sciences Inc.,San Dimas. Marketed by: Astellas Pharma., USFDA Approved
GMP status of the firm	Firm submit the scanned copy of CoPP which was valid till 15-09-2024. GMP certificate of Manufacturer Abroad M/s. Gufic Biosciences Ltd. Unit no.2 Survey no.171 Gujarat State India is submitted which is valid till 15-09-2027.
Evidence of approval of manufacturing facility	GMP certificate of Manufacturer Abroad dated 17-10-2024 is submitted in which it is mentioned that firm has Parenteral SVP.
Evaluation Remarks	
Firm in their reply submitted a declaration letter from the Manufacturer i.e. M/s. Gufic Bioscience in which they stated that “We have developed our product Gufisome (Liposomal Amphotericin -B Injection) similar to reference product Ambisome. Our product is qualitatively and quantitatively similar to Ambisome. We have proposed particle size specification of NLT 75 nm to NMT150 nm. Our specification of Particle size is proposed based on our own product nature as well RLD results and literature reference. Published literature entitled as "Comparison of the Physicochemical, Antifungal, and Toxic Properties of Two Liposomal Amphotericin B Products, Antimicrobial agents and chemotherapy, Jan. 2008, p. 259-268" confirms that minimum particle size of Ambisome is reported as 77.8±2.2 nm. This confirms that Ambisome lower particle size reported below 100 nm. Also, we have performed testing of Ambisome from Various markets (EU, South Africa and USA) which confirms Ambisome particle size reported up to 122.4 nm (above 100 nm) “. Our product liposomal Amphotericin-B Injection is approved in India, Ecuador and Sri Lanka and it is under review with South African Health Products Regulatory Authority (SAPHRA). We have submitted similar specification in all these authorities. Hence we confirm that our proposed specification of particle size is holds good for our product Liposomal AmphotericinB Injection 50 mg (Gufisome). However, the reference literature which the manufacturer referred clearly mentioned that The median particle size was 77.8 nm for AmBisome and 111.5 nm for comparative product Anfogen. Further, concluded that, the efficacy and toxicity of these two liposomal amphotericin B products were significantly different, and thus, the products were not comparable.	

	Decision	
	Deferred	
	The case is deferred for confirmation of export of the same product from the same manufacturing site to any country of a stringent regulatory authority or to a country whose regulatory agency is included in the approved list of RRAs.	
366	Case Category	Routine (Saima Hussain)
	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	(Z69-GPR-89X7, 2024-03-18)
	Detail of Fee Submitted	30000.0, 2023-08-29,
	The proposed proprietary name / brand name	Contimycin -IR 100mg Capsule
	Label Claim	Each Capsule contains: Doxycycline Hyclate (U.S.P.) equivalent to Doxycycline.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x10's, 5 x10's, 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 °C
	For generic drugs (me-too Status)	Vibramycin 100mg Capsule (Pfizer Pakistan Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	Tetracycline Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Changzhou Pharmaceutical Factory
	Detail of stability batches of drug product	Stability data of batches (21PD-117,21PD-123,21PD-124)2000 capsule each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has performed against the innovator product vibramycin capsule 100mg
	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	Vibramycin Hyclate 100mg Capsule (Pfizer Labs New York)
	GMP status of the firm	GMP certificate dated 16-11-2022 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 16-11-2022 mentioned that firm has capsule (general) section.
	Evaluation Remarks	
	Firm in their response submitted the revised assay method along verification report as per the USP monograph of Doxycycline Hyclate. Further, for the performance of ethanol content test firm stated that, We would like to bring to your attention that our facility is currently being equipped with Gas Chromatography (GC) for ethanol content testing prior to product commercialization. Although we've completed the Installation Qualification (IQ) of the GC, the Operational Qualification (OQ) and Performance Qualification (PQ) are still in progress and will take some time to complete. In the meantime, we have received the ethanol content test results from the drug substance manufacturer,	

which show a result of 5.0%. This meets the USP specification of 4.3-5.5%. As an evidence firm submit the purchase record and IQ reports.

Decision

Approved

The registration letter will be issued upon submission of the drug substance batch analysis report from the drug product manufacturer, including ethanol content test results, performed in accordance with the USP monograph.

367	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	The Searle Company Limited 32-KM Multan Road, Lahore (000647)
	Application Form Dy. No / Tracking ID & date of submission	(BL8-ZUH-LPE1, 2024-03-12)
	Detail of Fee Submitted	75000.0, 2024-01-04,
	The proposed proprietary name / brand name	BILFAXIN 2.5mg/ml Oral Solution
	Label Claim	Each mL contains: Bilastine.....2.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	Not applicable
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lee Pharma Limited Address: Survey No. 10/G-1, Gaddapotharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana State - 502319, INDIA.
	Detail of stability batches of drug product	Stability data of batches (T001,T002,T003) 6 litre each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice along with Form-6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies has been performed against reference product Ilaxtinn syrup 2.5mg/ml manufactured at A. Menarini Farmaceutica
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data as per zone-IV conditions are submitted
	The status in reference regulatory authorities	Approved by Health Canada with brand name of: BLEXTEN® 2.5mg/ml Oral Solution by Aralez Pharmaceutic
	GMP status of the firm	GMP Certificate dated 27-04-2021 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP Certificate dated 27-04-2021 confirms that firm has oral liquid section.

Evaluation Remarks

Registration Board in its 352nd meeting decided as under: Deferred to change the pH limit between 3.0 to 4.0 in the shelf life specification of drug product, as the innovator's SmPC clearly states that the pH of Ilaxten oral solution is maintained within this range. Submit the performance report of the pH test at

the next scheduled stability time point. Firm in their reply stated that This is to clarify that the stability studies for the said product have already been completed. Therefore, no additional stability time points are available for the implementation of the revised pH limits (3.0-4.0) on the trial batches. Accordingly, we hereby undertake and commit that the innovator's approved pH specification of 3.0-4.0 shall be strictly adhered to for all commercial-scale batches manufactured after registration of the product. Further, the shelf-life stability studies have been completed, and all results obtained are within the specified pH range of 3.0-4.0, in compliance with the innovator's specifications as per suggestion. All results conform to the innovator specifications. For your reference stability summary data and revised specifications are attached.

Decision

Deferred

The case has been deferred for submission of complete stability data of the drug product up to the claimed shelf life, for confirmation that the obtained pH values at each stability time point are within the revised specified limits.

368	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, and the complete study report should be submitted.	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 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.
Decision		
Deferred		
Deferred 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).		
369	Case Category	Routine (Saima Hussain)

Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)	
Application Form Dy. No / Tracking ID & date of submission	(URA-JDJ-3ZRU, 2024-06-05)	
Detail of Fee Submitted	75000.0, 2024-04-17,	
The proposed proprietary name / brand name	Peramol 500mg Tablet	
Label Claim	Each Film Coated tablet contains: Paracetamol..... 500mg	
Reference to Finished product specifications	British Pharmacopeia	
Proposed Pack Size	2x7's, 4x7s, 1 x 10'-As per SRO	
Shelf Life (Unit)	2 Year(s)Store in cool and dry place below 30 celcius	
For generic drugs (me-too Status)	N.A	
Pharmacotherapeutic Group of (API)	Analgesic and antipyretic	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Carryfor Pharmaceuticals (Pvt) Limited Address Plot. #: E-81, North Western industrial Zone. Port Qasim, Karachi	
Detail of stability batches of drug product	Stability data of batches TPY001,TPY002,TPY003 of batch sizes 2500 tablets are submitted.	
Documents for the procurement of API with approval from DRAP (in case of Import)	API procured from local API Manufacturer i.e. M/s. Carryfor Pharmaceuticals pvt. ltd. Karachi	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been performed against the reference product paracetamol Advance tablet of M/s. Haleon	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	stability data as per zone-iv is submitted.	
The status in reference regulatory authorities	Paracetamol 500 mg Film-coated Tablets M/s Balkanpharma – Dupnitsa AD 3, Samokovsko Shosse Str., 2600 Dupnitsa Bulgaria (HPRA Approved)	
GMP status of the firm		
Evidence of approval of manufacturing facility	Firm submitted the GMP certificate dated 14-11-2023 in which mentioned that firm has tablet (general section.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Provide complete details of the comparator (reference) product against which pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies were performed. Submit your response along with a photograph/snapshot of the actual reference product used for comparison with the tested product.	Comparator (reference) product against which pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies are as follows Product Name: Panadol Advance 500mg Tablet Marketing Authorization Holder: Glaxosmithkine Consumer Healthcare (Ireland) Limited, Dublin, Ireland Manufacturer: Glaxosmithkine Dugarvan Ltd., Co., WaterFord, Ireland Lot # 6V9J Mfg. March 2023 Exp. Feb 2025 S/N 7318580934857 While the Snap are Attached.

2.	Justify the use of UV spectrophotometry for performing dissolution and assay tests, whereas the BP monograph for Paracetamol Tablets recommends the use of HPLC for both tests.	The dissolution and assay testing were performed by UV spectrophotometry in accordance with the BP monograph applicable at the time of batch manufacture in 2023, which permitted the use of UV methods. Previous Monograph is Attached (See Attachment). The BP 2025 monograph, which revises the method to HPLC, represents a prospective update and does not apply retrospectively. The updated HPLC method will be implemented for future batches as per BP 2025 through change control.
3.	Submit the Batch Manufacturing Records (BMRs) of three trial batches for review.	Submitted

Decision

Approved

Firm shall submit requisite fee for pre-registration variation as per the revised fee SRO, prior the issuance of the Registration letter.

370	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 Heng kang 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

Sr. no	Shortcomings	Response of the Firm
1.	Justify the application of BP specifications to the finished product, given that the procured API complies with USP specifications.	Mesalazine Prolong Release Tablet is not available in USP Monograph. furthermore, the API complies with USP specifications, the finished product has been developed and validated using BP specifications to maintain consistency with the analytical procedures and acceptance criteria established during product development. Both the API (USP-compliant) and the finished product (BP-compliant) meet internationally recognized compendial standards, ensuring the product's safety, efficacy, and quality remain uncompromised. Therefore, the application of BP specifications to the finished product does not impact product quality, safety, or efficacy.
2.	Justify the procedure adopted for performing system suitability during the assay verification of the drug substance, considering that the USP monograph specifies the requirement to confirm the resolution between 4-aminosalicylic acid and mesalamine, which should be not less than (NLT) 2.0.	We have updated our protocol as per the requirement. Revised protocol attached as Annex-I
3.	Justify for not including the LOD test while the quality analysis of drug substance by the drug product manufacturer	LOD test is already included in API COA & Specification. We hereby again submitted the COA & Specification as Annex-II
4.	Provide evidence of the reference product confirming that the approved formulation is	During the development of Mesalazine 1 g tablets, a thorough review of the reference product information and supporting documents was conducted. No details regarding film coating were identified, and all listed excipients corresponded to core tablet components only. The absence of any coating-related excipients confirms that the reference product is an uncoated tablet formulation.

	classified as an uncoated product.	https://assets.hpra.ie/products/Human/23804/Licence_PA1009-006-007_21032025100650.pdf https://cima.aemps.es/cima/dochtml/ft/77022/FT_77022.html
5.	Provide the reference which has been used for setting the condition and acceptance criteria of dissolution test.	The dissolution test for Mesalamine Prolonged-Release 1 g Tablets has been developed in accordance with the British Pharmacopoeia (BP) monograph for Mesalazine Prolonged-Release Tablets, which states that “a suitable dissolution test is carried out to demonstrate the appropriate release of Mesalazine.” In line with this guidance, the dissolution conditions were selected based on the FDA Dissolution Database to ensure appropriate and scientifically justified testing parameters. Regarding the acceptance criteria, reference was made to the innovator product data, which indicates that the formulation provides drug release over a period of approximately 12 hours, corresponding to the elimination profile from systemic circulation. Therefore, a 12-hour prolonged-release dissolution specification has been established to reflect and simulate the in vivo release characteristics of the innovator product. BP Monograph is Attached.
6.	Later, firm claimed that As there is no specific dissolution method officially available in BP Monograph, reference was taken from the FDA Dissolution Database method for Mesalamine 1.2 g Delayed-Release Tablets, applying the same apparatus, rotation speed, dissolution medium, and temperature conditions to ensure relevance and alignment with existing regulatory expectations. Reference is attached. On the basis of their reference product which clearly indicates that the maximum drug release is achieved at approximately 6 hours, as the dissolution sampling is performed up to 8 hours. This is also confirmed from the innovator’s Pentasa	Firm replied that The optimized QC release points at 1, 4, 8 and 12 hours provide adequate control of early, mid and terminal release phases. Comparative dissolution profiling demonstrates a gradual release pattern comparable to the reference product. Hence, continued release up to 12 hours is consistent with the intended prolonged-release design of mesalazine formulations. However, the USFDA dissolution guideline for extended-release dosage form clearly stated that A minimum of three time points is recommended to set the specifications. These time points should cover the early, middle, and late stages of the dissolution profile. The last time point should be the time point where at least 80% of drug has dissolved. If the maximum amount dissolved is less than 80%, the last time point should be the time when the plateau of the dissolution profile has been reached.

	® 1.2 g delayed-release tablet literature, which specifies the recommended dissolution conditions and acceptance criteria as follows: USP Apparatus II at 100 rpm, using pH 1.0 HCl buffer for 2 hours, followed by pH 6.4 phosphate buffer for 1 hour, and pH 7.2 phosphate buffer with sampling at 1, 2, and 6 hours. So justify the adopted limit till 12 hours.	
7.	Justify, how the assay method adopted by you is valid without including the system suitability parameter in the analytical procedure.	We mistakenly overlooked the test therefore; we have revised our specification as per monograph. Updated Specification along with Deposited challan of Rs. 9,400/- having no. 7449006352 dated 12-11-2025 Attached
8.	Submit valid GMP certificate of API manufacturer issued by the authorized issuing authority.	Valid GMP Certificate attached.
Decision		
Deferred		
The case has been deferred for submission of references or method development studies to justify the acceptance limits adopted for the dissolution test of the applied product, as the submitted USFDA reference of mesalamine delayed-release tablets is not acceptable. Furthermore, the supporting justification should comply with the dissolution general chapter of the pharmacopeia and applicable international guidelines.		
371	Case Category	New Section (Saima Hussain)
	Name, address of Applicant.	Bio-Labs(Pvt) Ltd Plot 145, Industrial Triangle, Kahuta Road (000296)
	Application Form Dy. No / Tracking ID & date of submission	(SH4-3W7-XGSP, 2024-10-22)
	Detail of Fee Submitted	30000.0, 7000.0 2024-03-01, 2024-10-16
	The proposed proprietary name / brand name	Miniox Topical Solution 2% (w/v)
	Label Claim	Each ml contain: Minoxidil ... 20mg

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)	Minoxylotion 2% of M/s Danas Pharmaceuticals (Pvt) Ltd.
Pharmaceutical Group of (API)	D11AX01, Other dermatologicals
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Kumar Organic Products Limited, India.
Detail of stability batches of drug product	03 Batches, 150 Bottles each
Documents for the procurement of API with approval from DRAP (in case of Import)	Copy of I&E Clearance Certificate for Import of 100Kgs API by MaxiTech Pharma, Karachi has been enclosed. No information on Loan of API has been submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been conducted against Minoxin Lotion of M/s Brookes Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer
The status in reference regulatory authorities	ROGAINE (FOR MEN / WOMEN) Topical Solution 2%, USFDA approved (Over the counter)
GMP status of the firm	Not provided
Evidence of approval of manufacturing facility	Copy of Section approval letter from Licensing Division for Lotion (General) Section has been submitted.

Evaluation Remarks

Case was deferred in 348th meeting Registration Board and details are as under:

On July 2, 2025, in the Committee Room at DRAP Islamabad, Mr. Hafiz Tariq Khalil - Head of R&D and Ms. Darakhshan - Head of Regulatory from M/s Bio-Labs (Pvt.) Ltd., accompanied by Ms. Nazia Tauseef – Regulatory Affairs from M/s Maxitech Pharma (Pvt.) Ltd., appeared before the Registration Board. Ms. Darakhshan from M/s Bio-Labs (Pvt.) Ltd., explained that the intimation of loan / invoice submitted to DRAP on 02-08-2023 was an administrative oversight and offered a formal apology and reaffirmed commitment to strict compliance with DRAP regulations going forward. Meanwhile, Ms. Nazia Tauseef from M/s Maxitech Pharma (Pvt.) Ltd., confirmed that there was no transaction involved and the API was provided to M/s Bio-Labs (Pvt.) Ltd., on Loan basis and submitted the corresponding loan agreement. The Board accepted M/s Bio-Labs (Pvt.) Ltd.'s apology for the administrative oversight and decided to issue Warning to M/s Bio-Labs (Pvt.) Ltd., for strict adherence to DRAP procedures. Case was deferred for further deliberation.

Decision

Approved

372	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(6Q6-PRY-S9PA, 2024-10-30)
	Detail of Fee Submitted	75000.0, 2024-10-25,
	The proposed proprietary name / brand name	Gepone 18.2mg tablet

Label Claim	Each extended-release tablet contains;20 mg of Gepirone hydrochloride equivalent to 18.2 mg of Gepirone.(Innovator’s Specifications)	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	As per SRO-As per SRO	
Shelf Life (Unit)	24 Month(s)Store below 30°C in Cool & Dry Place.	
For generic drugs (me-too Status)	N/A	
Pharmacotherapeutic Group of (API)	It is indicated for the treatment of major depressive disorder (MDD) in adults: N06AX19	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Gansu Hoatin Pharmatech Co., Ltd.	
Detail of stability batches of drug product	2 batches of 5000 units each	
Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued by DRAP I&E office	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hamaz: PE & CDP submitted against refernce product Exxua tablet	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions	
The status in reference regulatory authorities	Registered drug by US FDA as EXXUA (Gepirone as HCl 18.2mg extended-release tablets), for ORAL Use.	
GMP status of the firm	Hamaz: GMP certificate issued dated 25-05-2021	
Evidence of approval of manufacturing facility	Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section	
Evaluation Remarks		
Registration Board in its 345th meeting decided as under: The Registration Board has decided to defer the case for the submission of evidence of approval of applied formulation in the approved reference regulatory agencies other than USFDA ,since it has been declared as discontinued by USFDA. Firm in their reply informed that the marketing status of applied formulation on USFDA website has changed to prescription.		
Sr.no.	Observations	Response of the Firm
1.	According to the innovator literature, the drug substance exists in two polymorphic forms. Please provide clarification regarding which polymorphic form is supplied by the API manufacturer. In addition, while the innovator literature reports identification and testing for the presence and absence of polymorphic forms, no such tests have been reported by the API manufacturer for confirmation or identification of the polymorphic form. Please justify this discrepancy and submit appropriate supporting data, if available.	Firm submitted that, “With reference to the observation on polymorphism, we hereby confirm that the API manufacturer supplies Gepirone Hydrochloride exclusively in Polymorphic Form I. The polymorphic form is consistently obtained through a well-controlled manufacturing and crystallization process; therefore, routine polymorphic testing is not included in the release specifications. Relevant supporting documents have been enclosed for reference”.
2.	Furthermore, the innovator literature indicates that the melting point of the drug substance is approximately 180 °C, whereas the Drug Master File (DMF) of the API specifies a melting point range of 192.5–195.5 °C. Please clarify this	Firm informed that, The Drug Substance provided by API Manufacturer also exhibit 180 °C melting point which is for polymorphic I and used by firm for product development. Melting point

	significant difference in melting point values, including its possible relation to polymorphic form, analytical method, or specification differences.	range provided in dossier is taken from google literature data which is for Polymorphic form II. Relevant document confirming the melting point has been attached here.
3.	Correlate the solubility characteristics described in the drug substance section with those reported for the innovator product, and provide scientific justification for any observed differences.	Firm replied that Solubility characteristics described in the drug substance section with those reported for the innovator product are the same. There is no difference in this characteristic. Innovator Literature Review by FDA has been attached here.
4.	Submit the Certificate of Analysis (CoA) of the reference or working standard that was actually used for the analysis of the drug substance.	Submitted
5.	Since only three-month stability data for the drug product have been submitted, Provide updated stability data.	Submitted

Decision

Approved

Approved with the following box warning mentioned on the label of innovator product approved in USFDA:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full

prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors (5.1). EXXUA is not

approved for use in pediatric patients (8.4).

373	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(AW8-Z4U-WYW6, 2024-10-30)
	Detail of Fee Submitted	75000.0, 2024-10-25,
	The proposed proprietary name / brand name	Gepone 54.5mg tablet
	Label Claim	Each extended-release tablet contains;60 mg of Gepirone hydrochloride equivalent to 54.5 mg of Gepirone.(Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)		gepirone is It is indicated for the treatment of major depressive disorder (MDD) in adults
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
Detail of stability batches of drug product		2 batches of 5000 units each
Documents for the procurement of API with approval from DRAP (in case of Import)		Clearance certificate issued by DRAP I&E office
Pharmaceutical Equivalence and Comparative Dissolution Profile		Hamaz: PE & CDP submitted against refernce product Exxua tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Submitted as per Zone IV conditions
The status in reference regulatory authorities		Registered drug by US FDA as EXXUA (Gepirone as HCl 54.5mg extended-release tablets), for ORAL Use.
GMP status of the firm		Hamaz: GMP certificate issued dated 25-05-2021
Evidence of approval of manufacturing facility		Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks		
Sr.no.	Observations	Response of the Firm
1.	According to the innovator literature, the drug substance exists in two polymorphic forms. Please provide clarification regarding which polymorphic form is supplied by the API manufacturer. In addition, while the innovator literature reports identification and testing for the presence and absence of polymorphic forms, no such tests have been reported by the API manufacturer for confirmation or identification of the polymorphic form. Please justify this discrepancy and submit appropriate supporting data, if available.	Firm submitted that, “With reference to the observation on polymorphism, we hereby confirm that the API manufacturer supplies Gepirone Hydrochloride exclusively in Polymorphic Form I. The polymorphic form is consistently obtained through a well-controlled manufacturing and crystallization process; therefore, routine polymorphic testing is not included in the release specifications. Relevant supporting documents have been enclosed for reference”.
2.	Furthermore, the innovator literature indicates that the melting point of the drug substance is approximately 180 °C, whereas the Drug Master File (DMF) of the API specifies a melting point range of 192.5–195.5 °C. Please clarify this significant difference in melting point values, including its possible relation to polymorphic form, analytical method, or specification differences.	Firm informed that, The Drug Substance provided by API Manufacturer also exhibit 180 °C melting point which is for polymorphic I and used by firm for product development. Melting point range provided in dossier is taken from google literature data which is for Polymorphic form II. Relevant document confirming the melting point has been attached here.
3.	Correlate the solubility characteristics described in the drug substance section with those reported for the innovator product, and provide scientific justification for any observed differences.	Firm replied that Solubility characteristics described in the drug substance section with those reported for the innovator product are the same. There is no difference in this

		characteristic. Innovator Literature Review by FDA has been attached here.
4.	Submit the Certificate of Analysis (CoA) of the reference or working standard that was actually used for the analysis of the drug substance.	Submitted
5.	Since only three-month stability data for the drug product have been submitted, Provide updated stability data.	Submitted

Decision

Approved

Approved with the following box warning as mentioned on the label of innovator product approved in USFDA:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors (5.1). EXXUA is not

approved for use in pediatric patients (8.4).

374	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(B6H-REQ-UVRH, 2024-10-30)
	Detail of Fee Submitted	75000.0, 2024-10-25,
	The proposed proprietary name / brand name	Gepone 36.3mg tablet
	Label Claim	Each extended-release tablet contains;40 mg of Gepirone hydrochloride equivalent to 36.3 mg of Gepirone.(Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	gepirone is It is indicated for the treatment of major depressive disorder (MDD) in adults
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
	Detail of stability batches of drug product	2 batches of 5000 units each
	Documents for the procurement of API with approval from DRAP	Clearance certificate issued by DRAP I&E office

(in case of Import)		
Pharmaceutical Equivalence and Comparative Dissolution Profile		Hamaz: PE & CDP submitted against reference product Exxua tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Submitted as per Zone IV conditions
The status in reference regulatory authorities		Registered drug by US FDA as EXXUA (Gepirone as HCl 36.3mg extended-release tablets), for ORAL Use.
GMP status of the firm		Hamaz: GMP certificate issued dated 25-05-2021
Evidence of approval of manufacturing facility		Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks		
The application is complete as per codal formalities for consideration by the Registration Board Registration Board in its 345th meeting decided as under: The Registration Board has decided to defer the case for the submission of evidence of approval of applied formulation in the approved reference regulatory agencies other than USFDA ,since it has been declared as discontinued by USFDA. Firm in their reply informed that the marketing status of applied formulation on USFDA website has changed to prescription.		
Sr.no.	Observations	Response of the Firm
1.	According to the innovator literature, the drug substance exists in two polymorphic forms. Please provide clarification regarding which polymorphic form is supplied by the API manufacturer. In addition, while the innovator literature reports identification and testing for the presence and absence of polymorphic forms, no such tests have been reported by the API manufacturer for confirmation or identification of the polymorphic form. Please justify this discrepancy and submit appropriate supporting data, if available.	Firm submitted that, “With reference to the observation on polymorphism, we hereby confirm that the API manufacturer supplies Gepirone Hydrochloride exclusively in Polymorphic Form I. The polymorphic form is consistently obtained through a well-controlled manufacturing and crystallization process; therefore, routine polymorphic testing is not included in the release specifications. Relevant supporting documents have been enclosed for reference”.
2.	Furthermore, the innovator literature indicates that the melting point of the drug substance is approximately 180 °C, whereas the Drug Master File (DMF) of the API specifies a melting point range of 192.5–195.5 °C. Please clarify this significant difference in melting point values, including its possible relation to polymorphic form, analytical method, or specification differences.	Firm informed that, The Drug Substance provided by API Manufacturer also exhibit 180 °C melting point which is for polymorphic I and used by firm for product development. Melting point range provided in dossier is taken from google literature data which is for Polymorphic form II. Relevant document confirming the melting point has been attached here.
3.	Correlate the solubility characteristics described in the drug substance section with those reported for the innovator product, and provide scientific justification for any observed differences.	Firm replied that Solubility characteristics described in the drug substance section with those reported for the innovator product are the same. There is no difference in this characteristic. Innovator Literature Review by FDA has been attached here.
4.	Submit the Certificate of Analysis (CoA) of the reference or working standard that was actually used for the analysis of the drug substance.	Submitted

5.	Since only three-month stability data for the drug product have been submitted, Provide updated stability data.	Submitted

Decision

Approved

Approved with the following box warning as mentioned on the label of innovator product approved in USFDA:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors (5.1). EXXUA is not

approved for use in pediatric patients (8.4).

375	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(P7P-T4N-YBMW, 2024-10-30)
	Detail of Fee Submitted	75000.0, 2024-10-25,
	The proposed proprietary name / brand name	Gepone 72.6mg tablet
	Label Claim	Each extended-release tablet contains;80 mg of Gepirone hydrochloride equivalent to 72.6 mg of Gepirone.(Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	gepirone is It is indicated for the treatment of major depressive disorder (MDD) in adults
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Hoatin Pharmatech Co., Ltd. Address: No. 11, Chongqing Road, small & medium sized enterprise business base baiyin gansu P.R, China.
	Detail of stability batches of drug product	2 batches of 5000 units each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate issued by DRAP I&E office
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hamaz: PE & CDP submitted against refernce product Exxua tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions

The status in reference regulatory authorities		Registered drug by US FDA as EXXUA (Gepirone as HCl 72.6mg extended-release tablets), for ORAL Use.
GMP status of the firm		Hamaz: GMP certificate issued dated 25-05-2021
Evidence of approval of manufacturing facility		Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks		
The application is complete as per codal formalities for consideration by the Registration Board Registration Board in its 345th meeting decided as under: The Registration Board has decided to defer the case for the submission of evidence of approval of applied formulation in the approved reference regulatory agencies other than USFDA, since it has been declared as discontinued by USFDA. Firm in their reply informed that the marketing status of applied formulation on USFDA website has changed to prescription.		
Sr.no.	Observations	Response of the Firm
1.	According to the innovator literature, the drug substance exists in two polymorphic forms. Please provide clarification regarding which polymorphic form is supplied by the API manufacturer. In addition, while the innovator literature reports identification and testing for the presence and absence of polymorphic forms, no such tests have been reported by the API manufacturer for confirmation or identification of the polymorphic form. Please justify this discrepancy and submit appropriate supporting data, if available.	Firm submitted that, "With reference to the observation on polymorphism, we hereby confirm that the API manufacturer supplies Gepirone Hydrochloride exclusively in Polymorphic Form I. The polymorphic form is consistently obtained through a well-controlled manufacturing and crystallization process; therefore, routine polymorphic testing is not included in the release specifications. Relevant supporting documents have been enclosed for reference".
2.	Furthermore, the innovator literature indicates that the melting point of the drug substance is approximately 180 °C, whereas the Drug Master File (DMF) of the API specifies a melting point range of 192.5–195.5 °C. Please clarify this significant difference in melting point values, including its possible relation to polymorphic form, analytical method, or specification differences.	Firm informed that, The Drug Substance provided by API Manufacturer also exhibit 180 °C melting point which is for polymorphic I and used by firm for product development. Melting point range provided in dossier is taken from google literature data which is for Polymorphic form II. Relevant document confirming the melting point has been attached here.
3.	Correlate the solubility characteristics described in the drug substance section with those reported for the innovator product, and provide scientific justification for any observed differences.	Firm replied that Solubility characteristics described in the drug substance section with those reported for the innovator product are the same. There is no difference in this characteristic. Innovator Literature Review by FDA has been attached here.
4.	Submit the Certificate of Analysis (CoA) of the reference or working standard that was actually used for the analysis of the drug substance.	Submitted
5.	Since only three-month stability data for the drug product have been submitted, Provide updated stability data.	Submitted
Decision		

Approved

Approved with the following box warning as mentioned on the label of innovator product approved in USFDA:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors (5.1). EXXUA is not

approved for use in pediatric patients (8.4).

376	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(NU3-Z35-WV6H, 2024-03-19)
	Detail of Fee Submitted	30000.0, 45000.0 2024-01-26, 2024-02-27
	The proposed proprietary name / brand name	Noxamit 100mg DR Tablet
	Label Claim	Each Delayed-Release Tablet contains: Posaconazole.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's,2x10's,2x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Posaconazole belongs to a class of drugs Azole antifungals that inhibits the enzyme lanosterol 14 α -demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of batches TCG001 TCG002 TCG003 (2500 tablet each) is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted by the Firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the comparator product posaconazole 100mg DR 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	Posaconazole 100mg DR Tablet by M/S Merck Sharp & Dohme LLC (118446553),(USFDA Approved)
	GMP status of the firm	GMP Certificate dated 20-04-2023 is submitted by the firm.

	Evidence of approval of manufacturing facility	GMP certificate dated 20-04-2023 mentioned that firm has tablet (general) section.
	Evaluation Remarks	
	Firm in response of minutes of 348th meeting stated that The use of Chiral HPLC for the assay test is generally recommended due to the presence of four chiral centers and potential polymorphism in the drug substance. It is noted, however, that the polymorphic form I of the drug substance has been thoroughly characterized by the manufacturer using a comprehensive suite of advanced analytical techniques, including elemental analysis, infrared (IR) spectroscopy, ultraviolet (UV) spectroscopy, nuclear magnetic resonance (NMR), high-resolution mass spectrometry (HRMS), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), X-ray powder diffraction (XRPD), specific rotation, and single-crystal X-ray diffraction. These studies have conclusively confirmed the structural identity of the drug substance as polymorphic form I, as detailed in section 3.2.S.3.1. Given this extensive characterization, routine assay analysis has been performed using conventional methods. Additionally, the determination of specific optical rotation in the drug substance specifications serves as a further confirmation of the structural integrity and stereochemical identity of the compound by the Drug substance manufacturer in the section 3.2.S.3.1 Characterization.	
	Decision	
	Approved	
377	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(WTQ-MX1-BB52, 2024-03-19)
	Detail of Fee Submitted	30000.0, 45000.0 2024-01-26, 2024-02-27
	The proposed proprietary name / brand name	Noxamit 40mg/ml oral suspension
	Label Claim	Each ml of oral suspension contains: Posaconazole.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x60ml, 1x90ml, 1x10-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Posaconazole belongs to a class of drugs Azole antifungals that inhibits the enzyme lanosterol 14 α -demethylase (CYP51), which catalyses an essential step in ergosterol biosynthesis.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Stability data of batches TCN001 TCN002 TCN003 4.5 liters each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the comparator product posaconazole 200mg/5ml oral suspension
	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	Posaconazole 40mg/ml oral suspension by Thornton & Ross Ltd. (trading as STADA)Linthwaite,Huddersfie
GMP status of the firm	GMP Certificate dated 20-04-2023 is submitted by the firm.
Evidence of approval of manufacturing facility	Issuance of DML letter dated 7th February,2014 mentioned that firm has tablet (general) section.

Evaluation Remarks

Firm in their response of decision of 348th meeting stated that, "the use of Chiral HPLC for the assay test is generally recommended due to the presence of four chiral centers and potential polymorphism in the drug substance. It is noted, however, that the polymorphic form I of the drug substance has been thoroughly characterized by the manufacturer using a comprehensive suite of advanced analytical techniques, including elemental analysis, infrared (IR) spectroscopy, ultraviolet (UV) spectroscopy, nuclear magnetic resonance (NMR), high-resolution mass spectrometry (HRMS), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), X-ray powder diffraction (XRPD), specific rotation, and single-crystal X-ray diffraction. These studies have conclusively confirmed the structural identity of the drug substance as polymorphic form I, as detailed in section 3.2.S.3.1. Given this extensive characterization, routine assay analysis has been performed using conventional methods. Additionally, the determination of specific optical rotation in the drug substance specifications serves as a further confirmation of the structural integrity and stereochemical identity of the compound by the Drug substance manufacturer in the section 3.2.S.3.1 Characterization.

Decision

Approved

378	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(H3E-R8A-7293, 2024-06-07)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	Trelamit 50mg Tablet
	Label Claim	Each Film Coated Tablet contains: Trelagliptin as Trelagliptin succinate.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1 X 10's, 2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool and dry Place below 30 celsius
	For generic drugs (me-too Status)	Trelaget 50mg Tablet M/s Getz Pharma Pakistan (Pvt) LTD
	Pharmacotherapeutic Group of (API)	Trelagliptin is a dipeptidyl peptidase-4 inhibitor indicated in the control of diabetes mellitus.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd. Address No. 21 Huancheng West Road Anqing Anhui 246000 China
	Detail of stability batches of drug product	Stability data of batches TGY001, TGY002, TGY003 (1500 tablets each)

Documents for the procurement of API with approval from DRAP (in case of Import)		Form-6 is submitted by the firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP have performed against the Comparator drug Product Zafatek Tablets 50 mg (Trelagliptin)
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		Zafatek Tablets 50 mg M/s Takeda Pharmaceutical Company Limited (PMDA approved)
GMP status of the firm		
Evidence of approval of manufacturing facility		GMP certificate dated 14-11-2023 mentioned that firm has tablet (general) section
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	According to USP General Chapter <1092> (USP, 1 Dec 2020), before dissolution method development can begin, it is essential to characterize the drug substance in order to appropriately select the dissolution medium, volume of medium, filter, and apparatus for evaluating the performance of the dosage form. In light of this guidance, please provide a scientific rationale for the selection of the dissolution medium, apparatus, and test conditions, based on the physical and chemical characterization of the drug substance. Provide documented evidence from the reference product in support of your reply.	Firm replied that Trelagliptin (as succinate) is a crystalline, low-dose DPP-4 inhibitor intended for immediate-release oral administration. Physicochemical characterization indicates that trelagliptin exhibits pH-dependent solubility, with higher solubility in acidic media and adequate chemical stability under acidic aqueous conditions. Based on solubility screening, 0.1 N hydrochloric acid (pH ~1.2) provides rapid and complete dissolution of the drug substance while maintaining sink conditions in a 900 mL medium volume, as recommended in USP <1092>. The selected medium is physiologically relevant, representing gastric conditions, and does not require the addition of surfactants, thereby preserving the discriminatory capability of the dissolution test. USP Apparatus 2 (paddle) was selected as it is the most suitable and widely accepted apparatus for immediate-release tablet dosage forms, offering consistent hydrodynamic conditions and reproducible results. A medium volume of 900 mL and testing at 37 ± 0.5 °C were selected in line with pharmacopeial recommendations to simulate in vivo conditions and ensure robustness of the method. Filter compatibility was verified to confirm no adsorption of trelagliptin, in compliance with USP <1092>. The analytical quantification method was demonstrated to be specific and suitable for accurate measurement of dissolved drug in the selected medium. Although no official USP monograph dissolution method is available for trelagliptin, the selected conditions (USP Apparatus 2, 0.1 N HCl, 900 mL) are consistent with dissolution approaches commonly applied to the reference product (Zafatek) and are aligned with international regulatory expectations for immediate-release oral tablets. Therefore, the selected dissolution method is

		scientifically justified, physiologically relevant, and suitable for routine quality control and comparative performance evaluation.
2.	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed	Firm submitted the snapshot of innovator pack that has been used for the comparative studies.
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the Form-6.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the GMP certificate of API manufacturer M/s. Anhui Haikang Pharmaceuticals which is valid till 06-09-2028.
5.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision

Approved

379	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(WGG-87D-5TLW, 2024-06-11)
	Detail of Fee Submitted	30000.0, 2024-04-17,
	The proposed proprietary name / brand name	Trelamit 100mg Tablet
	Label Claim	Each Film Coated Tablet contains: Trelagliptin as Trelagliptin succinate.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's, 1 X 10's, 2x7-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool and dry place below 30 celcius
	For generic drugs (me-too Status)	Trelaget 100mg Tablet M/s Getz Pharma Pakistan (Pvt) LTD
	Pharmacotherapeutic Group of (API)	Trelagliptin is a dipeptidyl peptidase-4 inhibitor indicated in the control of diabetes mellitus.

Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd AddressNo. 21 Huancheng West Road Anqing Anhui 246000 China	
Detail of stability batches of drug product	Stability data of batches TGZ001, TGZ002, TGZ003 (1500 tablets each)	
Documents for the procurement of API with approval from DRAP (in case of Import)	Form -6 is submitted by the firm	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have performed against the Comparator drug Product Zafatek Tablets 100 mg (Trelagliptin)	
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	Zafatek Tablets 100mg M/s Takeda Pharmaceutical Company Limited (PMDA Approved)	
GMP status of the firm		
Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (general) section	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	According to USP General Chapter <1092> (USP, 1 Dec 2020), before dissolution method development can begin, it is essential to characterize the drug substance in order to appropriately select the dissolution medium, volume of medium, filter, and apparatus for evaluating the performance of the dosage form. In light of this guidance, please provide a scientific rationale for the selection of the dissolution medium, apparatus, and test conditions, based on the physical and chemical characterization of the drug substance. Provide documented evidence from the reference product in support of your reply.	Firm replied that Trelagliptin (as succinate) is a crystalline, low-dose DPP-4 inhibitor intended for immediate-release oral administration. Physicochemical characterization indicates that trelagliptin exhibits pH-dependent solubility, with higher solubility in acidic media and adequate chemical stability under acidic aqueous conditions. Based on solubility screening, 0.1 N hydrochloric acid (pH ~1.2) provides rapid and complete dissolution of the drug substance while maintaining sink conditions in a 900 mL medium volume, as recommended in USP <1092>. The selected medium is physiologically relevant, representing gastric conditions, and does not require the addition of surfactants, thereby preserving the discriminatory capability of the dissolution test. USP Apparatus 2 (paddle) was selected as it is the most suitable and widely accepted apparatus for immediate-release tablet dosage forms, offering consistent hydrodynamic conditions and reproducible results. A medium volume of 900 mL and testing at 37 ± 0.5 °C were selected in line with pharmacopeial recommendations to simulate in vivo conditions and ensure robustness of the method. Filter compatibility was verified to confirm no adsorption of trelagliptin, in compliance with USP <1092>. The analytical quantification method was demonstrated to be specific and suitable for accurate measurement of dissolved drug in the selected medium. Although no official USP monograph dissolution method is available for trelagliptin, the

		selected conditions (USP Apparatus 2, 0.1 N HCl, 900 mL) are consistent with dissolution approaches commonly applied to the reference product (Zafatek) and are aligned with international regulatory expectations for immediate-release oral tablets. Therefore, the selected dissolution method is scientifically justified, physiologically relevant, and suitable for routine quality control and comparative performance evaluation.
2.	In compliance of notification no. 14-1/2022-PEC dated 16th January, 2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed	Firm submitted the snapshot of innovator pack that has been used for the comparative studies.
3.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the Form-6.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the GMP certificate of API manufacturer M/s. Anhui Haikang Pharmaceuticals which is valid till 06-09-2028.
5.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.
Decision		
Approved		
380	Case Category	Import (Saima Hussain)
	Name, address of Applicant.	Inaya traders Flat No. 1, first floor, plot No. A-152, block 8, KAECHS, Karachi-Pakistan (0470)
	Application Form Dy. No / Tracking ID & date of submission	(XV9-T21-GB1W, 2024-03-01)
	Detail of Fee Submitted	150000.0, 150000.0 2023-12-15, 2024-02-27
	The proposed proprietary name / brand name	Lincomycin injection (generic name)
	Label Claim	Each 2ml contains: Lincomycin (as HCL) USP.....600 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5× 2ml ampoules-As per SRO

Shelf Life (Unit)	2 Year(s)Room temperature
For generic drugs (me-too Status)	Olinic 600mg Bosch pharma
Pharmacotherapeutic Group of (API)	Antibacterial
Name, address of Manufacturing site:	Xinxiang Changle Pharmaceutical Co., Ltd.-The Eastern Suburb of Huixian City, Henan Province-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has performed against the Lincomycin Hydrochloride Injection / CR Double-crane Limin Pharmaceutical (Jinan)Co.,Ltd. of batch no. 20251023 expiry date: 09.2027
Name, address of Marketing Authorization Holder:	Xinxiang Changle Pharmaceutical Co., Ltd, The Eastern Suburb of Huixian City, Henan Province, China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of batches Batches of products used for stability testing: 130922027, 130922028, 130922029 performed at 40±2°C and relative humidity (RH) at 75±5% and t 25±2°C and relative humidity (RH) at 60±5%.
The status in reference regulatory authorities	Available TGA Australia

Evaluation Remarks

Sr.no.	Shortcomings	Response of the Firm
1.	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin, since the submitted CoPP has not been verified from the database of Certificate of Pharmaceutical Product available on the official website of National medical Products Administration, China.	Firm replied that China has 2 different Authorities authorised to issue COPP namely 'National medical Products Administration' and 'City Market Supervision Administrations', this COPP is issued by Huixian City Market Supervision Administration thus this COPP cannot be verified at NMPA website. This COPP has also been legalised by Pakistani Embassy in China and China Chamber of International Commerce and the genuinity of this COPP can be online verified at the website of China Chamber of International Commerce at the link provided below: https://www.rzccpit.com/vcc.html?barcode=d29d5c95eb4a4 ... 38d6af9d1b And can also be verified by scanning the QR code attached on the certificate.
2.	Submit valid legalized GMP certificate of Manufacturer Abroad issued by the competent authority of country of origin.	Firm replied that the CoPP we have submitted confirms the GMP compliance status of the manufacturer.
3.	Provide a justification for not including benzyl alcohol as a preservative in the proposed formulation, despite its recommendation in both the USP monograph for Lincomycin Injection and the innovator product approved by the USFDA.	Composition has been revised as per reference regulatory authority and innovator that the revised composition contains benzyl alcohol. Fees challan and all 3 modules have been resubmitted with new stability data and pharmaceutical equivalence data of revised composition. Pharmacopeia has also been revised to USP as per innovator's product.

4.	Clarify the condition of terminal sterilization that actually been adopted for the sterilization of drug product.	Firm in their reply submitted the revised process validation protocol, detail manufacturing procedure and validation report in which the terminal sterilization conditions are as under: Steam pressure ≥ 0.4 MPa Sterilization temperature ($^{\circ}\text{C}$) 121°C Sterilization time 30 min
5.	Submit the reference which has been used to set the acceptance limit for the test of benzyl alcohol.	We, Xinxiang Changle Pharmaceutical Co., Ltd., do hereby formally declare that the acceptance limit for the test of benzyl alcohol is according to the formulation quantity of the injection and the monograph of "Lincomycin Hydrochloride injection" on Chinese Pharmacopoeia 2020 as USP does not provide acceptance limit for benzyl alcohol.

Decision

Deferred

Deferred for submission of a valid, legalized, and original CoPP issued by the relevant regulatory authority of the country of origin, along with an auxiliary document providing complete information on the full composition of the concerned drug product. Furthermore, submit a legalized document evidencing approval of the formulation change from the relevant regulatory authority of the country of origin for the instant drug product. Additionally, submit the revised and complete Module III of the CTD.

381	Case Category	New Molecule/Formulation (Saima Hussain)
	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	(NW6-5TD-4LEQ, 2024-05-22)
	Detail of Fee Submitted	75000.0, 2024-02-12,
	The proposed proprietary name / brand name	Combifen
	Label Claim	Each mL contains: Ibuprofen 9.6mg Paracetamol.....32mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100mL-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)	Non-Steroidal Anti-inflammatory Drugs/ Analgesic and antipyretic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	PHARMAGEN LIMITED,ZENITH CHEMICAL INDUSTRIES (PVT.) LIMITED
	Detail of stability batches of drug product	Stability data of batches TF-01,TF-02,TF-02 of 500ml batch size each
	Documents for the procurement of API with approval from DRAP (in case of Import)	both API procured from local Manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE is performed against the Tachifereid 32mg/ml+9.6mg/ml Suspension of M/s. Angelini Pharma Spa.

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		Italian Medicines Agency (AIFA)
GMP status of the firm		GMP certificate Certificate No. 48/2023-DRAP (K) dated 26th June, 2023. is submitted by the firm
Evidence of approval of manufacturing facility		GMP certificate Certificate No. 48/2023-DRAP (K) dated 26th June, 2023 mentioned that firm has Oral Liquid (Syrup, Solutions & Suspension) (general) section.
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the Firm
1.	Submit the analysis report/COA of excipients propylene glycol and glycerin which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm submitted the COA of excipients propylene glycol and glycerin including results of impurity testing related to the presence of ethylene glycol and diethylene glycol
2.	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which pharmaceutical equivalence/Comparative dissolution profile studies have been performed	Firm submitted the snapshot of innovator Pack.
3.	As per Section 3.2.P.1, the identified Critical Quality Attributes (CQAs) include appearance, pH, and assay. However, Batch manufacturing Record of trial batches, revealed that pH is neither controlled nor monitored during manufacturing process of the batches, so clarification is required in this regard.	Firm replied that, we acknowledge the importance of monitoring this parameter for overall quality consistency. Therefore, we commit to include pH determination of the reconstituted solution in the finished product testing of commercial batches to ensure batch-to-batch uniformity and to verify the buffering efficiency of sodium citrate. Accordingly, the specification for the finished product will be updated to include: Test: pH of reconstituted solution · Acceptance criteria: 6.0 - 7.0 This control measure will ensure that the functional role of sodium citrate as a buffering agent is consistently achieved in all production batches, thereby complying with the identified
4.	Scientifically rationalize the 500ml batch size of each trial batch, considering a 100 mL per unit PET bottle volume size. Further, justify how the deliverable volume test was performed, considering that ten containers are required as per the finished product specification table given in section 3.2.P.5.1.	Firm in their reply informed that A batch size of 500 mL for each trial batch is more than sufficient for both accelerated and long-term stability studies. A total of 20 PET-HDPE bottles were selected, 25ml was filled in each bottle for sample testing. For each trial batch, only 400 mL (equivalent to 16 bottles) were utilized for both long-term and accelerated stability studies. HDPE-PET bottles were selected for testing which will simulates container

		closure used for commercial batch stability studies to ensure product's quality, safety & efficacy.
5.	Please clarify the actual filled volume of each bottle, as Section 1.5.4 of Module-I indicates the proposed pack size as 100 mL per bottle, and the Batch Manufacturing Record (BMR) also specifies 100 mL per bottle. In this context, kindly justify how bottles with a 25 mL fill volume were selected for stability studies. Provide your response along with a reference supporting the volume size of the innovator product and in accordance with the stability study requirements outlined in ICH guidelines.	We would like to clarify that while the proposed commercial pack size indicated in Section 1.5.4 of Module-I and the BMR is 100 mL per bottle, the initial stability studies were conducted using 25 mL fill volume in the same container-closure system intended for the commercial pack. As per ICH Q1A(R2), stability evaluation focuses on assessing the product's behavior under defined storage conditions using a representative container-closure system, the nominal fill volume is not a stability-indicating parameter. We further confirm that the fill volume of 25 mL was used only for pilot-scale stability assessment and does not impact the reliability or validity of the generated stability data. For commercial-scale production, all stability studies will be performed using the actual proposed 100 mL fill volume, while maintaining the same primary packaging system used during the initial studies. This ensures full compliance with ICH Q1A(R2) requirements and alignment with regulatory expectations for demonstrating long-term stability and packaging compatibility of the commercial pack.
6.	Ambiguity in the label claim of applied formulation is observed in section 3.2.P.3.1 and also in BMR, so clarification is required either the label claim and the dispensed weight of each API is in accordance with 1ml or 5ml.	Firm replied that Please note that it was typographic error in label claim mentioned in BMR, Label claim is in accordance with 1ml & aligns with innovator product i.e Each 1ml contains: Ibuprofen 9.6mg Paracetamol 32mg
7.	Provide reference which has been used to set the pH limit of applied formulation.	Firm replied that Paracetamol and Ibuprofen liquid formulations are available separately in USP, with their respective pH ranges of 4.0-6.4 and 3.6-4.6. Since both APIs exhibit greater stability under acidic conditions, we have decided to finalize the pH range for our formulation between these two ranges, specifically in the range of 4.5-5.0, to ensure optimal stability for both active pharmaceutical ingredients.
Decision		
Deferred		
Deferred for submission of relevant international guidelines in support of the conduct of initial stability studies on a 25 mL fill volume when the proposed commercial pack size is 100 mL.		

382	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Pharmatec Pakistan (Pvt.) Limited D-86/A, S.I.T.E., Karachi - 75700, Pakistan (000024)
	Application Form Dy. No / Tracking ID & date of submission	(5NL-T31-742M, 2024-05-02)
	Detail of Fee Submitted	30000.0, 45000.0 2023-10-11, 2024-04-26
	The proposed proprietary name / brand name	Paratec
	Label Claim	Each film coated tablet contains: Paracetamol....500mg Ibuprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	8's,10's,16's,20's,3-As per SRO
	Shelf Life (Unit)	2 Year(s)Donot store above 30 degree centigrade
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic/Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ibuprofen-Hubei Biocause Heilen Pharmaceutical Co., Ltd,Paracetamol- Citi Pharma (Pvt.) Ltd,
	Detail of stability batches of drug product	Stability data of batches 22PD041P1TO1A,22PD041P1TO1B,22PD041P1TO1C batch size 2500 each is submitted by the firm.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted the Loan letter dated 18th March,2021 in which 25kg Ibuprofen is taken as Loan from M/s. Abbott.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP has been performed against the reference product Maxigesic 500/150mg Tablet of M/s. AFT Pharmaceuticals
	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,UK Manufacturer AFT Pharmaceuticals Ltd. Maxigesic 500/150mg tablet
	GMP status of the firm	GMP certificate dated 01st January, 2024 is submitted by the firm
	Evidence of approval of manufacturing facility	GMP certificate dated 01st January,2024 mentioned that firm has tablet (general) scetion
	Evaluation Remarks	
	Submit the delivery challan of the API (Ibuprofen), mentioning the quantity, amount, manufacturer's name, and lot number of the API obtained from M/s. Abbott, along with an intimation letter addressed to DRAP. The said letter was required to be submitted by the loan acceptor within 15 days of obtaining the loan, as per the relevant notification issued by DRAP. Regarding the Intimation Letter, please note that the material used for product development was procured on a loan basis from M/s Abbott Laboratories, solely for developmental purposes. It is important to highlight that the API Borrowing Notification was issued in 2023, while the dossier submission was completed in 2024. Considering the timelines and the context of product development, we kindly request DRAP to accept our submission and favorably consider the case. Firm was again asked to submit the DRAP notification under which the loan of API was obtained from M/s. Abbott back dated 19/03/2021, for the manufacturing of stability batches in September 2022. Firm in their reply again submitted the same loan letter dated 18 March,2021 along with product receipt dated 19/03/2021 without any reference of DRAP notification under which under which the loan of API was obtained from M/s. Abbott back dated 19/03/2021.	

	Decision	
	Approved	
383	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(1EL-XJP-8WUT, 2024-06-24)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	CO-TRIM 160mg/800mg Tablet
	Label Claim	Each tablet contains: Trimethoprim.....160mg Sulfamethoxazole.....800mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5x10's, 10x10's, 1x1-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool and dry place below 30 celcius
	For generic drugs (me-too Status)	Septan DS Tablet M/s GlaxoSmithKline Pakistan Limited
	Pharmacotherapeutic Group of (API)	Trimethoprim is one of the recent antibacterial drugs with action on a unique target. It chemically belongs to the group of diaminopyrimidines. Sulfamethoxazole belongs to a group of medications called sulfonamide antibiotics. It will not treat colds, the flu, or infections caused by viruses.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shouguang Fukang Pharmaceutical Co., Ltd. Address North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, People's Republic of China
	Detail of stability batches of drug product	Stability data of batches TSS001, TSS002 (2500 Tablets), TSS003 (2500 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 comparator product Comparator drug Product Co-Trimoxazole 160 mg/800 mg forte Tablets
	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	Co-Trimoxazole 160 mg/800 mg Tablets M/s Aspen Pharma Trading Limited 3016 Lake DriveCitywest Business CampusDublin 24, Ireland (MHRA Approved))
	GMP status of the firm	

Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (general) section.

Evaluation Remarks

Sr.no.	Shortcomings	Response of the firm
1.	Provide a justification for adopting the innovator's finished product specifications despite the availability of a USP monograph for Sulfamethoxazole and Trimethoprim Tablets. Revise your finished product specification in accordance with the USP requirements and submit the corresponding performance report, including chromatograms and complete raw data sheets.	We would like to clarify that all finished product testing, including routine analysis and stability studies, is performed using the International Pharmacopoeia (Ph. Int.) analytical method. The method verification, system suitability, and acceptance criteria are established and applied in accordance with the International Pharmacopoeia requirements. The applicable International Pharmacopoeia method and reference documents are already attached in the dossier. The mention of "innovator specification" was inadvertently stated in Module 1 during a document revision and does not represent the actual analytical method or specifications used for testing.
2.	According to the International Pharmacopoeia, the test is not considered valid unless the resolution factor between the peaks of sulfamethoxazole and trimethoprim is at least 5.0. However, you have not reported the resolution factor between these two peaks. Please justify how your test can be considered compliant and acceptable in light of the International Pharmacopoeia requirements.	The resolution factor between sulfamethoxazole and trimethoprim was not reported in the test report format. In routine analysis, reporting the resolution is not required, so it was inadvertently overlooked. However, the actual resolution has been confirmed to be consistently above 5.0, fully meeting & compliance with the International Pharmacopoeia requirement. Supporting chromatograms are attached for the reference.

Decision

Approved

Firm shall submit the requisite fee for pre-registration variation as per the revised fee SRO prior the issuance of the Registration Letter.

384	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(UV2-UM6-YJ1Z, 2024-06-20)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	CO-TRIM 80mg/400mg Tablet
	Label Claim	Each tablet contains: Trimethoprim.....80mg Sulfamethoxazole.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5x10's, 10x10's, 1x10'-As per SRO

Shelf Life (Unit)	2 Year(s)	Store in cool and dry place below 30 celcius
For generic drugs (me-too Status)	Septran Tablet GlaxoSmithKline Pakistan Limited Reg. # 000388M/s	
Pharmacotherapeutic Group of (API)	Trimethoprim is one of the recent antibacterial drugs with action on a unique target. It chemically belongs to the group of diaminopyrimidines. Sulfamethoxazole belongs to a group of medications called sulfonamide antibiotics. It will not treat colds, the flu, or infections caused by viruses.	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Shouguang Fukang Pharmaceutical Co., Ltd. Address North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, People’s Republic of China	
Detail of stability batches of drug product	Stability data of batches TSS001, TSS002 (2500 Tablets), TSS003 (2500 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 comparator product Comparator drug Product Co-Trimoxazole 80 mg/400 mg forte Tablets	
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	Co-Trimoxazole 80 mg/400 mg Tablets M/s Aspen Pharma Trading Limited 3016 Lake DriveCitywest Business CampusDublin 24, Ireland (MHRA Approved))	
GMP status of the firm		
Evidence of approval of manufacturing facility	GMP certificate dated 14-11-2023 mentioned that firm has tablet (general) section.	
Evaluation Remarks		
Sr.no.	Shortcomings	Response of the firm
1.	Provide a justification for adopting the innovator’s finished product specifications despite the availability of a USP monograph for Sulfamethoxazole and Trimethoprim Tablets. Revise your finished product specification in accordance with the USP requirements and submit the corresponding performance report, including chromatograms and complete raw data sheets.	We would like to clarify that all finished product testing, including routine analysis and stability studies, is performed using the International Pharmacopoeia (Ph. Int.) analytical method. The method verification, system suitability, and acceptance criteria are established and applied in accordance with the International Pharmacopoeia requirements. The applicable International Pharmacopoeia method and reference documents are already attached in the dossier. The mention of “innovator specification” was inadvertently stated in Module 1 during a document revision and

		does not represent the actual analytical method or specifications used for testing.
2.	According to the International Pharmacopoeia, the test is not considered valid unless the resolution factor between the peaks of sulfamethoxazole and trimethoprim is at least 5.0. However, you have not reported the resolution factor between these two peaks. Please justify how your test can be considered compliant and acceptable in light of the International Pharmacopoeia requirements.	The resolution factor between sulfamethoxazole and trimethoprim was not reported in the test report format. In routine analysis, reporting the resolution is not required, so it was inadvertently overlooked. However, the actual resolution has been confirmed to be consistently above 5.0, fully meeting & compliance with the International Pharmacopoeia requirement. Supporting chromatograms are attached for the reference.
Decision		
Approved		
Firm shall submit the requisite fee for pre-registration variation as per the revised fee SRO prior the issuance of the Registration Letter.		
385	Case Category	Export Facilitation (Saima Hussain)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(5DP-498-JS1E, 2024-07-19)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	Feropride 10mg Injection
	Label Claim	Each 4mL contains Amisulpride 10mg
	Reference to Finished product specifications	
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 15°C to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anphar Laboratories 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	BARHEMSYS 10mg Injection (Acacia Pharma)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Firm in their response submit the revised batch analysis report of API, performed by the drug product manufacturer including the test of BET and Bioburden test with the claimed that results of both the tests		

are under defined specification and limit. However, the COA of API by the drug substance manufacturer has not included the test of BET.

Decision

Approved

Firm shall submit the requisite fee for pre-registration variation as per the revised fee SRO prior the issuance of the Registration Letter.

386	Case Category	Routine (Saima Hussain)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(QDM-UNP-YA85, 2024-07-19)
	Detail of Fee Submitted	30000.0, 2024-06-05,
	The proposed proprietary name / brand name	Feropride 5mg Injection
	Label Claim	Each 2mL contains Amisulpride 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's -As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 15°C to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Pshycoleptic (Benzamides)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anphar Laboratories Pvt Ltd
	Detail of stability batches of drug product	Stability data of batches 038D02 (250 vials), 038D03 (1250 vials), 038D04 (1250 vials)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 is submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE has been performed against the Barhemsys manufactured by Acacia Pharma Inc, USA5mg/2ml Injection
	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	BARHEMSYS 5mg Injection (Acacia Pharma)
	GMP status of the firm	GMP certificate dated 27-09-2023 is submitted by the firm.
	Evidence of approval of manufacturing facility	Firm submitted the renewal of DML letter/Grant additional section letter dated 07th May,2024 mentioned that firm has Injectable ampoule section.
Evaluation Remarks		
Firm in their response submit the revised batch analysis report of API, performed by the drug product manufacturer including the test of BET and Bioburden test with the claimed that results of both the tests are under defined specification and limit. However, the COA of API by the drug substance manufacturer has not included the test of BET.		
Decision		
Approved		

	Firm shall submit the requisite fee for pre-registration variation as per the revised fee SRO prior the issuance of the Registration Letter.	
387	Case Category	Export Facilitation (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	(8T7-24Y-6ARN, 2024-07-25)
	Detail of Fee Submitted	75000.0, 2024-07-23,
	The proposed proprietary name / brand name	Pitamibe
	Label Claim	Each film-coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin.....2mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	HMG-COA reductase Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ruyuan HEC Pharm CO., Ltd. Manufacturing Site: Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Manufacturing Site: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	23SB-598-01,23SB-599-02,23SB-600-03 1500 tablet batch size.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate for Pitavastatin Calcium and DRAP attested commercial invoice for ezetimibe.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP is performed against the innovator product Livazebe Combination Tablets Ld 2mg/10mg Tablets (B#853370) Kowa Co., Ltd. 3-4--14Nihonbashi Honmachi, Chuo-ku, Tokyo
	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	Livazebe Combination Tablets LD by Kowa Company Ltd, Japan PMDA
	GMP status of the firm	GMP certificate dated 13-06-2023 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 13-06-2023 mentioned that firm has Tablet (general).
Evaluation Remarks		
Firm in their response stated that, as previously communicated, the SRA reference product contains Pitavastatin Calcium Hydrate, while our formulation uses Pitavastatin Calcium Anhydrous. In response to DRB remarks, we are hereby submitting further scientific justification confirming that: The active moiety (Pitavastatin) remains identical in both hydrate and anhydrous forms. The difference is only in water content, with no impact on efficacy, safety, or therapeutic performance. The anhydrous form		

complies with all quality, purity, stability, and regulatory requirements established for Pitavastatin API. The finished product specifications, dissolution, impurity profile, and stability data submitted are within acceptable limits and fully aligned with internationally accepted standards. Several regulatory authorities accept either form (hydrate/anhydrous) as interchangeable, provided that equivalence of the active moiety is established—which we have demonstrated with data already submitted. Firm has not submitted any documented in support of this claim. In addition to the justification previously provided, we are enclosing: Updated scientific rationale addressing the hydrate vs. anhydrous comparison in more detail along with Manufacturing process controls demonstrating consistent quality of the anhydrous form. Additional supportive literature. Firm submitted the only the comparison table between hydrous and anhydrous along with an SmPc of product containing only pitavastatin calcium anhydrous approved in USFDA.

Decision

Deferred

Deferred for evidence of approval of applied formulation i.e. Pitavastatin Calcium (anhydrous) with ezetimibe in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the submitted reference product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe. Furthermore, provide documentary evidence from stringent reference regulatory authorities demonstrating acceptance of either form (hydrate/anhydrous) as interchangeable, and considering drug products containing different hydrate forms of the API as pharmaceutical equivalents.

388	Case Category	Export Facilitation (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	(98H-ZLB-JJJJ, 2024-09-11)
	Detail of Fee Submitted	75000.0, 2024-07-23,
	The proposed proprietary name / brand name	Pitamibe
	Label Claim	Each film-coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin.....4mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30oC. Protect from heat, light and moisture.
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	HMG-COA reductase Inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ruyuan HEC Pharm CO., Ltd. Manufacturing Site: Xiaba Development Zone, Ruyuan Country, Shaoguan City, Guangdong Province, P.R. China,Zhejiang Tianyu Pharmaceutical Co., Ltd. Manufacturing Site: No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City
	Detail of stability batches of drug product	23SB-601-01,23SB-602-02,23SB-603-03 1500 tablet batch size.
	Documents for the procurement of API with approval from DRAP	Clearance certificate for Pitavastatin Calcium and DRAP attested commercial invoice for ezetimibe.

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	E and CDP is performed against the innovator product Livazebe Combination Tablets Ld 4mg/10mg Tablets (B#853370) Kowa Co., Ltd. 3-4--14Nihonbashi Honmachi, Chuo-ku, Tokyo
	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	Livazebe Combination Tablets LD by Kowa Company Ltd, Japan PMDA
	GMP status of the firm	GMP certificate dated 13-06-2023 is submitted by the firm.
	Evidence of approval of manufacturing facility	GMP certificate dated 13-06-2023 mentioned that firm has Tablet (general).
	Evaluation Remarks	
	Firm in their response stated that, as previously communicated, the SRA reference product contains Pitavastatin Calcium Hydrate, while our formulation uses Pitavastatin Calcium Anhydrous. In response to DRB remarks, we are hereby submitting further scientific justification confirming that: The active moiety (Pitavastatin) remains identical in both hydrate and anhydrous forms. The difference is only in water content, with no impact on efficacy, safety, or therapeutic performance. The anhydrous form complies with all quality, purity, stability, and regulatory requirements established for Pitavastatin API. The finished product specifications, dissolution, impurity profile, and stability data submitted are within acceptable limits and fully aligned with internationally accepted standards. Several regulatory authorities accept either form (hydrate/anhydrous) as interchangeable, provided that equivalence of the active moiety is established—which we have demonstrated with data already submitted. Firm has not submitted any documented in support of this claim. In addition to the justification previously provided, we are enclosing: Updated scientific rationale addressing the hydrate vs. anhydrous comparison in more detail along with Manufacturing process controls demonstrating consistent quality of the anhydrous form. Additional supportive literature. Firm submitted the only the comparison table between hydrous and anhydrous along with an SmPc of product containing only pitavastatin calcium anhydrous approved in USFDA.	
	Decision	
	Deferred	
	Deferred for evidence of approval of applied formulation i.e. Pitavastatin Calcium (anhydrous) with ezetimibe in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the submitted reference product approved in PMDA Japan, LIVAZEBE Combination Tablets LD, contains pitavastatin calcium hydrate as the active ingredient along with ezetimibe. Furthermore, provide documentary evidence from stringent reference regulatory authorities demonstrating acceptance of either form (hydrate/anhydrous) as interchangeable, and considering drug products containing different hydrate forms of the API as pharmaceutical equivalents.	
389	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(PA7-Y2Q-JND7, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2024-12-04,
	The proposed proprietary name / brand name	dotard 0.5mg tablet
	Label Claim	Each tablet contains:Dotinurad.....0.5 mg(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)	24 Month(s)Store below 30°C in Cool & Dry Place.
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	selective urate reabsorption inhibitor (SURI)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Gansu Hoatin Pharmatech 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)	API Loan intimation letter submitted
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hamaz: PE & CDP submitted against reference product Urece Tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
The status in reference regulatory authorities	Registered drug by PMDA as URECE (Dotinurad 0.5mg Tablets), for ORAL Use.
GMP status of the firm	Hamaz: GMP certificate issued dated 25-05-2021
Evidence of approval of manufacturing facility	Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks	
The Registration Board, in its 345th meeting, deferred the case pending submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm stated that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm. The firm was asked to justify the selection of pH 4.5 buffer as the dissolution medium and the inclusion of sodium lauryl sulfate (SLS), considering that the comparative dissolution profile (CDP) data demonstrated more than 85% drug release in other dissolution media without SLS. In addition, the firm was asked to provide a scientific rationale, supported by relevant literature from the reference (innovator) product, to substantiate the necessity of SLS in the selected dissolution medium despite adequate drug release observed in surfactant-free media. In reply, the firm stated that Dotinurad is freely soluble in dimethyl sulfoxide (DMSO) and practically insoluble in ethanol and water. Solubility studies performed in buffer media at pH 1.2, 4.5, and 6.8 demonstrated low aqueous solubility of the active pharmaceutical ingredient (API), indicating pH-dependent solubility behavior. A gradual decrease in solubility was observed with increasing pH from 1.2 to 6.8; however, the overall solubility remained low across all evaluated buffer media. Comparative dissolution profile (CDP) studies were conducted using buffer media both with and without sodium lauryl sulfate (SLS). The inclusion of SLS resulted in a significant improvement in the solubility and dissolution performance of Dotinurad, demonstrating its effectiveness as a solubilizing agent. Accordingly, the use of SLS in the selected dissolution medium was justified to enhance solubility, maintain sink conditions, and ensure consistent and discriminatory dissolution performance.	
Decision	
Deferred	

	The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Furthermore, submit the open part of the Drug Master File (DMF) of the drug substance provided by the API manufacturer, containing detailed information on the chemical and physical characterization of the drug substance.	
390	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(JLV-ZU5-Y9SW, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2024-12-04,
	The proposed proprietary name / brand name	dotard 1mg tablet
	Label Claim	Each tablet contains:Dotinurad.....1mg(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)	24 Month(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	selective urate reabsorption inhibitor (SURI)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Hoatin Pharmatech 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)	API Loan intimation letter submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hamaz: PE & CDP submitted against reference product Urece tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	The status in reference regulatory authorities	Registered drug by PMDA as URECE (Dotinurad 1mg Tablets), for ORAL Use.
	GMP status of the firm	Hamaz: GMP certificate issued dated 25-05-2021
	Evidence of approval of manufacturing facility	Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks		
The Registration Board, in its 345th meeting, deferred the case pending submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm stated that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm along with its response: The firm was asked to justify the selection of pH 4.5 buffer as the dissolution medium and the inclusion of sodium lauryl sulfate (SLS), considering that the comparative dissolution profile (CDP) data demonstrated more than 85% drug release in other dissolution media without SLS. In addition, the firm was asked to provide a scientific rationale, supported by relevant literature from the reference (innovator) product, to substantiate the necessity of		

SLS in the selected dissolution medium despite adequate drug release observed in surfactant-free media. In reply, the firm stated that Dotinurad is freely soluble in dimethyl sulfoxide (DMSO) and practically insoluble in ethanol and water. Solubility studies performed in buffer media at pH 1.2, 4.5, and 6.8 demonstrated low aqueous solubility of the active pharmaceutical ingredient (API), indicating pH-dependent solubility behavior. A gradual decrease in solubility was observed with increasing pH from 1.2 to 6.8; however, the overall solubility remained low across all evaluated buffer media. Comparative dissolution profile (CDP) studies were conducted using buffer media both with and without sodium lauryl sulfate (SLS). The inclusion of SLS resulted in a significant improvement in the solubility and dissolution performance of Dotinurad, demonstrating its effectiveness as a solubilizing agent. Accordingly, the use of SLS in the selected dissolution medium was justified to enhance solubility, maintain sink conditions, and ensure consistent and discriminatory dissolution performance.

Decision

Deferred

The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Furthermore, submit the open part of the Drug Master File (DMF) of the drug substance provided by the API manufacturer, containing detailed information on the chemical and physical characterization of the drug substance.

391	Case Category	New Molecule/Formulation (Saima Hussain)
	Name, address of Applicant.	Hamaz Pharmaceuticals (Pvt) Ltd. 13-KM Bosan Road, Lutfabad (000427)
	Application Form Dy. No / Tracking ID & date of submission	(PQD-8GT-XJDE, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2024-12-04,
	The proposed proprietary name / brand name	dotard 2mg tablet
	Label Claim	Each tablet contains:Dotinurad.....2mg(As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	selective urate reabsorption inhibitor (SURI)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Gansu Hoatin Pharmatech 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)	API Loan intimation letter submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hamaz: PE & CDP submitted against refernce product Urece tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	The status in reference regulatory authorities	Registered drug by PMDA as URECE (Dotinurad 2mg Tablets), for ORAL Use.
	GMP status of the firm	Hamaz: GMP certificate issued dated 25-05-2021

Evidence of approval of manufacturing facility	Hamaz: GMP certificate issued dated 25-05-2021 confirms availability of tablet general section
Evaluation Remarks	
The Registration Board, in its 345th meeting, deferred the case pending submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm stated that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm. Reply of the firm along with shortcoming is as under: The firm was asked to justify the selection of pH 4.5 buffer as the dissolution medium and the inclusion of sodium lauryl sulfate (SLS), considering that the comparative dissolution profile (CDP) data demonstrated more than 85% drug release in other dissolution media without SLS. In addition, the firm was asked to provide a scientific rationale, supported by relevant literature from the reference (innovator) product, to substantiate the necessity of SLS in the selected dissolution medium despite adequate drug release observed in surfactant-free media. In reply, the firm stated that Dotinurad is freely soluble in dimethyl sulfoxide (DMSO) and practically insoluble in ethanol and water. Solubility studies performed in buffer media at pH 1.2, 4.5, and 6.8 demonstrated low aqueous solubility of the active pharmaceutical ingredient (API), indicating pH-dependent solubility behavior. A gradual decrease in solubility was observed with increasing pH from 1.2 to 6.8; however, the overall solubility remained low across all evaluated buffer media. Comparative dissolution profile (CDP) studies were conducted using buffer media both with and without sodium lauryl sulfate (SLS). The inclusion of SLS resulted in a significant improvement in the solubility and dissolution performance of Dotinurad, demonstrating its effectiveness as a solubilizing agent. Accordingly, the use of SLS in the selected dissolution medium was justified to enhance solubility, maintain sink conditions, and ensure consistent and discriminatory dissolution performance.	
Decision	
Deferred	
The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Furthermore, submit the open part of the Drug Master File (DMF) of the drug substance provided by the API manufacturer, containing detailed information on the chemical and physical characterization of the drug substance.	
Case Category	New Molecule/Formulation (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	(5P4-RAB-HL8S, 2024-12-02)
Detail of Fee Submitted	75000.0, 2024-09-27,
The proposed proprietary name / brand name	DOTINAB Tablet 0.5mg
Label Claim	Each Tablet contains: Dotinurad.....0.5mg (Innovator's Specification)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30°C.
For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	Anti-Gout (Preparation increasing excretion of uric acid)	
Name, address of Manufacturing site:	Self Manufacturing	
Name & address of API manufacturer	Beijing Jincheng Taier Pharmaceutical Co., Ltd.	
Detail of stability batches of drug product	Batch no. 851DS01 batch size 5000 tablet Batch no. 851DS02 batch size 5000 tablet	
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted the clearance certificate dated 06-03-2024	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Urece Tablet 0.5mg G053 (Fuji. Pharmaceutical Co. Ltd.)	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted (temp. 40±2°C/ 75±5% RH and temp. 30±2°C/ 65±5% RH)	
The status in reference regulatory authorities	PMDA approved: URECE Tablets 0.5mg manufactured by Fuji Yakuhin Co., Ltd.	
GMP status of the firm	Firm submitted GMP certificate dated 26-07-2023	
Evidence of approval of manufacturing facility	Firm submitted the GMP certificate includes tablet (General section)	
Evaluation Remarks		
The Registration Board, in its 345th meeting, deferred the case for submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm informed that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm. Reply of the firm along with communicated shortcoming is as under: According to USP General Chapter <1092> (USP, 1 Dec 2020), before dissolution method development can begin, it is essential to characterize the drug substance in order to appropriately select the dissolution medium, volume of medium, filter, and apparatus for evaluating the performance of the dosage form. In light of this guidance, please provide a scientific rationale for the selection of the dissolution medium, apparatus, and test conditions, based on the physical and chemical characterization of the drug substance. The justification should include, but not be limited to, relevant properties such as solubility, pKa, pH-dependent solubility behavior, polymorphic form, particle size, and any other characteristics that influenced the choice of dissolution conditions. Supporting experimental data and/or relevant literature references should be submitted to demonstrate that the selected dissolution method is appropriate and discriminatory for the drug product. In reference to the above reply, it is stated the formal BCS classification of Dotinurad has not been published in the publicly available innovator review document; however, its physicochemical characteristics are consistent with those of a low-solubility drug substance within the BCS framework. Since the solubility profile as mentioned below represent that solubility of Dotinurad drug substance is very less across physiological pH range but the solubility of Dotinurad increases as the pH increases towards more alkaline conditions as mentioned in table below. https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005 1) Solubility in Various Solvents		
Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Water	238,185 ± 5,672.5	Almost insoluble
Ethanol (99.5%)	452 ± 11.1	Hard to dissolve
N,N-Dimethylformamide	< 1	Extremely soluble

Methanol	220 ± 2.5	Hard to dissolve
1-Octanol	1,790 ± 52.5	Extremely insoluble
0.1 mol/L Hydrochloric acid test solution	714,286 ± 0.0	Almost insoluble

2) Solubility in Various pH Solvents

Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Dissolution test 1st fluid	714,286 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 2	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 3	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 4	833,333 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 5	265,650 ± 8,002.1	Almost insoluble
Britton-Robinson buffer pH 6	35,171 ± 188.8	Almost insoluble
Dissolution test 2nd fluid	4,451 ± 46.0	Extremely insoluble
Britton-Robinson buffer pH 7	4,155 ± 6.0	Extremely insoluble
Britton-Robinson buffer pH 8	963 ± 7.0	Hard to dissolve

The adaption of medium pH 6.8 buffer is the reason for selection based on scientific rationale i.e. pKa value of dotinurad drug substance is 4.6 represents that drug substance is a weakly acidic compound. Therefore at pH 6.8, which is above its pKa of 4.6, dotinurad will be significantly more soluble than in a highly acidic environment like pH 1.2 buffer (Dissolution test 1st fluid as an example). Comparative Dissolution profile studies of test product and reference product at various pH range like 0.1 N HCl, pH 4.5 acetate buffer and in pH 6.8 buffer also represents that towards alkaline pH solubility and release of drug substance increases for both test and reference product. Moreover, comparative dissolution profile studies report sameness/similarity of dissolution profile in all selected media which represents sameness of test product and reference product. However, the above solubility characteristics clearly evident that the API is extremely insoluble in dissolution test 2nd fluid i.e. pH 6.8 medium.

Decision

Deferred

The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product.

393	Case Category	New Molecule/Formulation (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	(HBJ-XYU-WT49, 2024-12-02)
	Detail of Fee Submitted	75000.0, 2024-09-27,
	The proposed proprietary name / brand name	DOTINAB Tablet 1mg
	Label Claim	Each Tablet contains: Dotinurad..... 1mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-Gout (Preparation increasing excretion of uric acid)

Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Beijing Jincheng Taier Pharmaceutical Co., Ltd.
Detail of stability batches of drug product	Batch no. 852DS01 batch size 5000 tablet Batch no. 852DS02 batch size 5000 tablet
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted the clearance certificate dated 06-03-2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence and comparative dissolution profile against URECE 1 mg Tablet
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted (temp. 40±2°C/ 75±5% RH and temp. 30±2°C/ 65±5% RH)
The status in reference regulatory authorities	PMDA approved: URECE Tablets 1mg manufactured by Fuji Yakuhin Co., Ltd.
GMP status of the firm	Firm submitted GMP certificate dated 26-07-2023
Evidence of approval of manufacturing facility	Firm submitted the GMP certificate includes tablet (General section)

Evaluation Remarks

The Registration Board, in its 345th meeting, deferred the case for submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm informed that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm. Reply of the firm along with communicated shortcoming is as under: According to USP General Chapter <1092> (USP, 1 Dec 2020), before dissolution method development can begin, it is essential to characterize the drug substance in order to appropriately select the dissolution medium, volume of medium, filter, and apparatus for evaluating the performance of the dosage form. In light of this guidance, please provide a scientific rationale for the selection of the dissolution medium, apparatus, and test conditions, based on the physical and chemical characterization of the drug substance. The justification should include, but not be limited to, relevant properties such as solubility, pKa, pH-dependent solubility behavior, polymorphic form, particle size, and any other characteristics that influenced the choice of dissolution conditions. Supporting experimental data and/or relevant literature references should be submitted to demonstrate that the selected dissolution method is appropriate and discriminatory for the drug product. In reference to the above reply, it is stated the formal BCS classification of Dotinurad has not been published in the publicly available innovator review document; however, its physicochemical characteristics are consistent with those of a low-solubility drug substance within the BCS framework. Since the solubility profile as mentioned below represent that solubility of Dotinurad drug substance is very less across physiological pH range but the solubility of Dotinurad increases as the pH increases towards more alkaline conditions as mentioned in table below. <https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005> 1) Solubility in Various Solvents

Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Water	238,185 ± 5,672.5	Almost insoluble
Ethanol (99.5%)	452 ± 11.1	Hard to dissolve
N,N-Dimethylformamide	< 1	Extremely soluble
Methanol	220 ± 2.5	Hard to dissolve
1-Octanol	1,790 ± 52.5	Extremely insoluble

0.1 mol/L Hydrochloric acid test solution	714,286 ± 0.0	Almost insoluble
2) Solubility in Various pH Solvents		
Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Dissolution test 1st fluid	714,286 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 2	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 3	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 4	833,333 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 5	265,650 ± 8,002.1	Almost insoluble
Britton-Robinson buffer pH 6	35,171 ± 188.8	Almost insoluble
Dissolution test 2nd fluid	4,451 ± 46.0	Extremely insoluble
Britton-Robinson buffer pH 7	4,155 ± 6.0	Extremely insoluble
Britton-Robinson buffer pH 8	963 ± 7.0	Hard to dissolve
The adaption of medium pH 6.8 buffer is the reason for selection based on scientific rationale i.e. pKA value of dotinurad drug substance is 4.6 represents that drug substance is a weakly acidic compound. Therefore at pH 6.8, which is above its pKA of 4.6, dotinurad will be significantly more soluble than in a highly acidic environment like pH 1.2 buffer (Dissolution test 1st fluid as an example). Comparative Dissolution profile studies of test product and reference product at various pH range like 0.1 N HCl, pH 4.5 acetate buffer and in pH 6.8 buffer also represents that towards alkaline pH solubility and release of drug substance increases for both test and reference product. Moreover comparative dissolution profile studies report sameness/similarity of dissolution profile in all selected media which represents sameness of test product and reference product. However, the above solubility characteristics clearly evident that the API is extremely insoluble in dissolution test 2nd fluid i.e. pH 6.8 medium.		
Decision		
Deferred		
The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product.		
394	Case Category	New Molecule/Formulation (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	(RV9-9HR-5786, 2024-12-02)
	Detail of Fee Submitted	75000.0, 2024-10-04,
	The proposed proprietary name / brand name	DOTINAB Tablet 2mg
	Label Claim	Each Tablet contains: Dotinurad.....2mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Anti-Gout (Preparation increasing excretion of uric acid)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Beijing Jincheng Taier Pharmaceutical Co., Ltd.

Detail of stability batches of drug product	Batch no. 853DS01 batch size 5000 tablet Batch no. 853DS02 batch size 5000 tablet	
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm submitted the clearance certificate dated 06-03-2024	
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Urece tablet 2mg	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted (temp. 40±2°C/ 75±5% RH and temp. 30±2°C/ 65±5% RH)	
The status in reference regulatory authorities	PMDA approved: URECE Tablets 2mg manufactured by Fuji Yakuhin Co., Ltd.	
GMP status of the firm	Firm submitted GMP certificate dated 26-07-2023	
Evidence of approval of manufacturing facility	Firm submitted the evidence of availability of facility of non-sterile inhalation liquid	
Evaluation Remarks		
The Registration Board, in its 345th meeting, deferred the case for submission of documentary evidence of approval, including Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs), verifiable from the official website of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, or alternatively, evidence of approval of the applied formulation from other reference regulatory authorities (RRAs). In response, the firm informed that the applied formulation is listed in the main PMDA Japan database, including the approved SmPC and PIL, and that this claim has been verified from the official PMDA website. Following confirmation of the availability of the reference regulatory authority (RRA), further evaluation identified the following deficiency, which was communicated to the firm. Reply of the firm along with communicated shortcoming is as under: According to USP General Chapter <1092> (USP, 1 Dec 2020), before dissolution method development can begin, it is essential to characterize the drug substance in order to appropriately select the dissolution medium, volume of medium, filter, and apparatus for evaluating the performance of the dosage form. In light of this guidance, please provide a scientific rationale for the selection of the dissolution medium, apparatus, and test conditions, based on the physical and chemical characterization of the drug substance. The justification should include, but not be limited to, relevant properties such as solubility, pKa, pH-dependent solubility behavior, polymorphic form, particle size, and any other characteristics that influenced the choice of dissolution conditions. Supporting experimental data and/or relevant literature references should be submitted to demonstrate that the selected dissolution method is appropriate and discriminatory for the drug product. In reference to the above reply, it is stated the formal BCS classification of Dotinurad has not been published in the publicly available innovator review document; however, its physicochemical characteristics are consistent with those of a low-solubility drug substance within the BCS framework. Since the solubility profile as mentioned below represent that solubility of Dotinurad drug substance is very less across physiological pH range but the solubility of Dotinurad increases as the pH increases towards more alkaline conditions as mentioned in table below. https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/3949005 1) Solubility in Various Solvents		
Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Water	238,185 ± 5,672.5	Almost insoluble
Ethanol (99.5%)	452 ± 11.1	Hard to dissolve
N,N-Dimethylformamide	< 1	Extremely soluble
Methanol	220 ± 2.5	Hard to dissolve
1-Octanol	1,790 ± 52.5	Extremely insoluble
0.1 mol/L Hydrochloric acid test solution	714,286 ± 0.0	Almost insoluble

2) Solubility in Various pH Solvents

Solvent Name	Amount of solvent required to dissolve 1 g (mL)	Solubility
Dissolution test 1st fluid	714,286 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 2	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 3	1,000,000 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 4	833,333 ± 0.0	Almost insoluble
Britton-Robinson buffer pH 5	265,650 ± 8,002.1	Almost insoluble
Britton-Robinson buffer pH 6	35,171 ± 188.8	Almost insoluble
Dissolution test 2nd fluid	4,451 ± 46.0	Extremely insoluble
Britton-Robinson buffer pH 7	4,155 ± 6.0	Extremely insoluble
Britton-Robinson buffer pH 8	963 ± 7.0	Hard to dissolve

The adaption of medium pH 6.8 buffer is the reason for selection based on scientific rationale i.e. pKa value of dotinurad drug substance is 4.6 represents that drug substance is a weakly acidic compound. Therefore at pH 6.8, which is above its pKa of 4.6, dotinurad will be significantly more soluble than in a highly acidic environment like pH 1.2 buffer (Dissolution test 1st fluid as an example). Comparative Dissolution profile studies of test product and reference product at various pH range like 0.1 N HCl, pH 4.5 acetate buffer and in pH 6.8 buffer also represents that towards alkaline pH solubility and release of drug substance increases for both test and reference product. Moreover comparative dissolution profile studies report sameness/similarity of dissolution profile in all selected media which represents sameness of test product and reference product. However, the above solubility characteristics clearly evident that the API is extremely insoluble in dissolution test 2nd fluid i.e. pH 6.8 medium.

Decision

Deferred

The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product.

395	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	(S43-D1V-V14P, 2024-09-20)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-25, 2024-09-19
	The proposed proprietary name / brand name	Mipram 5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Escitalopram as Oxalate...5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s) 15-30 degree Celsius
	For generic drugs (me-too Status)	Precipra Tablets 5mg by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	Antidepressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shodhana Laboratories Private Limited India
	Detail of stability batches of drug product	3 batches: 1500 Tablet

	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from Biorex Pharma submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Precipra Tablet of Pfizer: 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	MHRA 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	
	Registration Board in its 344th meeting decided as under: Deferred for submission of evidence of procurement of API used in the manufacturing of stability batches. Firm in their reply informed that the stability data required for regulatory approval was generated using an API from a previous batch and submit an invoice of year 2017. However, the quality attributes of the API used in the current drug product batch are consistent with the previous lot, ensuring that there is no impact on the stability profile or performance of the drug product.	
	Decision	
	Deferred	
	Deferred for clarification on how stability batches were developed on 08-09-2023 using an API with only one month of remaining shelf life, as per the submitted invoice (Batch No. EO-207/18; Mfg. Date: Oct-2018; Expiry Date: Oct-2023). Furthermore, submit complete API borrowing documentation, including DRAP-attested commercial invoice, loan letter on the lender's letterhead clearly mentioning batch number, quantity, manufacturing date, and expiry date, and receipt of loan material containing all relevant details.	
396	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(5L5-V6L-Q2NT, 2025-06-11)
	Detail of Fee Submitted	37000.0, 2025-06-10,
	The proposed proprietary name / brand name	GU-N Powder
	Label Claim	Each 100 gram contains: Nicotinamide BP.....0.32gm, Menadione Bisulfite BP.....0.115gm, Potassium citrate.....18gm, Sodium citrate.....12gm, Vitamin B1 BP.....0.03gm, VitaminB2 BP.....0.015gm. Vitamin C BP.....1.10gm”
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 12gm, 50gm,10-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.

	For generic drugs (me-too Status)	Hydrone WSP 116951 by M/s Biolabs, Karachi
	Pharmacotherapeutic Group of (API)	Multivitamins & Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 27.05.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
397	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(189-4AH-7TM6, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	ARCH NOR 50 LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g Colistin Sulphate BP.....50MIU (As Per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	COLINOR ORAL LIQUID. (071066)
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was issued on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
398	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(2NM-Y8X-61DQ, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	TAMOL POWDER

	Label Claim	Each 100gm powder contains Paracetamol BP.....20.0g Vitamin-C BP.....5g Potassium Carbonate.....12.5g Sodium Bicarbonate.....12.5g Vitamin E BP.....12.5g (As Per Innovators' specifications.)
	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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	PIPERAPURE -1000 WATER SOLUBLE POWDER (Reg.No 034530)
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic.
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
399	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(3A6-LDQ-NMNH, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	OXTRA-950 W/S POWDER
	Label Claim	Each KG contains: Oxytetracycline HCL BP.....950 gm (As per innovator's 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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	OXY-950 Powder Reg. No (034526)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
400	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(3LA-Z2R-QD7S, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	VITAZURIL ORAL LIQUID
	Label Claim	Each 1000ml contains TOLTRAZURIL..... 25 GM VITAMIN K3 BP.....3 GM (As per innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	EMI RAFT ORAL LIQUID (078253)
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
401	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(EML-LA9-LDW6, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	AMILEX ORAL LIQUID
	Label Claim	Each 100ml contains: Enrofloxacin USP..... 10g Guaifenesin USP..... 10g Aminophylline USP..... 4g (As per innovator's Specifications.)
	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)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	GUXANIN-AG ORAL LIQUID (103895) by M/S D-HAANS PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotic, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued to firm on 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
402	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(YQ6-Q61-GNY7, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	ARCH COX POWDER
	Label Claim	EACH KG CONTAINS: - SULPHADIMIDINE SODIUM.... 82500MG, SULPHAQUINOXALINE SODIUM..... 200000MG, DIAVERIDINE..... 40000MG, VIT A BP..... 2800000 IU, VIT K BP..... 2000MG (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)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	COXICURE-AK POWDER (Reg. No. 013684)
	Pharmacotherapeutic Group of (API)	Antibacterial, Vitamins, Anti Diarrhea
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was issued on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
403	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK

		(000991)
	Application Form Dy. No / Tracking ID & date of submission	(BHH-S6R-G3TV, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	ARCH NOR 60 LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g Colistin Sulphate BP.....60MIU (As Per Innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre, 5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NOR-C MAASON LIQUID. (071056)
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
404	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27- 28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(B3M-EYV-Y8L9, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	BILOSIN-98% W/S POWDER
	Label Claim	Each gm contains: Tylosin Tartrate BP. 980 mg (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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	Marcus Powder Reg. No: (099478)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
405	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(EUH-NE7-MY1X, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	BIO DOXY 200 ORAL LIQUID
	Label Claim	Each 100ml contains Doxycycline HCl BP..... 20g Tylosin Tartrate BP..... 10g Colistin sulphate BP.....50MIU Bromhexine HCl BP.. 1g (As per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	HAANS MED ORAL LIQUID (103899)
	Pharmacotherapeutic Group of (API)	Antibacterial, Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
406	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(L99-S96-HRRR, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	BIRO FLUSH Water Soluble Powder
	Label Claim	Each 100gm powder contains; Potassium Citrate BP.....18g Sodium Citrate BP.....12g Vitamin B1 BP..... 0.03g Vitamin B2 BP..... 0.015g Nicotinamide BP..... 0.32g Menadione Bisulfite BP..... 0.115g Vitamin

		C BP..... 1.10g (As Per Innovators' 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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	BIMBO-H WATER SOLUBLE POWDER (Reg. No. 102231)
	Pharmacotherapeutic Group of (API)	Multivitamin & Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
407	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(YAY-7DW-YNVV, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	BISOLVON W/S ORAL POWDER
	Label Claim	EACH 100 GM CONTAINS: Bromhexine HCl BP.....1 GM Tartaric Acid.....15 GM (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	BROMOTARIC WATER SOLUBLE POWDER REG NO. (089822)
	Pharmacotherapeutic Group of (API)	Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

408	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(LTN-HL8-5YVG, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	BROMT-10% ORAL LIQUID
	Label Claim	Each ml contains Bromhexine HCl BP.....10mg (As per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	BROMOSOL ORAL LIQUID (080725)
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued on 7.8.2024.
	Evidence of approval of manufacturing facility	
409	Evaluation Remarks	
	Decision	
	Approved	
409	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(S2L-YJG-53DA, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	BRO NOR TIN LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g Colistin Sulphate BP.....60MIU Bromhexine Hcl BP.....0.5g (As Per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.

	For generic drugs (me-too Status)	BROCONOR LIQUID. (071067)
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was granted on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
410	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(XU2-ZA4-QWBJ, 2025-06-20)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	CETA C LYTE POWDER
	Label Claim	EACH 100 GM CONTAINS: - Paracetamol BP..... 2.0 gm Vitamin C BP..... 20.0 gm Calcium Carbonate BP.....4.5 gm Magnesium Sulphate BP....3.5 gm Potassium Chloride BP.....4.0 gm (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	SPIN-C POWDER 078239 by M/s Leads Pharma
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic.
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
411	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(MB3-LAN-1PJH, 2025-07-22)

	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	COSIN-T 25% ORAL LIQUID
	Label Claim	Each 1000 ml Contains: Tilmicodin Phosphate (USP) eq. to Tilmicodin.....250gm (As per innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	ZOTIL-250 ORAL LIQUID (080936)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate granted on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
412	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(GW9-T8A-3725, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	DIPHYLINE ORAL LIQUID
	Label Claim	Each 100ml contains: Enrofloxacin USP..... 10 GM Guaifenesin USP..... 4 GM Aminophylline USP..... 10 GM (As per innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	GUNAXIN-AE ORAL LIQUID (103896)
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
413	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(J57-8Z4-Q3VL, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	DOXSURE 50% ORAL POWDER
	Label Claim	Each gm powder contains Doxycycline HCl BP..... 500mg (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)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	HANSYDOX-50% Powder REG NO.102208
	Pharmacotherapeutic Group of (API)	ANTI-INFECTIVE, ANTI-BACTERIAL
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
414	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(PBL-E79-RZ9Q, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	ERAPRIM W/S POWDER
	Label Claim	EACH KG CONTAINS: Erythromycin Thiocyanate.....100 GM Trimethoprim BP.....20 GM Sulphadiazine as sodium BP.....100 GM (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	PULMONIL WATER SOLUBLE POWDER (Reg. No. 058895
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
415	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(GZG-W9L-QLP1, 2025-06-20)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	FLOX 200 ORAL POWDER
	Label Claim	Each 100gm contains: Enrofloxacin HCl USP.....20 gm (As per innovator's Specifications)
	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)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	ENSTER 20 ORAL WATER SOLUBLE POWDER REG NO. 101502
	Pharmacotherapeutic Group of (API)	ANTI-INFECTIVE, ANTI-BACTERIAL
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
416	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)

	Application Form Dy. No / Tracking ID & date of submission	(MBJ-Y94-3H6B, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	FLOX NOR 20% LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g (As Per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NORBAK 20% LIQUID. (049780)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was issued to firm on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
417	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27- 28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(64A-V4N-M5YN, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	FLUSBITOL Oral Powder
	Label Claim	Each 100 gm contains; Ammonium chloride 45 gm Magnesium sulphate BP.....20 gm Sodium citrate 20 gm Sorbitol USP.....5 gm Vitamin C BP.....5 gm (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	PULMONIL WATER SOLUBLE POWDER (Reg. No. 058895
	Pharmacotherapeutic Group of (API)	Diuretic, Expectorant, vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
418	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(AYB-N7G-MR9E, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	LAXIS W/S Powder
	Label Claim	Each 1000gm contains; Furosemide BP.....20 gm Calcium Carbonate BP..... 40 gm Sodium Chloride BP.....35 gm Magnesium Sulphate BP.....35 gm (As Per Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	DIALYSIS WATER SOLUBLE POWDER (Reg. No. 075692)
	Pharmacotherapeutic Group of (API)	Diuretic, Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
419	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(8Y2-MMN-SAUL, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	N FLOXIN 25% LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 25g (As Per Innovator's Specifications.)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NOXABAK 25 ORAL LIQUID. (063828)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
420	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(RY4-34Y-HBDZ, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	NOR PHYLINE G LIQUID
	Label Claim	Each ml contains: Norfloxacin BP..... 200mg Guaifenesin USP.....200mg Aminophylline USP..... 80mg (As Per Innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	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	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
421	Case Category	Routine (Sara Mehreen)

	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(7GB-5Q4-T9LG, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	OXLANIC 10% ORAL LIQUID
	Label Claim	Each 1000ml contains Oxolinic Acid BP.....100g (As Per Innovator's Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	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	cGMP certificate was granted on 7.8.2024 to firm.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
422	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(QX7-XY8-QZPQ, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	PEFLOX ORAL LIQUID
	Label Claim	Each 100 ML contains: Pefloxacin methanesulfonate eq to Pefloxacin BP.....10gm (As per innovator Specifications.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	PEFROX-BH ORAL LIQUID Reg. No (103952)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 7.8.2024.

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
423	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(9BL-V3D-PVG9, 2025-07-22)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	PENTA PRIM ORAL LIQUID
	Label Claim	Each ml contains: Tylosin Tartrate BP.....50mg Sulfamethoxypyridazine BP.....50mg Trimethoprim BP.....10mg Colistin Sulphate BP.....500,000IU Bromhexine HCl BP.....5mg (As Per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep in Cool and dry place. Keep out of reach of children.
	For generic drugs (me-too Status)	COMPLIMATES Liquid (072681)
	Pharmacotherapeutic Group of (API)	Antibiotic, Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was granted to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
424	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(LWJ-PMS-ZVUS, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-07-11,
	The proposed proprietary name / brand name	TRIM NOR LIQUID

	Label Claim	Each 100ml contains Norfloxacin BP..... 10g Sulfamethoxypyridazine BP.....15g Trimethoprim BP.....3g (As Per Innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml,150ml,250ml, 500ml, 1Litre, 2.5Litre, 5Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NORPLUS LIQUID. (034534)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
425	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(MSU-QYU-ED5T, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	URIPOL W/S POWDER
	Label Claim	Each 1000gm contains; Furosemide BP.....20 gm Potassium Chloride BP.....4 gm Calcium Carbonate BP..... 45 gm Manganese sulphate BP..... 1.0 gm (As per Innovators Specifications)
	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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	CLARINYL WATER SOLUBLE POWDER (Reg. No. 058909)
	Pharmacotherapeutic Group of (API)	Diuretic, Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP was issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
426	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(WAE-DST-UVHD, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	VC 100 Oral Powder
	Label Claim	Each 100gm powder contains. Vitamin C BP.....100gm (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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	SANNAVIT C-100 ORAL POWDER Reg No. (025368)
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
427	Evaluation Remarks	
	Decision	
	Approved	
427	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(GXZ-BHX-NAJ9, 2025-07-01)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	WORM-ZINE W/S POWDER
	Label Claim	Each gm contains: Piperazine Citrate USP.....1000 mg (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) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	PIPERAPURE -1000 WATER SOLUBLE POWDER (Reg.No 034530)
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 7.8.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
428	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BAARIQ PHARMACEUTICALS Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore (000715)
	Application Form Dy. No / Tracking ID & date of submission	(77V-7Q6-D9SW, 2025-04-19)
	Detail of Fee Submitted	37000.0, 2025-04-18,
	The proposed proprietary name / brand name	SpiraX Oral Powder
	Label Claim	Each 100 gm Powder Contains Lincomycin HCL (BP).....5 gm Spectinomycin HCL (BP).....7.5 gm Spiramycin Adipate (BP).....2.5 gm Bromhexine HCL (BP).....0.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg-De-Controlled, 100 gm-De-Controlled, 1000 gm-De-Controlled, 2.5 Kg-De-Controlled, 25 Kg-De-Controlled, 250 gm-De-Controlled, 5 Kg-De-Controlled, 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Do not store above 30° C. Protect from direct sunlight.
	For generic drugs (me-too Status)	SPIRALINC-B powder
	Pharmacotherapeutic Group of (API)	Antibiotics & Mucolytic agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection for renewal of DML conducted on 21.03.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
429	Case Category	Routine (Sara Mehreen)

Name, address of Applicant.	BAARIQ PHARMACEUTICALS Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore (000715)
Application Form Dy. No / Tracking ID & date of submission	(EGV-2HR-J58L, 2025-05-08)
Detail of Fee Submitted	37000.0, 2025-05-06,
The proposed proprietary name / brand name	NEPHROBAR ORAL POWDER
Label Claim	Each Gram Powder Contains: Ammonium Chloride (BP).....450 mg Magnesium Sulphate (BP).....250 mg Sodium Sulphate (BP).....245 mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100 gm-De-Controlled, 1000 gm-De-Controlled, 2500 gm-De-Controlled, 25000 gm-De-Controlled, 500 gm-De-Controlled, 5000 gm-De-Controlled
Shelf Life (Unit)	2 Year(s) Do not store above 30° C. Protect from direct sunlight.
For generic drugs (me-too Status)	NEPHROTOX (063727)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	--
GMP status of the firm	Inspection for renewal of DML conducted on 21.03.2023.
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
430	
Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	BAARIQ PHARMACEUTICALS Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore (000715)
Application Form Dy. No / Tracking ID & date of submission	(SEU-JPB-3A69, 2025-04-23)
Detail of Fee Submitted	37000.0, 2025-04-22,
The proposed proprietary name / brand name	TARTARIQ-B Oral Powder
Label Claim	Each 100 gm Powder Contains: Bromhexine HCl BP.....1 gm Tartaric Acid BP.....15 gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100 gm-De-Controlled, 1000 gm-De-Controlled, 10000 gm-De-Controlled, 250 gm-De-Controlled, 2500 gm-De-Controlled, 25000 gm-De-Controlled, 500 gm-De-Controlled, 5000 gm-De-Controlled
Shelf Life (Unit)	2 Year(s) Do not store above 30° C. Protect from direct sunlight.

	For generic drugs (me-too Status)	BROMOTARIC (089822)
	Pharmacotherapeutic Group of (API)	Bronchodilator, Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection for renewal of DML conducted on 21.03.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
431	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(5GU-QPN-BNHP, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	CLOZAPLEX Oral Liquid VET
	Label Claim	Each ml contains, Oxyclozanide BP.....30mg Levamisole HCl BP..... 15mg Cobalt Sulphate BP..... 0.75mg Sodium Selenite 0.35mg Vitamin K3 BP.....3.0mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De- Controlled,2.5Liters-De-Controlled,250ml-De- Controlled,5 Liters-De-Controlled,500ml-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	SHINAZAN PLUS Liquid, Reg# 079221, Mallard Pharmaceuticals Multan
	Pharmacotherapeutic Group of (API)	Antibiotics, Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
432	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(MJV-VNS-2JT6, 2025-05-22)

	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	COLRO Oral Liquid (Vet)
	Label Claim	Each 100ml Contains: - Enrofloxacin.....10 gm Colistin Sulphate USP.....50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De- Controlled,2.5Liters-De-Controlled,500ml-De- Controlled,5Liters-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	Enroton Solution DRAP Reg# 049793, M/S Attabak Pharmaceutical, Islamabad
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
433	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(G5E-AQW-PHAR, 2025-06-12)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	ENCOZIN Oral Liquid VET
	Label Claim	Each 100ml contains: Enrofloxacin 10 gm Bromhexine HCl BP 5 gm Colistin Sulphate USP..... 50 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,2.5Liters-De- Controlled,200ml-De-Controlled,500ml-De- Controlled,5Liters-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	INTER FLOX Liquid DRAP Reg # 078241, M/S. Leads Pharmaceuticals, Islamabad.
	Pharmacotherapeutic Group of (API)	Antibiotic / Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
434	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(Y36-P1D-9NDZ, 2025-06-13)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	HEPARIX ORAL POWDER (VET)
	Label Claim	Each ml contains:- L-Carnitine USP..... 50mg Betain USP..... 20mg Inositol USP..... 7mg Choline Chloride USP..... 100mg Sorbitol USP..... 200mg Magnesium Sulphate USP..... 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ML-De-Controlled,10LITER-De- Controlled,2.5LITER-De-Controlled,200ML-De- Controlled,500ML-De-Controlled,5LITER-De- Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	HEPABAR Oral Liquid DRAP Reg # 080733, M/S. BAARIQ Pharmaceuticals, Lahore.
	Pharmacotherapeutic Group of (API)	Hepatoprotective and Lipotropic Agents
	Name, address of Manufacturing site:	--
	GMP status of the firm	PANEL RECOMENDED THE RENEWAL OF DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
435	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(LQV-M7X-T4DG, 2025-06-13)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	HEPTAFIC-E Oral Suspension VET
	Label Claim	Each 100ml contains:- Silymarine BP.....2100mg Vitamin E

		BP.....15000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,10Liters-De-Controlled,2.5Liters-De-Controlled,200ml-De-Controlled,500ml-De-Controlled,5Liters-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	Liver Fit Oral Suspension DRAP Reg # 063743, M/s Westmont Pharmaceutical Industry, Gujar Khan Rawalpindi.
	Pharmacotherapeutic Group of (API)	Hepatoprotectant / Liver Tonic (VET)
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
436	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(PPQ-H78-MVUS, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	LEVAFINE Oral Powder VET
	Label Claim	Each 100 gm contains Levamisole HCl USP..... 15 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,10kg-De-Controlled,2.5Kg-De-Controlled,200gm-De-Controlled,25kg-De-Controlled,5 Kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	LEVASHELL 15 Powder DRAP Reg.# 075766, Inshall Pharma Islamabad.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
437	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(6P7-7YM-8NAS, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	LINCOFIC Oral Powder VET
	Label Claim	Each gm Powder Contains:- LINCOMYCIN HCL USP.....110mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,10kg-De-Controlled,2.5kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	I-Link Powder Drap Reg#062065,M/S International Pharma, Lahore
	Pharmacotherapeutic Group of (API)	Atibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
438	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(WDB-P9P-R3VG, 2025-05-22)
	Detail of Fee Submitted	37000.0, 2025-05-19,
	The proposed proprietary name / brand name	VITAL-GP Oral Powder VET
	Label Claim	Each 1000 gm contains, Vitamin A USP..... 25MIU Vitamin D3 USP..... 2.5MIU Vitamin E USP 5000mg Vitamin K3 USP 4000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,10kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	LIONS ADED Oral Powder DRAP Reg.# 058979,M/S. Biogen Pharma, Rawat.
	Pharmacotherapeutic Group of (API)	Multivitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License. inspection was conducted on12.12.2022 for renewal of DML.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
439	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Biorific Pharma Plot 143, Industrial Triangle, Kahuta Road. (000848)
	Application Form Dy. No / Tracking ID & date of submission	(YV7-L1X-ANWJ, 2025-06-12)
	Detail of Fee Submitted	37000.0, 2025-06-03,
	The proposed proprietary name / brand name	TYLOFIC-98 Oral Powder VET
	Label Claim	Each 100gm Contains:- Tylosin as Tartrate USP.....98gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,10kg-De-Controlled,2.5kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in dry and cool place away from direct sun light.
	For generic drugs (me-too Status)	AMSETYL-98 ORAL POWDER REG# 101999, M/S. AMSTER LABORATORIES RAWAT
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Recommended the Renewal of Drug Manufacturing License
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
440	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)

	Application Form Dy. No / Tracking ID & date of submission	(631-34S-MT42, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Xylan Injection 50ml
	Label Claim	EACH ML CONTAINS: - XYLAZINE HCL USP....23.32MG (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25° C. Protect from direct sunlight and heat
	For generic drugs (me-too Status)	XYLAX INJECTION 50mL Reg. # 078207 M/S. MYLAB PHARMA, BAHAWALPUR
	Pharmacotherapeutic Group of (API)	Hypnotics and sedatives
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
441	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(UG1-U42-WAM4, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Xylan Injection 100ml
	Label Claim	EACH ML CONTAINS: - XYLAZINE HCL.... 23.32MG (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25° C. Protect from direct sunlight and heat
	For generic drugs (me-too Status)	XYLAX INJECTION 100mL Reg. # 078207 M/S. MYLAB PHARMA, BAHAWALPUR
	Pharmacotherapeutic Group of (API)	Hypnotics and sedatives
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

442	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(9PT-TQU-Y5X3, 2025-06-23)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Marbocin Injection 20ml
	Label Claim	EACH ML CONTAINS: - MARBOFLOXACIN.....100MG (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Protect from Direct sunlight and heat, store at room temperature.
	For generic drugs (me-too Status)	MARBOFLOX INJECTION 20mL By M/S. SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Fluoroquinolones
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
443	Decision	
	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(G3T-DE3-GDH7, 2025-06-23)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Marbocin Injection 50ml
	Label Claim	EACH ML CONTAINS: - MARBOFLOXACIN.....100MG (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Protect from Direct sunlight and heat, store at room temperature.
	For generic drugs (me-too Status)	MARBOXIN INJECTION 50mL By M/S. LEADS PHARMA, ISLAMABAD (Reg. No. 117121)
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Fluoroquinolones
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
444	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(5Y5-A5S-T8BB, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	Furoset Injection 50ml
	Label Claim	EACH ML CONTAINS:- FUROSEMIDE.....50MG (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25° C. Protect from direct sunlight and heat
	For generic drugs (me-too Status)	Duretic Injection 50mL Reg. # 078208 M/S. MYLAB PHARMA, BAHAWALPUR
	Pharmacotherapeutic Group of (API)	Diuretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
445	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(ARS-7RG-L5A9, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	ADE-MEC Injection 50ml
	Label Claim	EACH ML CONTAINS:- IVERMECTIN USP.....10MG VITAMIN A.....25000IU VITAMIN D3.....3750IU VITAMIN E.....25MG (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25° C. Protect from direct sunlight and heat
	For generic drugs (me-too Status)	Biomec Injection 50mL Reg. # 046563 M/s Leads Pharma, Islamabad

	Pharmacotherapeutic Group of (API)	ANTHALMINTIC/VITAMIN
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
446	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(ZD4-A5R-Y29W, 2025-06-23)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	DI-PRIM Injection 50ml
	Label Claim	Each 1ml contains: TRIMETHOPRIM BP..... 80mg SULPHADIAZINE USP..... 400mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Protect from Direct sunlight and heat, store at room temperature.
	For generic drugs (me-too Status)	TRISUL-48% Injection of M/S. INTERVAC PHARMA, LAHORE
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
447	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(UA4-NRM-Q58P, 2025-06-23)
	Detail of Fee Submitted	37000.0, 2025-06-19,
	The proposed proprietary name / brand name	DI-PRIM Injection 100ml
	Label Claim	Each ml contains: TRIMETHOPRIM BP..... 80mg SULPHADIAZINE USP..... 400mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25° C. Protect from direct sunlight.
	For generic drugs (me-too Status)	TRISUL-48% Injection of M/S. INTERVAC PHARMA, LAHORE
	Pharmacotherapeutic Group of (API)	ANTIBACTERIAL
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate issued on 08.102024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
448	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(3YJ-4XV-6H3A, 2025-07-25)
	Detail of Fee Submitted	37000.0, 2025-06-11,
	The proposed proprietary name / brand name	Lysovit Oral Powder
	Label Claim	Each gm contains:- Lysozyme 220mg Vitamin E (50 SD)..... 5mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Vitozyme Powder Reg. # 049622(selmore pvt ltd)
	Pharmacotherapeutic Group of (API)	Immune Booster
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
449	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(5WY-XYR-AXZW, 2025-07-03)

	Detail of Fee Submitted	37000.0, 2025-06-18,
	The proposed proprietary name / brand name	Hycosul Powder
	Label Claim	Each gm contains: Colistin Sulphate BP..... 4mg Neomycin Sulphate USP.....70mg Chlortetracycline Hydrochloride USP.....80mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,2kg-De- Controlled,3kg-De-Controlled,500gm-De- Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Trifle-C Powder Registration No: 088097 Company Name: Selmore Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP to firm was granted on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
450	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(BS5-UQZ-TUAN, 2025-07-04)
	Detail of Fee Submitted	37000.0, 2025-06-11,
	The proposed proprietary name / brand name	Doxylate Powder
	Label Claim	Each 100 gm contains: Doxycycline hyclate USP.....50g (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg- De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Dox Plus 50% Water Soluble Powder Reg. # 082498(Bio-Labs (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
451	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(H3B-BDQ-9QPU, 2025-07-04)
	Detail of Fee Submitted	37000.0, 2025-06-18,
	The proposed proprietary name / brand name	Multivet Powder
	Label Claim	Each gm contains: Vitamin A..... 20,000 IU Vitamin B2 USP.....20mg Vitamin D 4,000 IU Vitamin B6 USP.....6mg Vitamin E 8mg Vitamin B12 USP.....30mcg Vitamin K3 USP.....9mg Folic Acid BP.....2mg Vitamic C BP.....10mg Nicotinic Acid BP.....100mg Vitamin B1 USP.....1.25mg Calcium Pantothenate BP..... 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm,100gm,500gm,1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Soluvit Super Registration No: 046661 Company Name: Selmore Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Multivitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
452	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(J97-YPT-4GXM, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Vitastar Powder
	Label Claim	Each kg contains: Vitamin A.....10.0MIU Vitamin D3.....3.0MIU Vitamin

		E.....5000IU Vitamin K3.....3000mg Vitamin C BP.....30000 mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Bio-Dek C Water Soluble Powder Reg. # 035042(Bio-Labs (Pvt.) Ltd.)
	Pharmacotherapeutic Group of (API)	Multivitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
453	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(LW5-RTL-4RDD, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-06-11,
	The proposed proprietary name / brand name	Vitasom Powder
	Label Claim	Each 100 gm contains: Ammonium Chloride BP.....70g Methionine BP.....10g Sorbitol BP.....5g Vitamin A.....150000 IU Vitamin C BP.....10g (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm,100gm,500gm,1kg,2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Gumbo Rex Water Soluble Powder Reg. # 039977(Bio-Labs (Pvt.) Ltd. (Animal)
	Pharmacotherapeutic Group of (API)	Diuretic/ Hepatic stimulator
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
454	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(M7Y-723-HXSJ, 2025-07-04)
	Detail of Fee Submitted	37000.0, 2025-06-11,
	The proposed proprietary name / brand name	Growvit Powder
	Label Claim	Each gm contains: Ammonium Chloride BP.....450mg Magnesium Sulphate Heptahydrate BP....250mg Sodium Sulphate BP.....245mg Sorbitol BP.....55mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,250gm-De-Controlled,2kg-De-Controlled,3kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Bio-Reyl Water Soluble Powder Reg. # 043176(Bio-Labs (Pvt.) Ltd. (Animal)
	Pharmacotherapeutic Group of (API)	Renal Tonic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
455	Evaluation Remarks	
	Decision	
	Approved	
455	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(MQ8-6HP-T1PW, 2025-07-03)
	Detail of Fee Submitted	37000.0, 2025-06-18,
	The proposed proprietary name / brand name	Bromtar Powder
	Label Claim	Each gm contains: Bromhexine HCl BP.....10mg Tartaric Acid BP.....150mg (innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm,100gm,500gm,1kg,2kg,3kg,5kg-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Bronchofit Powder(reg.071073)SELMORE PHARMACEUTICALS (PVT) LTD
	Pharmacotherapeutic Group of (API)	Mucolytic Agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was issued to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
456	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(MSN-X92-EHRH, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Uronax-SC Powder
	Label Claim	Each 100 gm contains: Methenamine BP.....90 gm Vitamin B1 USP.....700 mg Vitamin C BP.....100 mg Sorbitol BP.....5000mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Vety Flush W/S Powder Reg. # 019938
	Pharmacotherapeutic Group of (API)	Diuretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
457	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(PJ6-X4R-HU7G, 2025-07-04)

	Detail of Fee Submitted	37000.0, 2025-06-18,
	The proposed proprietary name / brand name	Residovit Powder
	Label Claim	Each 100gm contains: Paracetamol BP..... 20g Vitamin C BP.....5g Potassium carbonate BP.....12.5g Sodium Bicarbonate....12.5g Vitamin E 12.5g (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 500g, 1Kg, 2.5Kg, 5Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	CEMOL ORAL POWDER (SELMORE PHARMACEUTICALS (PVT) LTD)
	Pharmacotherapeutic Group of (API)	Antipyretic, Analgesic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
458	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(QHJ-NMD-D2TN, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Cyclosta Powder
	Label Claim	Each gm contains: Chlortetracycline HCl USP.....200mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg- De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Chlortin 200 Water Soluble Powder Reg. # 041290
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

459	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(TS7-HU4-5P1G, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-06-11,
	The proposed proprietary name / brand name	Durafer Extra Powder
	Label Claim	Each 100 gm contains: Furosemide USP.....2000mg Extract belladonna. 200mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Frusa Fas W/S Powder Reg. # 058757
	Pharmacotherapeutic Group of (API)	Diuretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
460	Evaluation Remarks	
	Decision	
	Approved	
460	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(VTG-LDY-1BJV, 2025-07-12)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Prevecocx-50 Powder
	Label Claim	Each gm contains: Amprolium HCl USP.....500mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50gm,100gm,500gm,1kg,2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	Ras Amprolium 50 Oral Powder Reg. # 101960(Ras Pharmaceutical (Pvt.)Ltd.
	Pharmacotherapeutic Group of (API)	Anticoccidal Agent
	Name, address of Manufacturing site:	--

	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
461	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission	(ZT3-54V-LU8W, 2025-07-07)
	Detail of Fee Submitted	37000.0, 2025-06-18,
	The proposed proprietary name / brand name	Doxycol Powder
	Label Claim	Each 100gm contains: Doxycycline HCl 20gm Colistin Sulphate BP.....40,000,000 IU (innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm,100gm,500gm,1kg, 2kg,3kg,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Keep away from heat, moisture & children.
	For generic drugs (me-too Status)	SELDOX-C POWDER Registration No: 058710 Company Name: Selmore Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted to firm on 08.06.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
462	Approved	
	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(J6Z-D2N-X75U, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Synoxy Cure 200 LA Injection
	Label Claim	Each ml contains: Oxytetracycline (as HCl) USP.....200mg (USP Specifications)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-Oxyne 20% Injection (Reg. No. 088832) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved subject to pre-registration change of Oxytetracycline HCl to Oxytetracycline base along with submission of requisite fee of pre-registration variation and confirmation of pack size.	
463	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore (001005)
	Application Form Dy. No / Tracking ID & date of submission	(BU8-D1Q-777Y, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	BROTA Oral Liquid
	Label Claim	Each ml Contains: Bromhexine HCl ----- ----- 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled, 100ml-De-Controlled, 2.5 L-De-Controlled, 25 L-De-Controlled, 250ml-De-Controlled, 5 L-De-Controlled, 500ml-De-Controlled, 50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Bromozone Liquid of M/s Mallard Pharmaceuticals (Reg. No. 063780)
	Pharmacotherapeutic Group of (API)	Mucolytic Agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 28.03.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
464	Case Category	Routine (Sara Mehreen)

	Name, address of Applicant.	Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore (001005)
	Application Form Dy. No / Tracking ID & date of submission	(LZP-U5Q-LPN8, 2025-04-22)
	Detail of Fee Submitted	37000.0, 2025-04-22,
	The proposed proprietary name / brand name	Fleva-150 Oral Powder
	Label Claim	Each 100gm Contains: Levamisole HCl BP..... 15gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10kg-De-Controlled,12gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Lemisole 15% Water Soluble Powder of M/s Attabak Pharma (Reg. No. 058883)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 28.03.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
465	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore (001005)
	Application Form Dy. No / Tracking ID & date of submission	(9PJ-N8Y-U5T7, 2025-04-08)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	F-SIL 2.5% Oral Liquid
	Label Claim	Each 100ml Contains: Toltrazuril ----- 2.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 L-De-Controlled,25 L-De-Controlled,250ml-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Toltrazic Oral Liquid of M/s Westmont Pharmaceuticals (Reg. No.063750)

	Pharmacotherapeutic Group of (API)	Antiparasitic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 28.03.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
466	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore (001005)
	Application Form Dy. No / Tracking ID & date of submission	(33H-65Y-UUR3, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	TILMI-F Oral Liquid
	Label Claim	Each ml Contains: Tilmicosin Phosphate USP----- ----- 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 L-De-Controlled,25 L-De-Controlled,250ml-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	Motil Liquid of M/s Breez Pharma (Reg. No. 075671)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 28.03.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
467	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Medhouse Pharmaceuticals (PVT) Ltd Mouza Mangowal Garbi, 1-Km off Chahmughlan Road (000949)
	Application Form Dy. No / Tracking ID & date of submission	(3B7-EJQ-6M23, 2025-06-11)
	Detail of Fee Submitted	37000.0, 9400 2025-05-20, 2025-11-19
	The proposed proprietary name / brand name	ENROCYSTINE ORAL SOLUTION

	Label Claim	Each 1000ml contains:- Enrofloxacin USP 100 Gm N-Acetylcysteine BP..... 186 Gm Propylene Glycol BP..... 100 Gm Benzyl Alcohol BP..... 20 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at cool and dry place. 4 of 8 ☐ Store at temperature (about 25°C) ☐ Protect from direct sun light and heat. ☐ Keep the bottle tightly sealed when not in use.
	For generic drugs (me-too Status)	Penprol Solution (Reg. No. 063718)
	Pharmacotherapeutic Group of (API)	Antibiotic and Antioxidant
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection for grant of DML was conducted on 05.11.2021 & DML was granted on 27.12.2021
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
468	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	POULVET PHARMACEUTICAL (PVT) LTD 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN (000970)
	Application Form Dy. No / Tracking ID & date of submission	(1YZ-BN9-DU73, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-12-17,
	The proposed proprietary name / brand name	Hepa Poul Oral Solution
	Label Claim	Each 100ml contains L-Carnitine - 50mg Vitamin B6 - 50mg Vitamin B12 - 1.5mg Nicotinamide - 15mg Calcium Pantothenate - 100mg Sorbitol - 10gm DL Methionine - 1000mg L-arginine - 300mg L Citruline - 200mg L-Glycine - 200mg L-Aspartic Acid - 150mg L-Lysine - 100mg L-Glutamic Acid - 150mg L-Ornithine- 2000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s) Do not store above 30°C. Protect from direct sun light.
	For generic drugs (me-too Status)	Crdisol Oral Solution of RAS Pharma (Reg#106724)
	Pharmacotherapeutic Group of (API)	Multivitamins & Amino Acids
	Name, address of Manufacturing site:	--
	GMP status of the firm	INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL

		DIRECTOR, DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG, DRAP, LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for confirmation of me-too status.	
469	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	BAARIQ PHARMACEUTICALS Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore (000715)
	Application Form Dy. No / Tracking ID & date of submission	(PYT-RN8-M331, 2025-04-21)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	Vitariq-C 1000
	Label Claim	Each 100 gm Powder Contains: Vitamin C (B.P).....100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled, 1000 gm-De-Controlled, 10000 gm-De-Controlled, 250 gm-De-Controlled, 2500 gm-De-Controlled, 25000 gm-De-Controlled, 500 gm-De-Controlled, 5000 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Do not store above 22° C. Protect from direct sunlight.
	For generic drugs (me-too Status)	SANNAVIT C-100 (025368)
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection for renewal of DML conducted on 21.03.2023.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
470	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(VSP-XA3-L1PR, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,

	The proposed proprietary name / brand name	Albosyn-2.5 Oral Suspension
	Label Claim	Each 100 ml contains: Albendazole.....2.5gm (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Zolatin Oral Suspension (Reg. No. 101437) by Aamster Laboratories, Islamabad
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
471	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(9Y6-XJS-LQ4X, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Albosyn-10 Oral Suspension
	Label Claim	Each 100 ml contains: Albendazole.....10gm (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Henzole-10% Suspension (Reg. No. 120743) by Huzaifa International, Sargodha
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

472	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(RYE-1AW-2PG1, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Amantasyn-98 Oral Powder
	Label Claim	Each 100 grams contains: Amantadine HCl.....98gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Amentaskill-98% Powder (Reg. No. 111238) by Bioskils Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
473	Evaluation Remarks	
	Applicant attached an article titled as "Development of a competitive immunochromatographic assay for the sensitive detection of amantadine in chicken muscle" while describing clinical pharmacology of Amantadine.	
	Decision	
	Deferred	
473	Deferred for confirmation of target species.	
	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(X25-LY1-PRMZ, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Amprosyn-90 Oral Powder
	Label Claim	Each 100gm contains Amprolium HCl USP.....90gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN

	For generic drugs (me-too Status)	Hanster-90% Water Soluble Powder (Reg. No. 102218) by Dhaans Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
474	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(TEP-V7B-3QWJ, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Doxysyn-20 Oral Powder
	Label Claim	Each 100gm contains: Doxycycline HCl USP.....20gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Wealdox Powder (Reg. No. 049562) by Mallard Pharmaceuticals (Pvt.) Ltd., 23-Km Lahore Road, Multan
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
475	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(WZ2-BD9-6GG8, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-06-26,

	The proposed proprietary name / brand name	Doxysyn-50 Oral Powder
	Label Claim	Each 100gm contains: Doxycycline HCl.....50gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Vetroxin Oral Water Soluble Powder (Reg. No. 115052) by Athan Pharmaceuticals, Hattar
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
476	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(QUH-2P7-2GL6, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Doxysyn Plus-10/20
	Label Claim	Each 1000gm contains: Doxycycline HCl USP.....200gm Tylosin Tartrate USP.....100gm Colistin Sulphate BP.....400MIU Bromhexine HCl BP.....3gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Resbro Oral Water Soluble Powder (Reg. No. 092174) by Sanna Laboratories
	Pharmacotherapeutic Group of (API)	Antibiotic, Mucolytic, Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
477	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(HVVH-J7S-4QLV, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Doxysyn Plus-20/40 Oral Powder
	Label Claim	Each 100gm contains: Doxycycline HCl USP.....40gm Tylosin Tartrate USP.....20gm Colistin Sulphate BP.....10gm Bromhexine HCl BP.....2gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Respiskill-400 Powder (Reg. No. 113505) by Bioskils Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic, Mucolytic, Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
Evaluation Remarks		
Decision		
Approved		
478	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(Y3Y-XSJ-PDMX, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Enrosyn-10 Injection
	Label Claim	Each ml contains: Enrofloxacin USP.....100mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.

	For generic drugs (me-too Status)	Bio-E-Floxacin 10% Injection (Reg. No. 117227) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved subject to change of finished product specifications from Innovator to BP and submission of requisite fee for pre-registration variation fee.	
479	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(P81-A2S-6GPR, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Enrosyn-10 Oral Liquid
	Label Claim	Each 100ml contain: Enrofloxacin USP.....10 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li- De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-E-Floxacin 10% Miscible Liquid (Reg. No. 021289) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved subject to change of finished product specifications from Innovator to BP and submission of requisite fee for pre-registration variation fee.	
480	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(HEZ-4QQ-Q9VV, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,

	The proposed proprietary name / brand name	Enrosyn-20 Injection
	Label Claim	Each ml contains: Enrofloxacin USP.....200mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-E-Floxacin 20% Injection (Reg. No. 117223) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved subject to change of finished product specifications from Innovator to BP and submission of requisite fee for pre-registration variation fee.	
481	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(UWA-9GE-6MN9, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Enrosyn-25 Oral Liquid
	Label Claim	Each 100ml contain: Enrofloxacin USP.....25 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li- De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Enro Gold Oral Solution (Reg. No. 058961) by Medicure Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

	Approved subject to change of finished product specifications from Innovator to BP and submission of requisite fee for pre-registration variation fee.	
482	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(JXZ-Z56-4L45, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Enrosyn-C 10 Oral Liquid
	Label Claim	Each 100ml contain: Enrofloxacin USP.....10gm Colistin Sulphate USP 50MIU (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	EC Skill-10 Liquid (Reg. No. 111251) by Bioskils Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
483	Evaluation Remarks	
	Decision	
	Approved	
483	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(TTA-PQ1-AYW1, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Florosyn-23 Oral Liquid
	Label Claim	Each 100 ml contains: Florfenicol.....23gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Floskill-23% Liquid (Reg. No. 113510) by Bioskils Pharmaceuticals

	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
484	Approved	
	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(S2M-PUL-RB33, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Florosyn C-25 Oral Liquid
	Label Claim	Each 100 ml contains: Florfenicol.....25gm Colistin Sulphate USP.....50MIU (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml, 100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li- De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Florotin-25 Liquid (Reg. No. 093840) by Aptly Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
485	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(Z9Y-4EQ-A3VW, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Gentasyn-5 Injection
	Label Claim	Each ml contains: Gentamicin (as Gentamicin Sulphate) USP.....50mg (USP Specifications)

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Gentasym 5% Injection (Reg. No. 022739) by Symans Pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
486	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(SN5-DHH-YBXW, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Gentasyn-20 Injection
	Label Claim	Each ml contains: Gentamicin (as Gentamicin Sulphate) USP.....200mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Gelox-20 Injection (Reg. No. 099436) by Wimits Pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
487	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)

	Application Form Dy. No / Tracking ID & date of submission	(TVX-UZE-5HSE, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Gentasyn Forte Injection
	Label Claim	Each 100ml contains: Gentamicin Sulphate USP.....5gm Tylosin Tartrate USP.....10gm Colistin Sulphate USP.....20MIU (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Cartel Injection (Reg. No. 116952) by Mylab (Pvt.) Ltd., Bahawalpur
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
488	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(ZSW-89P-1D3T, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Iversyn-10 Injection
	Label Claim	Each ml contains: Ivermectin 10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Animectin 1% Injection (Reg. No. 117230) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Pack size needs to be confirmed.	
	Decision	
	Approved	
489	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(SL9-ZJE-6BMN, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Iversyn-20 Injection
	Label Claim	Each ml contains: Ivermectin BP.....20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Animectin 2% Injection (Reg. No. 117229) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
490	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(SSQ-HZA-5HQR, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Iversyn-30 Injection
	Label Claim	Each ml contains: Ivermectin BP.....31.5mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.

	For generic drugs (me-too Status)	Vectin Injection (Reg. No. 112158) by Aamster Lab, Rawalpindi
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
491	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(E8Z-AY1-11UA, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Levasyn-15 Oral Powder
	Label Claim	Each 100gm contains: Levamisole HCl USP.....15gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Levapoul Water Soluble Powder (Reg. No. 116808) by Star Laboratories (Pvt.) Ltd., Lahore
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
492	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(XJX-Z9W-QY5W, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,
	The proposed proprietary name / brand name	Levasyn Forte Oral Drench

	Label Claim	Each 100 ml contains: Levamisole HCl USP.....1.5gm Oxytoclozanide BP.....3gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml, 100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Clozasol Drench (Reg. No. 078328) by Wimits Pharmaceuticals, Lahore
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
493	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(DN7-76W-NZWD, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Lincosyn-1.1 Oral Powder
	Label Claim	Each 100gm contains: Lincomycin as HCl USP.....1.1gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-Mycin Water Soluble Powder (Reg. No. 082499) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
494	Case Category	New License (Sara Mehreen)

Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
Application Form Dy. No / Tracking ID & date of submission	(DHE-5SD-Z8BZ, 2025-07-20)
Detail of Fee Submitted	37000.0, 2025-06-26,
The proposed proprietary name / brand name	Lincosyn-4.4 Oral Powder
Label Claim	Each 100gm contains: Lincomycin as HCl USP.....4.4gm (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
For generic drugs (me-too Status)	Lincoskill-4.4 Powder (Reg. No. 111242) by Bioskils Pharmaceuticals
Pharmacotherapeutic Group of (API)	ANTIBIOTIC
Name, address of Manufacturing site:	--
GMP status of the firm	DML was granted on 03.06.2025.
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	New License (Sara Mehreen)
Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
Application Form Dy. No / Tracking ID & date of submission	(H1D-3WW-XUBM, 2025-07-20)
Detail of Fee Submitted	37000.0, 2025-06-26,
The proposed proprietary name / brand name	Lincosyn-11 Oral Powder
Label Claim	Each 100gm contains: Lincomycin as HCl USP.....11gm (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
For generic drugs (me-too Status)	Bio-Mycin 11% Powder (Reg. No. 103971) by Bio-Labs
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	DML was granted on 03.06.2025.
Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
496	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(U6E-T5Z-433G, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Meloxsyn-5 Injection
	Label Claim	Each ml contains: Meloxicam BP.....5mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Diclostar Super Injection (Reg. No. 053957) by Star Labs
	Pharmacotherapeutic Group of (API)	NSAID, Analgesic; Anti-inflammatory.
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
497	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(NL2-6PM-L6WL, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Meloxsyn-7.5 Injection
	Label Claim	Each ml contains: Meloxicam BP.....7.5mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP

		OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Melo Grand 7.5 Injection (Reg. No. 111554) by Grand Pharma (Pvt.) Ltd., Rawat, Rawalpindi
	Pharmacotherapeutic Group of (API)	NSAID, Analgesic, Anti inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
498	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(XY4-T25-Q2W3, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Meloxsyn-10 Injection
	Label Claim	Each ml contains: Meloxicam BP.....10mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Camrold 10 Liquid Injection (Reg. No. 109003) by Harrolds Pharma, AJK
	Pharmacotherapeutic Group of (API)	NSAID, Analgesic, Anti inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
499	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(TN1-A9V-Y23V, 2025-07-21)

	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Meloxsyn-20 Injection
	Label Claim	Each ml contains: Meloxicam BP.....20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Camrold 20 Liquid Injection (Reg. No. 109006) by Harrolds Pharma, AJK
	Pharmacotherapeutic Group of (API)	NSAID, Analgesic, Anti inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
500	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(BN4-8H4-YVBY, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Neosyn-72 Oral Powder
	Label Claim	Each 100gm contains: Neomycin Sulphate....72 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Neomycin-72 Water Soluble Powder (Reg. No. 029669) by Farm Aid Group
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
501	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(XX1-Z9H-SUSL, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Synobrom-10 Oral Liquid
	Label Claim	Each 100ml Contains: Bromhexine HCl BP.....10 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	ET Bromhexine Oral Liquid (Reg. No. 112312) by Eterna Pharma (Pvt.) Ltd. AJK.
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
502	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(3Q4-A56-8HXS, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Synoxy Cure-95 Oral Powder
	Label Claim	Each 100gm contains: Oxytetracycline HCl USP.....95gm (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.

	For generic drugs (me-too Status)	Oxymix Powder (Reg. No. 023439) by Symans Pharmaceuticals (Pvt.) Ltd., Lahore
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
503	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(ZV4-8GW-RYWW, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Synoxy Cure-300 Injection
	Label Claim	Each ml contains: Oxytetracycline (as HCl) USP.....300mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-Oxyne 30% Injection (Reg. No. 088833) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved subject to change of finished product specifications from Innovator to BP and submission of requisite fee for pre-registration variation fee.	
504	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(Y71-DJU-LGUH, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Tilmosyn-25 Oral Liquid

	Label Claim	Each ml contains: Tilmicosin (as Phosphate) USP.....250mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Martil Liquid (Reg. No. 093772) by Aptly Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
505	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore (001005)
	Application Form Dy. No / Tracking ID & date of submission	(X1E-SPN-SU63, 2025-04-08)
	Detail of Fee Submitted	37000.0, 2025-04-07,
	The proposed proprietary name / brand name	BROTHOL Oral Solution
	Label Claim	Each ml Contains: Bromhexine HCl BP----- -- 20mg Menthol USP----- 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 L-De-Controlled,25 L-De-Controlled,250ml-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C. Protect from direct sunlight, heat and moisture.
	For generic drugs (me-too Status)	E-Mint Solution of M/s Evergreen Pharmaceuticals (Reg. No. 088858)
	Pharmacotherapeutic Group of (API)	Mucolytic Agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 28.03.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

506	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(WL3-MEN-YE66, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Florosyn-25 Oral Liquid
	Label Claim	Each 100 ml contains: Florfenicol.....25gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li- De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Floskill-25% Liquid (Reg. No. 113511) by Bioskils Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
507	Decision	
	Approved	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(23B-RHS-371Q, 2025-05-18)
	Detail of Fee Submitted	37000.0, 2025-05-15,
	The proposed proprietary name / brand name	JF ZURIL 2.5% Oral Suspension
	Label Claim	Each ml Contains: Toltrazuril 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 ml and 500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Blow 30 degree cecius
	For generic drugs (me-too Status)	NOCOX 2.5%
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate issued on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
508	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(GJ6-LN9-ZWRG, 2025-04-27)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	AMOXYCOLI INJECTION
	Label Claim	Each ml Contains Amoxycillin (as Trihydrate) USP.....100mg Colistin (as Sulphate) USP 25MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml & 50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool, dry place, protected from light and at a temperature not exceeding 25°C.
	For generic drugs (me-too Status)	Colimoxin Selmore Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
509	Decision	
	Rejected	
	Rejected due to non-confirmation of Penicillin Injection Section.	
509	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(J9N-TMY-SNYL, 2025-04-24)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	GENTAMYCIN - 40 INJECTION
	Label Claim	Each ml contains Gentamycin Sulphate Eq. Gentamycin USP..... 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Glass Vial 50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C. Tightly sealed. Keep the vial in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	Gentawan 100ml) of M/s Nawan Laboratories Karachi
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotic
	Name, address of Manufacturing site:	--

	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
510	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(WAB-HDZ-VPAR, 2025-06-02)
	Detail of Fee Submitted	37000.0, 2025-05-31,
	The proposed proprietary name / brand name	JF-AMOXICLAV
	Label Claim	Each gm Contains Amoxicillin as Amoxicillin Trihydrate.....160 mg Clavulanic Acid as Potassium Clavulanate.....40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg & 500mg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Keep the container tightly closed in order to protect from moisture. Store in a dry place.
	For generic drugs (me-too Status)	CLAVET POWDER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Found comply with cGMP in Control, Process and documentation
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm was asked about Penicillin Section and they replied as "Penicillin injection section not approved".	
	Decision	
	Rejected	
	Rejected due to non-confirmation of Penicillin Oral Powder Section.	
511	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(SUM-YTL-1574, 2025-04-26)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JFMEC Injection
	Label Claim	Each ml contains Ivermectin 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml, 50ml,100ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)Blow 30 degree cecius
	For generic drugs (me-too Status)	Vectin 2% Injection (Reg. No. 109907)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
512	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(68P-ABQ-XNWQ, 2025-04-29)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JFMELOX INJECTION
	Label Claim	Each ml contains Meloxicam 7.5ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 & 100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Protect from light.
	For generic drugs (me-too Status)	Melo Grand 7.5 Injection (Reg. No. 111554)
	Pharmacotherapeutic Group of (API)	Analgesic & Anti-inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
513	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(UEM-T4X-NUEL, 2025-04-24)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JFNIRTO 34% INJECTION
	Label Claim	Each ml contains Nitroxnil 340mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Glass Vial 10m/50ml -De-Controlled

	Shelf Life (Unit)	2 Year(s)Blow 30 degree cecius
	For generic drugs (me-too Status)	Troxy-34% Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 034597)
	Pharmacotherapeutic Group of (API)	Antiparasitic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
514	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(T7B-QHT-GY7A, 2025-05-20)
	Detail of Fee Submitted	37000.0, 2025-05-16,
	The proposed proprietary name / brand name	JF-TILMI 250 Oral Liquid
	Label Claim	Each ml contains: Tilmicosin (as phosphate) USP.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 IITER & 500 ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30°C. Protect from direct sunlight.
	For generic drugs (me-too Status)	HICOS 250
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, macrolides
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
515	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(GYN-SV4-N2MG, 2025-04-30)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JF- TOLD INJECTION 20%
	Label Claim	Each ml Contains Toldimfos Sodium..... 200mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 300C. Protect from light. Keep out of the reach of children.
	For generic drugs (me-too Status)	Toldivet Injection Reg.No#043557
	Pharmacotherapeutic Group of (API)	Digestive system, other mineral products
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
516	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(TE6-YYT-Y14U, 2025-05-19)
	Detail of Fee Submitted	37000.0, 2025-05-15,
	The proposed proprietary name / brand name	JF ZITOX ORAL POWDER
	Label Claim	Each Kg Contains Sodium Benzoate USP.....500 g Ethanol beta amino Phosphoric acid 100 g Vitamin A Acetate 10,000,000 IU Vitamin E USP..... 2500 mg Vitamin K3 USP..... 1000 mg Vitamin C USP..... 2500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg & 500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place and away from light.
	For generic drugs (me-too Status)	ANTOTOX Reg # 044924
	Pharmacotherapeutic Group of (API)	Multivitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
517	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(P95-BYA-RL7U, 2025-07-20)

	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Neosyn Pro-15 Oral Powder
	Label Claim	Each gm contains: Neomycin Sulphate BP.....150mg Florfenicol.....100mg Oxytetracycline HCl USP.....300mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 2kg, 5kg, 10kg, 20kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Insha-Flor Powder (Reg. No. 103854) by Inshal Pharmaceutical Industries
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
518	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(UGJ-8ZW-5JGG, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Synoxy Cure-50 Injection
	Label Claim	Each ml contains: Oxytetracycline (as HCl) USP.....50mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Bio-Oxyne 5% Injection (Reg. No. 122043) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
	Approved subject to pre-registration change of Oxytetracycline HCl to Oxytetracycline base along with submission of requisite fee of pre-registration variation and confirmation of pack size.	
519	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(WH3-B2G-N89X, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Tylosyn-D Oral Liquid
	Label Claim	Each ml contains: Tylosin Tartrate USP.....200mg Doxycycline HCl USP.....250mg Colistin Sulphate USP.....0.5MIU Bromhexine HCl BP.....12mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Grand Tylcobrox Oral Liquid (Reg. No. 103805) by Grand Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic, Expectorant
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Pack size needs to be confirmed.	
	Decision	
	Approved	
520	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(ZN7-MPH-95HL, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	Oxyvet Forte Injection
	Label Claim	Each ml contains: Oxytetracycline (as HCl) USP.....300mg Flunixin (as Meglumine) USP.....20mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	5ml, 10ml, 50ml, 100ml, 1000ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Oxymore-F Injection (Reg. No. 120803) by Moreno Iglesias Research Laboratories (Pvt) Ltd., Lahore
	Pharmacotherapeutic Group of (API)	Antibiotic, NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
521	Case Category	Routine (Sara Mehreen)
	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	(ZN9-AVB-6ARD, 2025-03-27)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	Vetec Gold
	Label Claim	Each KG Contains Vitamin A USP.....0.8 gm Vitamin D3 USP.....0.16 gm Vitamin E USP..... 0.38 gm Vitamin B1 USP.....1 gm Vitamin B2 USP.....1.25 gm Vitamin 12 USP.....0.001 gm Vitamin B3 USP.....6.25 gm Copper sulphate.....0.25gm Magnesium sulphate USP.....25gm Calcium chloride USP.....0.023gm Manganese sulphate.....10gm Potassium iodide.....0.5gm Sodium selenite USP.....0.01gm Dicalcium phosphate USP.....150gm Sodium chloride USP.....120gm Vitamin B6 USP.....4gm Zinc sulphate USP.....2.17gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store below 25 o C. ☐ Protect from moisture and sunlight. ☐ Keep out of children's

		reach.
	For generic drugs (me-too Status)	White Gold w/s poder,058842
	Pharmacotherapeutic Group of (API)	Multivitamins & Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	GOOD
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
522	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(SJJ-725-PGL4, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	ENDO FORTE LIQUID
	Label Claim	Each 100ml contains: Fenbendazole BP..... 5gm Triclabendazole BP..... 5gm Ivermectin BP..... 0.100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,10Ltr-De-Controlled,150ml-De-Controlled,1Ltr-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled,5Ltr -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ENDO TRY LIQUID REG. # 120770 M/S BIORISE PHARMA
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
523	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(Q3G-YX5-AJV7, 2025-01-14)

	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	ENRO PRO 20 % INJECTION (10ML)
	Label Claim	Each ml contains: Enrofloxacin BP.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	Apro-En Injection Reg. No. 121959 (M/S Aptly Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
524	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(XBL-9ZR-YXWA, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	ETER GLUCONATE INJECTION
	Label Claim	Each ml contains: Calcium gluconate 440mg Boric acid 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	GLUCAL 44 INJECTION REG. # 087820 M/S GHAZI BROTHERS KARACHI.
	Pharmacotherapeutic Group of (API)	Calcium supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
525	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur,

		Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(2ZM-5BN-HYMB, 2025-01-16)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	ETER RICOZOLE 4% SUSPENSION
	Label Claim	Each ml contains: Recobendazole 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled, 10Ltr-De-Controlled, 150ml-De-Controlled, 1Ltr-De-Controlled, 250ml-De-Controlled, 500ml-De-Controlled, 50ml-De-Controlled, 5Ltr-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	RICOMIN 4% SUSPENSION REG. # 063596 STAR LABORTORIES (PVT) LTD LAHORE
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
526	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate, Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(4AE-V89-1ZZ9, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	Eter Ricozole 15% Suspension.
	Label Claim	Each ml contains: Recobendazole 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled, 100ml-De-Controlled, 10LTR -De-Controlled, 150ml-De-Controlled, 250ml-De-Controlled, 25LTR-De-Controlled, 500ml-De-Controlled, 50ml-De-Controlled, 5Ltr-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	RICOMIN 15% SUSPENSION REG. # 063597 STAR LABORTORIES (PVT) LTD LAHORE
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
527	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(14W-DMW-HPG3, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	Eter Vita Lyte Water Soluble Powder
	Label Claim	Each kg contains : - Sodium (Salt)..... 60,000mg Potasium (KCI) 100,000mg Magnesium sulphate..... 25,000mg Vitamin A-50 50, 00,000IU Vitamin D3 16,55,000IU Vitamin E-50..... 4,250mg Cal-D-Pantothenate..... 9,590mg Folic acid 500mg Vitamin B2-80 1500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	25Kg-De-Controlled,1 Kg-De-Controlled,100 gm-De-Controlled,10gm-De-Controlled,10Kg -De-Controlled,2.5Kg-De-Controlled,250 gm -De-Controlled,500 gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	SYMANS VITAMIN AND ELECTROLYTES SOLUBLE POWDER REG. # 023444 M/S SYMANS PHARMACEUTICALS (PVT) LTD LAHORE
	Pharmacotherapeutic Group of (API)	Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
528	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)

	Application Form Dy. No / Tracking ID & date of submission	(R3D-AW9-N3BH, 2025-01-16)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	FLUMEQ LIQUID
	Label Claim	Each ml Contains: - Flumequine BP.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,10Ltr -De-Controlled,150ml-De-Controlled,1Ltr-De-Controlled,250ml-De-Controlled,25Ltr-De-Controlled,500ml-De-Controlled,5Ltr -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	FLUME-Z 20% LIQUID REG. # 090671 M/S. ZOIC INTERNATIONAL
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
529	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(ZN9-3LD-1E7W, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2025-01-10,
	The proposed proprietary name / brand name	GENCOTYL INJECTION (10ML)
	Label Claim	Each 100ml contains: Gentamycin Sulphate BP..... 5gm Tylosin tartrae USP..... 10gm Colistin Sulphate BP..... 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ML-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	GENTAFATE INJECTION REG. # 099348 (INSHAL PHARMACEUTICAL INDUSTRIES ISLAMABAD)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
530	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(9UT-A27-VTQX, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	MYCO METHOPRIM WATER SOLUBLE POWDER
	Label Claim	Each 100gm contains:- Josamycin BP.....18MIU Trimethoprim.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Kg -De-Controlled,100gm-De-Controlled,1Kg-De-Controlled,25 Kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	JOSAPRIM WATER SOLUBLE POWDER REG. # 074010 M/S MYLAB (PVT) LTD. BAHAWALPUR
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
531	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(914-1DA-RN63, 2025-01-17)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	TOLTRA FORTE SOLUTION
	Label Claim	Each 100ml Contains:- Toltrazuril.....5gm Triethanolamine 30gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,10Lt-De-Controlled,150ml-De-Controlled,1Ltr-De-Controlled,250ml-De-

		Controlled,500ml-De-Controlled,50ml-De-Controlled,5Ltr -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	TOLTRA-DS SOLUTION. REG. # 039987 BIO LABS (PVT.) LTD. ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
532	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(E31-T2Z-QASB, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	3- ZOLE ORAL LIQUID
	Label Claim	Each 100ml contains Triclabendazole.....12gm Ivermectin BP.....0.2gm Albendazole BP.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	: 50ml,100ml, 200ml, 250ml, 500ml, 1 liter-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	THUNDER DRENCH (058941) by M/S STAR LABS
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
533	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi

		(001018)
	Application Form Dy. No / Tracking ID & date of submission	(JQ5-BAP-2YYD, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Coli Ford 48 Oral Powder
	Label Claim	Each gm powder contains Colistin Sulphate (BP)..... 48,00,000 IU (INNOVATORS Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g, 250g, 500g, 1kg, 5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	BIO-COLSTIN ORAL POWDER (078291) BIO LAB PHARMACEUTICALS.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
534	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(7BD-ZAM-4UY8, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	coli ford 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, 5KG, 10KG , 25KG -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly
	For generic drugs (me-too Status)	COLIZOC WATER SOUBLE ORAL POWDER (080942) ZOIC INTERNATIONAL PHARMA S
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
535	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(ULJ-49Y-XZA4, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Coli Ford 55 Oral Powder
	Label Claim	Each KG contains: Colistin Sulphate (BP)..... 550 MIU
	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 a Cool and dry place. Protect from light and children. Opened packs should be used promptly.
	For generic drugs (me-too Status)	COLIMYXIN G W/S ORAL POWDER (085155) DIVINE PHARMACEUTICALS.
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
536	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(VRY-X1B-7RG3, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	coli ford 60 oral powder
	Label Claim	Each gm contains: Colistin Sulphate BP.....6,000,000 IU. (INNOVATORS Spec.)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100g, 250g, 500g, 1kg, 1.5 KG ,5KG, 10 KG, 25KG -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at a Cool and dry place. Protect from light and children. Opened packs should be used promptly.
	For generic drugs (me-too Status)	NEFLOREX 60 W/S POWDER (089855) BREEZ PHARMA.
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
537	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(6AB-N95-MZHQ, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Fenicol 23% Oral Liquid
	Label Claim	Each 100ml contains Florfenicol USP..... 23g Colistin sulphate BP..... 50MIU (Innovator's 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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	FLORUTH 23% ORAL LIQUID (125843) RUTH PHARMACEUTICALS GUJRANWA
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
538	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi

		(001018)
	Application Form Dy. No / Tracking ID & date of submission	(XWN-8LH-6L4S, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	fenicol c 25 % oral liquid
	Label Claim	Each 100ml contains: Florfenicol USP..... 25g Colistin sulphate BP..... 50MIU (Innovator's 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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	Floruth 25% oral Liquid by M/s Ruth Pharmaceutical Gujranwala
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
539	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(264-Q84-9UMZ, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	ford fush 2.5% oral powder
	Label Claim	Each 100gm powder contains: Furosemide BP..... 2.5g Sodium Chloride BP.....3.5g Magnesium Sulphate BP.....3.5g Manganese Sulphate BP.....0.1g Calcium Carbonate BP.....4.5g Potassium Chloride BP.....0.4g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	GIPSOMIDE 25 POWDER (109143) HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Diuretic & Minerals

	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
540	Decision	
	Approved	
	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(YBP-JVR-9EPZ, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Ford Fush 2% Oral Powder
	Label Claim	Each 100gm powder contains: Furosemide BP..... 2g Sodium Chloride BP.....3.5g Magnesium Sulphate BP.....3.5g Manganese Sulphate BP.....0.1g Calcium Carbonate BP.....4.5g Potassium Chloride BP.....0.4g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	GIPSOMIDE 20 POWDER (109142) HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Frusumide & Electrolyte
541	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
541	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(S29-7BX-XM7G, 2025-12-16)

	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	fosy - tyl - 100 oral powder
	Label Claim	Each 100 gm powder contains: Fosfomycin Calcium (BP)..... 20g Tylosin Tartrate(BP).....5g Fructose 1,6 Diphosphate (USP).....18g Sodium Phosphate (BP).....15g Magnesium phosphate (BP).....10g (Innovator,sSpec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	GENERIC Each 100 gm powder contains (Innovator,sSpec.) Fosfomycin Ca-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	ROLD FOS FORTE W/S ORAL POWDER (109283) HAAROLDS PHARMA MIRPUR
	Pharmacotherapeutic Group of (API)	Antibacterial, Electrolytes Replenishes
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
542	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(ZJJ-5QZ-B6U4, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	fosy - tyl -200 oral powder
	Label Claim	Each 100 gm powder contains (Innovator's Spec.) Fosfomycin Calcium BP..... 20gm Tylosin as Tartrate BP.....10gm Fructose USP.....18gm Sodium Phosphate BP.....15gm Magnesium phosphate BP.....10gm
	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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	ROLD FOS WATER SOLUBLE POWDER (109282) HAAROLD PHARMA

	Pharmacotherapeutic Group of (API)	Antibacterial, Electrolytes Replenishes
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
543	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(P4M-14A-TSGG, 2025-12-18)
	Detail of Fee Submitted	38700, 2025-12-17,
	The proposed proprietary name / brand name	HEXO FORD 1% ORAL LIQUID
	Label Claim	Each ml contains: Bromhexine HCl BP 10mg (Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ML,200ML,500ML,1LITER-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	BROMOSOL 1% ORAL LIQUID (080725) M/S INERVAC (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
544	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(3MD-BMP-1J9V, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	HEXO FORD 5 % ORAL LIQUID
	Label Claim	Each 100ml contains: Bromhexine HCl BP 5gm (Innovator's Spec.)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	BROMO SHELL LIQUID (075762) M/S INSHAL PHARMACEUTICAL RAWAT
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
545	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(BQQ-QAY-TB37, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	HEXO FORD 10 % ORAL LIQUID
	Label Claim	Each 100ml contains: Bromhexine HCl BP 10gm (Innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 500ml, 1Litre, 2.5Litre, 5 L-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	EBROM -LYTIC 10% ORAL LIQUID (099317) M/S VETEC LABORTERIES RAWAT
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
546	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)

Application Form Dy. No / Tracking ID & date of submission	(BUR-BZH-T385, 2025-12-16)
Detail of Fee Submitted	38700, 2025-12-11,
The proposed proprietary name / brand name	LYZO FORD ORAL POWDER
Label Claim	Each Gm powder contains Lysozyme.....220mg Vitamin E BP.....5mg (As Per Innovator Specification.)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100g, , 500g, 1kg-De-Controlled
Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
For generic drugs (me-too Status)	VITOZYME POWDER (049622) Selmore Pharmaceuticals (Pvt.) Ltd.
Pharmacotherapeutic Group of (API)	NUTRITIONAL SUUPLEMENT
Name, address of Manufacturing site:	--
GMP status of the firm	OK
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	New License (Sara Mehreen)
Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
Application Form Dy. No / Tracking ID & date of submission	(TZN-V4H-VNW1, 2025-12-13)
Detail of Fee Submitted	38700, 2025-12-11,
The proposed proprietary name / brand name	Mentho ford 2 oral liquid
Label Claim	Each ml contains: Bromhexine HCl BP 20mg Menthol BP 40mg (Innovator Spec.)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100ml, 250ml, 450ml,500ml, 1Litre, 2.5Litre,5lit - De-Controlled
Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
For generic drugs (me-too Status)	BROMENT ORAL SOLUTION (094458) BAARIQ PHARMA
Pharmacotherapeutic Group of (API)	Mucolytic,
Name, address of Manufacturing site:	--
GMP status of the firm	OK

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
548	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(MDX-RTX-BW2P, 2025-12-13)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Mentho ford 4 oral liquid
	Label Claim	Each ml contains: Bromhexine HCl BP 50mg Menthol BP 40mg (innovators 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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	Hexthol LIQUID (097984) Nawal PHARMA
	Pharmacotherapeutic Group of (API)	Mucolytics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
549	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(R1P-4N2-57TQ, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	neo ford 72 % oral powder
	Label Claim	Each 100 Gm Powder contains: Neomycin Sulphate BP..... 72g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NEO RUTH 72% ORAL POWDER (125820) RUTH PHARMACEUTICAL GUJRANWALA
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
550	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(953-GD3-RVZG, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	NOR FORD C 50 ORAL LIQUID
	Label Claim	Each 100ml contains: Norfloxacin BP..... 20g Colistin Sulphate BP.....50MIU (As Per Innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre, 25Litre -De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	Colinor oral Liquid. (071066) ATTABAK PHARMACEUTICALS ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
551	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi

		(001018)
	Application Form Dy. No / Tracking ID & date of submission	(M89-MGQ-Q16W, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	NOR FORD C 60 ORAL LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g Colistin Sulphate BP.....60MIU (As Per Innovator's Specification.)
	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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NOR-C MAARSON LIQUID. (071056) ATTABAK PHARMACEUTICALS ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
552	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(9TL-U25-E8X1, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Olum Ford 50% Oral Powder
	Label Claim	Each 100GM contains: Amprolium HCl USP..... 50GM (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)Keep in Cool and dry place. Keep out of the reach of children.
	For generic drugs (me-too Status)	EMPROLIM 50% ORAL powder (125817) M/S RUTH PHARMA GUJRAWALA
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
553	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(9R9-7NN-JY8R, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	olium ford 90% oral powder
	Label Claim	Each 100Gm contains (USP Spec) Amprolium HCL USP 90g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100g,250g,500g,1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s) Keep in Cool and dry place. Keep out of the reach of children.
	For generic drugs (me-too Status)	EMPROLIUM- 90% powder (125815) M/S RUTH PHARMA GUJRAWALA
	Pharmacotherapeutic Group of (API)	Anticoccidial
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
554	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(S3W-5A2-H1XT, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	OXALINIC FORD ORAL LIQUID
	Label Claim	Each 100ml contains: Oxolinic acid BP..... 10g (As Per Innovators 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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be

		used promptly.
	For generic drugs (me-too Status)	OXOLINIL ORAL SOLUTION (058830) VETGROW PHARMACEUTICALS LA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
555	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(PDH-JRQ-JG5L, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Oxflor - N 500 ORAL POWDER
	Label Claim	Each 100g contains: Oxytetracycline HCl BP.....300mg Florfenicol 100mg Neomycin sulphate BP.....150mg (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	RABIX FORTE W/S ORAL POWDER (1091389) HAAROLDS PHARMACEUTICAL BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
556	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(EE8-M1A-7ZU5, 2025-12-16)

	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Para Ford C Oral 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 BP.....12.5g (As Per Innovators Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500g, 1kg, 2.5kg, 5kg-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	CHILLAFARAL ORAL POWDER (093784) APPLY PHARMACEUTICALS FAISLABAD
	Pharmacotherapeutic Group of (API)	Antioxidant, Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
557	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(7T4-V5S-5Y1X, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Thrush CRD 10/20 ORAL POWDER
	Label Claim	Each gm powder contains: Doxycycline HCl BP..... 200mg Tylosin as tartrate BP..... 100mg Colistin sulphate BP..... 0.5MIU Bromhexine HCl BP..... 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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	CRD ARCH 20 ORAL POWDER (121994) M/S ARCHAR PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibacterial

	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
558	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(8PM-8HT-2AWP, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Tilmic ford oral liquid
	Label Claim	Each 100 ml contains: Tilmicosin as Phosphate USP..... 25g (innovator's Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 300ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	SB TIL ORAL LIQUID (109887) SB PHARMA MODEL TOWN ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
559	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(Y6J-78U-WDXZ, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	TRI FLOX ORAL LIQUID
	Label Claim	Each 100ml contains Norfloxacin BP..... 20g Guaifenesin USP.....20g Aminophylline

		BP.....8g (As Per Innovator's Specification.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s) ☐ Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	NOR+ AG SOLUTION. (058968) BIO GEN PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
560	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(HJX-U5A-RE9D, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Tri ford 24 oral powder
	Label Claim	Each 100gm powder contains: Oxytetracycline HCl BP.....20g. Colistin sulphate BP.....24MIU Neomycin Sulphate BP.....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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	STIAGULSTIN 24 W/S POWDER (109134) M/S HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	ANTIBIOTIC
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

561	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(W3P-NUZ-2PB4, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Tri Ford 30 Oral Powder
	Label Claim	Each 100gm powder contains: Oxytetracycline HCl BP.....25g. Colistin sulphate BP.....30MIU Neomycin Sulphate BP.....25g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	STIAGULSTIN 30 W/S POWDER (109135) M/S HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
562	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(Y67-DX8-MYJN, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-12,
	The proposed proprietary name / brand name	Tri Ford 55 Oral Powder
	Label Claim	Each 100gm powder contains: Oxytetracycline HCl BP.....20g. Colistin sulphate BP.....55MIU Neomycin Sulphate BP.....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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.

	For generic drugs (me-too Status)	STIAGULSTIN 55 W/S POWDER (109137) M/S HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
563	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DDF PAKISTAN Office No.7, 4th Floor, Plot 63-C, Bukhari Commercial Lane 5, Phase 6, DHA (0126)
	Application Form Dy. No / Tracking ID & date of submission	(7EX-564-JPZG, 2025-01-10)
	Detail of Fee Submitted	75000.0, 2025-01-09,
	The proposed proprietary name / brand name	Limoxin-200 LA
	Label Claim	Each ml contains: Oxytetracycline (as dihydrate) 200mg
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Store dark at room temperature. Shelf-life after first opening is 28 days.
	For generic drugs (me-too Status)	OXYTRON LA INJECTION (112253) by M/s Kayans Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Interchemie werken "De Adelaar" BV-5804 CG Venray, The Netherlands -Netherlands
	Name, address of Marketing Authorization Holder:	DDF PAKISTAN, Suite #8, Plot 63-C, Bukhari Commerical Lane, Phase VI, DHA, 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	
	Firm has provided scanned copies of CoPP, GMP, Agency Agreement.	
	Decision	
	Deferred	
	Deferred for confirmation of free sale status in country of origin.	
564	Case Category	Routine (Sara Mehreen)

Name, address of Applicant.	DDF PAKISTAN Office No.7, 4th Floor, Plot 63-C, Bukhari Commercial Lane 5, Phase 6, DHA (0126)
Application Form Dy. No / Tracking ID & date of submission	(3E8-9YM-S31M, 2025-01-13)
Detail of Fee Submitted	75000.0, 225000.0 2025-01-13, 2025-07-11
The proposed proprietary name / brand name	Biocillin-150 LA
Label Claim	Each ml contains: Amoxicillin (as trihydrate) 150 mg
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	100ml-De-Controlled, 50ml-De-Controlled
Shelf Life (Unit)	3 Year(s) Store dark below 25 °C. Shelf-life after first opening: 2 weeks.
For generic drugs (me-too Status)	KARIMOCILLIN-L.A INJECTION (112128) by M/s Ras Pharmaceuticals.
Pharmacotherapeutic Group of (API)	Anti-infectives / Antibacterials for systemic use, beta-lactam antibacterials
Name, address of Manufacturing site:	Interchemie werken "De Adelaar" BV-5804 CG Venray, The Netherlands -Netherlands
Name, address of Marketing Authorization Holder:	DDF PAKISTAN, Suite #8, Plot 63-C, Bukhari Commerical Lane, Phase VI, DHA, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
Evaluation Remarks	
Firm has provided scanned copies of CoPP, GMP, Agency Agreement.	
Decision	
Approved	
565	Case Category
Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
Application Form Dy. No / Tracking ID & date of submission	(6S6-9QB-4REL, 2025-05-21)
Detail of Fee Submitted	37000.0, 9400 2025-05-16, 2026-01-02
The proposed proprietary name / brand name	JF RIM-P Oral Powder
Label Claim	Each Kg contains: Erythromycin USP..... 90 g Sulphadizine Sodium USP.....75 g Trimethoprim USP.....15 g
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 kg Jar & 500 gm-De-Controlled
Shelf Life (Unit)	2 Year(s) Store in cool & dry place, Protect from light.
For generic drugs (me-too Status)	ERYTHROFAS PLUS POWDER

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
566	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(PSV-J4H-GQN8, 2025-04-30)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JF-FENAC INJECTION
	Label Claim	Each ml Contains Acelofenec 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml in amber glass -De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 25 °C. Protect from light.
	For generic drugs (me-too Status)	ACLOWAN INJECTION 091887
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory and antirheumatic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
567	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(BQ2-M7J-99A3, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	Synoxy-G Spray
	Label Claim	Each ml Contains: Oxytetracycline HCL USP.....40mg Gentian Violet uSP.....4mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 125ml, 150ml, 250ml, 300ml, 500ml, 10-De-Controlled

	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Gentox Spray (Reg. No. 120805) by Leads Pharma (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
568	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(JER-BM2-16PQ, 2025-07-20)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Enrosyn-20 Oral Liquid
	Label Claim	Each 100ml contain: Enrofloxacin USP.....20 gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li- De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Flenrox Liquid (Reg. No. 021290) by Bio-Labs
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
569	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(MDJ-2A9-D3AR, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-07-04,

	The proposed proprietary name / brand name	Synblast Oral Drench
	Label Claim	Each ml contains: Triclabendazole USP.....120mg Ivermectin USP.....2mg Albendazole USP.....100mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Thunder Drench (Reg. No. 058941) by Star Laboratories (Pvt.) Ltd., Lahore
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
570	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(VWG-PMZ-NLS1, 2025-07-21)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	Albosyn-12.5 Oral Suspension
	Label Claim	Each 100 ml contains: Albendazole.....12.5gm (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ml,100ml, 250ml, 500ml, 1 liter, 5 liter, 10 li-De-Controlled
	Shelf Life (Unit)	2 Year(s)PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Albadec Super Oral Suspension (Reg. No. 079838) by Decent Pharma, Islamabad
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
571	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Archard Pharmaceuticals Pvt Ltd Plot No 27-28/B Small Industrial Estate Bhimber AJK (000991)
	Application Form Dy. No / Tracking ID & date of submission	(EA4-Y83-YJHD, 2025-06-21)
	Detail of Fee Submitted	37000.0, 2025-06-13,
	The proposed proprietary name / brand name	DIMULIN ORAL POWDER
	Label Claim	Each 100gm contains: Tiamulin Hydrogen Fumarate equivalent to Tiamulin base BP.....45 gm
	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)Store at a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	TIAMUBAK 45% POWDER (Reg. No. 048170)
	Pharmacotherapeutic Group of (API)	ANTI-INFECTIVE, ANTI-BACTERIAL
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 07.08.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
572	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(GRX-EMR-1WND, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	thrush CRD 20/40 ORAL POWDER
	Label Claim	Each gm powder contains: Doxycycline HCl BP..... 400 mg Tylosin as tartrate BP..... 200mg Colistin sulphate BP..... 0.5MIU Bromhexine HCl BP.....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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	CRD ARCH 40 ORAL POWDER (121193) M/S ARCHARD PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
573	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(QGU-9BB-BUWB, 2025-12-15)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Rescue Drench
	Label Claim	Each 100ml contains Oxyclozanide BP..... 6.25gm Oxfendazole BP..... 2.265gm Cobalt Sulphate..... 0.167gm Sodium Selenite..... 0.05gm (As Per Innovator Specification)
	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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	PUNCH DRENCH (032206) SELMORE PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

574	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(THP-QV7-23RV, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	thrush crd - 500 oral powder
	Label Claim	Each 100gm powder contains: Doxycycline HCl BP..... 20g Tylosin tartrate BP..... 10g Colistin sulphate BP..... 5MIU Bromhexine HCl BP.....0.2g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be used promptly.
	For generic drugs (me-too Status)	STRICK CRD 50 W/S POWDER (109129) M/S HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
575	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Oxford Health Care Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi (001018)
	Application Form Dy. No / Tracking ID & date of submission	(UNV-JQD-9GEQ, 2025-12-16)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	thrush CRD 1000 ORAL POWDER
	Label Claim	Each 100gm powder contains: Doxycycline HCl BP..... 40g Tylosin tartrate BP..... 20g Colistin sulphate BP..... 100MIU Bromhexine HCl BP.....1 g (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 a Cool and dry place. ☐ Protect from light and children. ☐ Opened packs should be

		used promptly.
	For generic drugs (me-too Status)	STRICK CRD 71 W/S POWDER (109126) M/S HAAROLDS PHARMA BHIMBER
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	OK
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
576	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(JYM-148-RJUP, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	Aldazole-5% Drench
	Label Claim	Each ml Contains: Albendazole USP.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	ALBORISE-5% ORAL DRENCH (109980) by M/s Biorise Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
577	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)

	Application Form Dy. No / Tracking ID & date of submission	(V89-1V4-HT4A, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	Aldazole-10% Drench
	Label Claim	Each ml Contains: Albendazole USP.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	ALBENSEL-10 DRENCH (043143) by Selmore
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
578	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(QS9-YZT-3X78, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	Aldazole-11.25%
	Label Claim	Each ml Contains: Albendazole USP.....112.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	V-Zole Oral Liquid (088048) by M/s Vetz Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter

		No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
579	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(BV1-V54-G5VH, 2025-11-21)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	ALDAZOLE 12.% DRENCH
	Label Claim	Each ml Contains: Albendazole USP.....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	VETAZOLE 12.5% Oral Liquid by Vetz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
580	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(DLW-7S2-Z6VU, 2025-11-25)

	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Enro 10% Oral Liquid
	Label Claim	Each ml Contains: Enrofloxacin USP 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Envet 10% Oral Liquid by M/s Vetz Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
581	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(PJT-191-TTS9, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Enro 20% Oral Liquid
	Label Claim	Each ml Contains: Enrofloxacin USP ...200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Envet 20% Oral Liquid by m/s Vetz Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE

		Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
582	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(LUM-JHW-WWHD, 2025-04-28)
	Detail of Fee Submitted	37000.0, 9400 2025-04-24, 2026-01-02
	The proposed proprietary name / brand name	JF-PB INJECTION
	Label Claim	Each ml Contains Phenylbutazone USP 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2 °C – 8 °C). Protect from light.
	For generic drugs (me-too Status)	Vutazon SS Injectable Solution
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Firm has mentioned target species in Form-5 as Horses and Ponies (non-food producing).	
583	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Synvest Vet Care Pvt Ltd 10-km, Sahiwal Road, Arifwala District Pakpattan (001011)
	Application Form Dy. No / Tracking ID & date of submission	(QGB-1GX-QEGV, 2025-07-23)
	Detail of Fee Submitted	37000.0, 2025-07-10,
	The proposed proprietary name / brand name	Syntraz Plus-12.5% Spray
	Label Claim	Each ml contains: Amitraz USP.....125mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml, 100ml, 125ml, 150ml, 250ml, 300ml, 500ml, 10-De-Controlled

	Shelf Life (Unit)	2 Year(s) PROTECT FROM DIRECT SUNLIGHT. DO NOT STORE ABOVE 25°C (77°F). KEEP OUT OF THE REACH OF CHILDREN.
	For generic drugs (me-too Status)	Frazal Spray (Reg. No. 109276) by Haarolds Pharmaceuticals (Pvt.) Ltd., AJK.
	Pharmacotherapeutic Group of (API)	Parasiticide
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted to firm on 03.06.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
584	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(95Y-ZNW-X65T, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Linco Powder
	Label Claim	Each 100gram contains: Lincomycin as Hcl (USP)..... 40gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	LINCOLIDE 40 Powder by M/s Neotech Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
585	Case Category	New License (Sara Mehreen)

Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
Application Form Dy. No / Tracking ID & date of submission	(9JJ-NG4-DS2J, 2025-11-21)
Detail of Fee Submitted	38700, 2025-11-17,
The proposed proprietary name / brand name	G-Oxfendazole Liquid
Label Claim	Each ml contains: Oxfendazole USP ... 22.65mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
For generic drugs (me-too Status)	EL-OXANIL SUSPENSION by M/s ELKO ORGANISATION KARACHI
Pharmacotherapeutic Group of (API)	Anthelmintic
Name, address of Manufacturing site:	--
GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	New License (Sara Mehreen)
Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
Application Form Dy. No / Tracking ID & date of submission	(HPQ-5U2-WJYP, 2025-11-27)
Detail of Fee Submitted	38700, 2025-11-17,
The proposed proprietary name / brand name	G-Mycin 100% Oral Powder
Label Claim	Each gm Contains: Neomycin Sulfate USP.....1000mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
For generic drugs (me-too Status)	NEOKAM-100 Powder by M.A.kamil Farma Pvt Limited

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
587	Case Category	Routine (Shahrukh Ali)
	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	(PXT-2BE-91YA, 2024-05-13)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	Coxitab Tablet 90 mg
	Label Claim	Each Film Coated Tablet contains: Etoricoxib 90 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year Accelerated 40°C± 2°C/75%±5%RH, Long term 30 °C± 2°C /65%±5%RH
	For generic drugs (me-too Status)	“Starcox TM Immediate Release film coated Tablet is DRAP Approved
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Assurgen Pharma Private Limited.
	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	ARCOXIA ® Immediate Release Tablet is approved in AEMPS Spain
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

1.3.5 Evidence of Approval of Manufacturing Facility: Section approval letter required.	Submitted
1.3.5 Valid copy of DML required	Submitted
1.6.5: Valid copy of GMP certificate of the drug product manufacturer & drug substance manufacturer issued by concerned/relevant regulatory authority shall be submitted	Submitted
3.2.S.7: Drug substance stability study data for real time is provided for 18 months. Complete data required till shelf life of product.	Submitted
3.2.P.8.3 Provide HPLC log, evidence of CFR 21 compliance, complete BMR along with signed and stamped stability sheets.	Submitted
Chromatogram for 6th month stability study not provided, Hplc log shared is for 0-month study only	Submitted

Decision

Approved

588	Case Category	Routine (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	(XRH-D2M-LMND, 2024-06-11)
	Detail of Fee Submitted	30000.0, 2024-04-15,
	The proposed proprietary name / brand name	Leridal Oral Solution
	Label Claim	Each 5 ml contains: Levocetirizine dihydrochloride 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml-As per SRO,90ml-As per SRO
	Shelf Life (Unit)	24 MonthStore at 20-25°C
	For generic drugs (me-too Status)	T-Day syrup
	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	U.S. Food & Drug ADministration
	GMP status of the firm	

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	1.3.5 Valid copy of DML required	Request for renewal submitted
	3.2.S.4.4 Justification required for not performing identification test for chloride as provided in USP pharmacopoeia	Firm has submitted revised specs with inclusion of chloride test.
	3.2.P.8 Stability: justify 2 peaks that are present before Levocetirizine peak	Firm has submitted that these peaks are for excipients methyl paraben, propyl paraben
589	Decision	
	Approved	
	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Islam Pharmaceuticals 7km Pasrur Road Sialkot (000885)
	Application Form Dy. No / Tracking ID & date of submission	(D54-LX2-D9V9, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-04-04,
	The proposed proprietary name / brand name	Nepco 100mg Capsule
	Label Claim	Each capsule contains: Pregabalin.....100mg (BP Specs)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	14's & 28's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	Gablin Capsule by CCL Pharmaceuticals Pvt. Limited
	Pharmaceutical Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Progress Life Sciences Pvt Ltd. Cabin # 3 Gala no. D4, House no. 1414/4, Ground Floor, Global Park Complex Co., OP. SOC Ltd. Anjur Road, Rahnal Village, Bhiwandi, 421302, Dist, Thane-Zone3
	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	Lyrica Capsule by Pfizer Global Research & Development
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills the codal formalities.	

	Decision	
	Approved	
590	Case Category	Priority As Per 257-M of RB (Shahrukh Ali)
	Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065-016174D)
	Application Form Dy. No / Tracking ID & date of submission	(WMM-6HU-P5YB, 2025-08-21)
	Detail of Fee Submitted	313500.0, 2025-08-13,
	The proposed proprietary name / brand name	Everose 2.5mg Tablet
	Label Claim	Each tablet contains.....Everolimus 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's (1x30)-As per SRO
	Shelf Life (Unit)	36 MonthStore below 30°C.
	For generic drugs (me-too Status)	Afinitor 2.5mg Tablet (Novartis)
	Pharmaceutical Group of (API)	Biocon Limited 20th KM Hosur Road Electronics City Bengaluru 560 100 Karnataka, India
	Name, address of Manufacturing site:	CTCbio -228-16, Gangchon-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea-North Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Relavant section of Module 3.
	Name, address of Marketing Authorization Holder:	Samyang Holding Corporation , 79, Sinildong-ro, Daedeok-gu, Daejeon, , Republic of Korea , North Korea
	Details of Certificates (CoPP/FSC/cGMP):	06.02.2027 (Valid till)
	Details of Authorization Letter :	Not Applicable for Finished drug Product importer.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 Months
	The status in reference regulatory authorities	Afinitor 2.5mg Tablet (Novartis Pharmaceuticals, Korea)
	Evaluation Remarks	
	Deffered for provision of Valid copy of Legalized and notarized COPP of 2.5mg strength & Dissolution STUDIES OF 2.5MG strength.	Firm has submitted Valid copy of Legalized and notarized COPP of 2.5mg strength & Dissolution STUDIES OF 2.5MG strength.
	Decision	
	Approved	
591	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	QADIR PHARMACEUTICALS FATEH GHAR SAHUWALA ROAD SIALKOT (000944)

Application Form Dy. No / Tracking ID & date of submission		(Z4X-JW7-NQGD, 2024-06-13)
Detail of Fee Submitted		30000.0, 2024-05-31,
The proposed proprietary name / brand name		ENZI 10MG
Label Claim		Each Film Coated Tablet Contain Cetirizine Dihydrochloride . 10mg
Reference to Finished product specifications		United States Pharmacopeia
Proposed Pack Size		1 X 10's-As per SRO
Shelf Life (Unit)		2 Year(s)Below 30
For generic drugs (me-too Status)		Me-Too
Pharmacotherapeutic Group of (API)		H-1 receptor antagonist R06AE09
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		KARUNESH REMEDIES
Detail of stability batches of drug product		3 Batch manufactured each having 952 Tablets
Documents for the procurement of API with approval from DRAP (in case of Import)		E-Computerized No: E-7075007556491 Date of issue: 25-Oct-2023
Pharmaceutical Equivalence and Comparative Dissolution Profile		Results Zyrtec 10mg Tablet GSK B# DD6K
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		EMC , FDA
GMP status of the firm		54/2024-drap 21.3.24
Evidence of approval of manufacturing facility		1-5/2017-LIC 17.09.21 Tablet section
Evaluation Remarks		
1.6.5: Valid copy of GMP certificate of the drug product manufacturer issued by concerned/relevant regulatory authority shall be submitted.		Valid copy of GMP certificate of the drug product manufacturer
3.2.P.8 Stability: Chromatogram and audit trail record of HPLC attached are for dates 11.05.23, 02.06.24, 5.07.24 and are not matching with the stability data performed as in summary table which shows study conducted on 11.23,2-24& 5-24. Justification required		Firm has submitted justification
System suitability chromatogram not submitted as this was the requirement of assay in USP monograph		Firm has submitted system suitability data along with calculation of RSD and tailing factor
Documents for procurement of API with approval from DRAP shall be submitted		Computerized No: E-7075007556491 dated 25.10.23 Clearance certificate
Decision		
Approved		
592	Case Category	Routine (Shahrukh Ali)
	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	(XUD-VUJ-UJPG, 2024-06-14)
Detail of Fee Submitted	30000.0, 2024-04-16,
The proposed proprietary name / brand name	CALTRIM 1% W/V LOTION
Label Claim	Each ml of lotion contains: Clotrimazole.....10mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)25°C
For generic drugs (me-too Status)	Stiemazol 1%w/v Lotion M/s Stiefel (GLAXOSMITHKLINE)
Pharmacotherapeutic Group of (API)	Antifungals for topical use D01A C01
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	
Detail of stability batches of drug product	500 Bottles 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	2859/2021-DRAP 02.8.21 Halcyon Labs Private Limited India 16/11/2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	STIEMAZOLE 1% W/V LOTION Stiefel (GLAXOSMITHKLINE). Batch No : 2162
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Clotrimazole Topical Solution M/s Taro Pharmaceuticals Inc., Brampton, Ontario, CANADA L6T 1C1
GMP status of the firm	11-91/2021-Caliph-DRAP-841 dated 2-3-21
Evidence of approval of manufacturing facility	No F.3-6/2005-Lic (Vol-I)dated 17-January -2019 cream ointment lotion section General
Evaluation Remarks	
1.3.5 Valid copy of DML required	Submitted
1.6.5: Valid copy of GMP certificate of the drug product & Substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	GMP certificate of the drug product manufacturer GMP-C-CCBD8D date of issue 21.08.25. GMP certificate of the drug Substance manufacturer valid till 21.03.26
3.2.P.8.3 Provide HPLC log	Manual record submitted
Import document for testosterone propionate& Clotrimazole related compound A	The import documents of Clotrimazole are provided in Annexure III, while the testosterone and related compound A working standards were provided by the API manufacturer along with consignment.
Chromatograms of Sample solution are showing peaks of clotrimazole related compound A and testosterone propionate justification required	Testosterone and related compound A are used as internal standards as defined in the USP monograph. These were added to sample solution as per USP method, so chromatogram is showing the peak of testosterone.
Decision	
Approved	

	Approved subject to submission of evidence for procurement of Testosterone Priopionate and Clotirmazole related compound A.	
593	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(6MJ-9YJ-VTS7, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-06-30,
	The proposed proprietary name / brand name	Biomisol Forte Oral Liquid
	Label Claim	EACH ML CONTAINS:- LEVAMISOLE AS HCL 1.5% VITAMIN C 0.025% (Product Complies with Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 50ml, 100ml, 150ml, 200ml, 250 ml, 450 ml, 5-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C, cool and dry place. Store in closed packing.
	For generic drugs (me-too Status)	LEVA-C LIQUID by M/S. ATTABAK PHARMACEUTICALS, ISLAMABAD (Reg No. 062190)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is working at satisfactory level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
594	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(19E-R1M-JMZW, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-06-30,
	The proposed proprietary name / brand name	Bithiolev Oral Drench
	Label Claim	EACH 100ML CONTAINS:- BITHIONOL SULFOXIDE....10 GM LEVAMISOL HYDROCHLORIDE....1.5GM (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml, 50ml, 100ml, 150ml, 200ml, 250 ml, 450 ml, 5-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C, cool and dry place. Store in closed packing.

	For generic drugs (me-too Status)	BITHNISOL ORAL DRENCH by M/S. PRIX PHARMACEUTICA, LAHORE (Reg No. 063677)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is working at satisfactory level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
595	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	BIORISE PHARMACEUTICALS 19KM, LAHORE ROAD, MULTAN (000934)
	Application Form Dy. No / Tracking ID & date of submission	(193-LLH-Q6Y8, 2025-07-24)
	Detail of Fee Submitted	37000.0, 2025-07-15,
	The proposed proprietary name / brand name	Bromotyl-72 Water Soluble Powder
	Label Claim	Each 100 gm. Contains Tylosin Tartrate = 20 gm. Doxycycline Hyclate = 40gm. Colistin Sulphate = 10gm Bromhexine HCl = 2gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 100 gm., 250 gm., 500 gm., 1000gm., 2500 gm. -De-Controlled
	Shelf Life (Unit)	2 Year Below 30°C, cool and dry place. Store in closed packing.
	For generic drugs (me-too Status)	Brocotyd Powder by M/s Univet Pharmaceuticals Rawalpindi (Reg No. 058962)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Firm is working at satisfactory level of GMP compliance
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
596	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Aptly Pharmaceuticals 5-Km, Sargodha Road Bypass, Faisalabad. (000887)
	Application Form Dy. No / Tracking ID & date of submission	(JNS-BTZ-2DQM, 2025-07-23)

	Detail of Fee Submitted	37000.0, 2025-07-21,
	The proposed proprietary name / brand name	MULTEIN Injection (100ml)
	Label Claim	each 100 ml contains L- CARNITINE.....500MG THIOCTIC ACID.....20MG PYRIDOXINE HCL.....15MG CYANOCOBALAMIN.....3MG DL- ACETYLMETHIONINE.....2000MG L- ARGININE.....240MG L- ORNITHINE.....120MG L- CITRULINE.....120MG L- LYSINE.....50MG GLYCINE.....150MG TAURINE.....150MG ASPARTIC ACID.....150MG GLUTAMIC ACID.....150MG FRUCTOSE.....5000MG SORBITOL.....8000MG (As Per Innovator's Specification*)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml vial-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25 Degree Celsius at cool and dry place
	For generic drugs (me-too Status)	MULTIMINO-V INJECTION Reg. # 058712
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
597	Case Category	New License (Shahrukh Ali)
	Name, address of Applicant.	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
	Application Form Dy. No / Tracking ID & date of submission	(5ZG-X93-NXN6, 2024-05-02)
	Detail of Fee Submitted	30000.0, 2023-10-16,
	The proposed proprietary name / brand name	Artham Tablets
	Label Claim	Artham Tablets: Each Tablet Contains:- Artemether 40mg/Lumefantrine 240mg(Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size		As per SRO-As per SRO
Shelf Life (Unit)		2 Year(s)25
For generic drugs (me-too Status)		Arceva 40/240 Tablets manufactured by SAMI Pharmaceuticals Pvt. Ltd (Reg. No. 053226)
Pharmacotherapeutic Group of (API)		
Name, address of Manufacturing site:		Self Manufacturing
Name & address of API manufacturer		
Detail of stability batches of drug product		
Documents for the procurement of API with approval from DRAP (in case of Import)		
Pharmaceutical Equivalence and Comparative Dissolution Profile		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		
The status in reference regulatory authorities		USFDA Approved
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Sr. No	Shortcomings	Replies
1.	Justification shall be submitted for claiming innovator specifications, since Pharmacopoeial monograph is available for applied formulation in International Pharmacopoeia.	Firm stated that they use in-house method for finished product and stability study testing. Once we get registration after we will follow the International Pharmacopoeia method.
2.	Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation since the submitted limits are in contrary to the provision of Pharmacopoeia general monographs for immediate release formulations.	Firm stated that they follow the in-house method for dissolution test. Further There is no dissolution test specified for Artemether Lumefantrine tablet in International pharmacopoeia. Firm submitted literary reference.
3.	Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis.	Firm stated that they follow the in-house method for dissolution. Further There is no dissolution test specified for Artemether Lumefantrine tablet in International pharmacopoeia. Firm submitted literary reference.
4.	Justification shall be submitted that how the “specificity” of the applied drug product analytical method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.	Peak purity submitted by taking RSD of stsndard. System suitability/RSD submitted
5.	Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed.	Firm stated that their software set upon channel description. Our instrument method has desired wavelength. Instrument method evidence is submitted

	6.	Readable copy of the commercial invoice attested by DRAP I&E office shall be submitted for evidence of import of drug substance.	Readable copy of the commercial invoice & commercial invoice with ADC 1731/2022-DRAP dated 3.02.22
	7.	Evidence of approval of change of Qualified person form Licensing division shall be submitted.	approval of change of Qualified person record is attached Annex-5
Decision			
Deferred			
Deferred for change of specification's as per International Pharmacopoeia and revise dissolution limits as per Pharmacopoeia general monographs for immediate release formulations.			
598	Case Category		Routine (Shahrukh Ali)
	Name, address of Applicant.		Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission		(PU1-2HT-P65Q, 2025-10-06)
	Detail of Fee Submitted		38700, 2025-09-25,
	The proposed proprietary name / brand name		Bromocare Oral Liquid
	Label Claim		Each ml Contain Bromhexin HCL BP..... 50mg (As per innovator specifications)
	Reference to Finished product specifications		As per Innovators Specification
	Proposed Pack Size		Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml an- De-Controlled
	Shelf Life (Unit)		2 Year(s)store at room temperaure
	For generic drugs (me-too Status)		Bromotech Oral Liquid by biorific pharma
	Pharmacotherapeutic Group of (API)		mucolytic
	Name, address of Manufacturing site:		--
	GMP status of the firm		New DML
	Evidence of approval of manufacturing facility		LHI-37T-A6BB 31st july 2025 liquid syrup Gen Vet Oral powder gen vet Oral powder Penicillin vet
	Evaluation Remarks		
	Decision		
	Approved		
599	Case Category		Routine (Shahrukh Ali)
	Name, address of Applicant.		STAR LABORATORIES PVT. LTD. 23KM MULTAN ROAD LAHORE (000130)
	Application Form Dy. No / Tracking ID & date of submission		(X7Z-JAT-R8VH, 2025-05-16)
	Detail of Fee Submitted		37000.0, 2025-05-08,

	The proposed proprietary name / brand name	Amporex Powder
	Label Claim	Each gm contains: Amprolium HCL..... 200mg, Ethopabate 20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm,100gm,500gm,1kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Ethoprol Oral Powder Reg. # 049617
	Pharmacotherapeutic Group of (API)	Antiparasitic agent
	Name, address of Manufacturing site:	--
	GMP status of the firm	97/2023-Drap-AD 11318646033 8-6-23
	Evidence of approval of manufacturing facility	1-27/85-Lic(Vol-VIII) dated 31-oct-23
	Evaluation Remarks	
	Decision	
	Approved	
600	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(BAB-E2R-89ZV, 2025-10-06)
	Detail of Fee Submitted	38700, 2025-09-25,
	The proposed proprietary name / brand name	Amoxicare Oral Powder
	Label Claim	Each gm Contain Amoxicillin Trihydrate Equivalent to Amoxicillin BP 600mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1K-De-Controlled
	Shelf Life (Unit)	2 Year(s)store at room temperaure
	For generic drugs (me-too Status)	Triger Oral Dry Powder by selmore pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	LHI-37T-A6BB 31st july 2025 liquid syrup Gen Vet Oral powder gen vet Oral powder Penicillin vet
	Evaluation Remarks	
601		
	Decision	
	Approved	
	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	(XR6-4BA-VUT3, 2024-06-05)
	Detail of Fee Submitted	75000.0, 2024-05-15,
	The proposed proprietary name / brand name	Tramadex 75mg/25mg Tablet
	Label Claim	Each Film Coated tablet contains: Tramadol HCl 75mg Dexketoprofen trometamol Equivalent to Dexketoprofen 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10'-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	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	Metrochem API Pvt Ltd,PROTOCHEMICALS
	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	Skudexa 75 mg/25 mg Menarini – Von Heyden GmbH Leipziger Strasse 7-13 01097 Dresden Germany
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The application fulfills the codal formalities.	
	Decision	
	Approved	
602	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	GT Pharma Pvt. Ltd 713- Sundar Industrial Estate, Sundar Raiwind Road, (000829)
	Application Form Dy. No / Tracking ID & date of submission	(Z85-P7N-9B55, 2024-05-20)
	Detail of Fee Submitted	30000.0, 2024-03-27,
	The proposed proprietary name / brand name	Zoledrin Infusion 5mg/100ml
	Label Claim	Zoledrin Infusion 5mg/100ml (Zoledronic Acid as Monohydrate)

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 YearControlled Room
For generic drugs (me-too Status)	ACLASTA NOVARTIS
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	SYNNAT PHARMA PRIVATE LIMITED
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	
1.6.5: Valid copy of GMP certificate of the drug product manufacturer & drug substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate of the drug substance manufacturer valid till 13/11/25
3.2.P.3.5 Process validation: Firm has submitted Process validation study data of some other product with brand name zordin infusion, attached data dates are also different from study performed. Justification required	Firm claims that brand name zordin infusion was a typographic mistake, Dates are different as batch was on hold for sterility testing
3.2.P.8.3 Firm has submitted stability data that has different dates then the study performed. Justification required along with HPLC log, evidence of CFR 21 compliance, complete BMR along with signed and stamped stability sheets.	Firm has submitted HPLC log, evidence of CFR 21 compliance, complete BMR along with signed and stamped stability sheets.
3.2. P.8.3 •Documents for procurement of API with approval from DRAP	This is to clarify that the material in question was not imported by our company The sole indentor in Pakistan of Synnat Pharma India (Emerald Enterprises) provided sample material, which was received solely for trial and evaluation purposes. This sample was used only during trial batches to assess feasibility and performance, in line with internal development requirements.
Decision	
Deferred	
For submission of import document conforming complete trail	



Drug Regulatory Authority of Pakistan

(Biological Evaluation & Research Division)



Division of Biological Evaluation & Research

Sr. No	Title	Description
1	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (017/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission	(ENL-AH4-32XY, 2025-07-01)
	Detail of Fee Submitted	300000.0, 2024-07-30,
	The proposed proprietary name / brand name	Premi-RIG (FD)/Rabies Antiserum 5.0 ml (200 IU/ml).
	Label Claim	After reconstitution, each ml of Rabies Antiserum contains not less than 200 IU. Equine Rabies immunoglobulin – F(ab') ₂ fraction (API).....NMT 1000 IU/Vial
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	4 Year(s)Store in cool (< 30 0C) and dark place
	For generic drugs (me-too Status)	Brand name: Equirab 1000 IU/5ml Market Authorization holder:Hakimsons (Impex) Pvt. Ltd. Manufacturer: Bharat Serums And Vaccines Limited (Registration No: 052223)
	Pharmacotherapeutic Group of (API)	Immune-Sera ATC Code: J06AA06.
	Name, address of Manufacturing site:	Premium Serums and Vaccines Pvt. Ltd.-Premium Serums and Vaccines Pvt. Ltd. S. No. 354-1,354-2A/1, At &post Narayangaon, Tal. Junnar, District Pune – 410 504, State Maharashtra, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Premium Serums and Vaccines Pvt. Ltd., Premium Serums and Vaccines Pvt. Ltd. S. No. 354-1,354-2A/1, At &post Narayangaon, Tal. Junnar, District Pune – 410 504, State Maharashtra, INDIA, India
	Details of Certificates (CoPP/FSC/cGMP):	Firm has submitted COPP/CERT/PD/141509/2024/11/52045/248639 dated 09-10-2024 valid till 01-08-2027 issued by Food & Drug Administration. M.S. Bandra-kurla Complex Bandra (E), Mumbai -400 051 Maharashtra,INDIA. The certificate specifies the free sale and G

Details of Authorization Letter :	N/A
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (L/06/18001, L/06/18002, L/06/18003) at real time conditions and accelerated conditions. For Accelerated Time Stability Study: 25OC $\pm$ 2oC & 60% $\pm$ 5% RH for 6 Months and for real time 5oC $\pm$ 3oC for 60 Months.
The status in reference regulatory authorities	Brand name: Premi-RIG Manufacturer : Premium Serum and Vaccine PVT LTD-India Reference authorities: Myanmar

Evaluation Remarks

The application was evaluated and some queries were asked from the firm. The firm submitted a response which is tabulated below;

Sr.No.	Queries	Response of the firm	Remarks
1	Stability of finished product is submitted till 36 months while claimed shelf life is 4 years. Submit complete data till claimed shelf life.	48 months' stability data is attached	submitted
2	Single dose and repeat dose toxicity studies required in Module 4.	Single dose toxicity study is mentioned in Intox toxicity study report which is part of Module-4 already submitted with initial application. We have attached the same study report for your reference. Repeat dose toxicity study is not applicable to our product as it is administered as single dose.	Repeat dose toxicity not performed.
3	Phase III clinical trial studies of applied product is not provided.	Phase III clinical data is not available however post marketing surveillance literature data is available in initially submitted Module-5 (Same is attached below also)	Phase III clinical trial data not provided.
4	Public safety update report attached with the dossier shows that Rabies antiserum 300IU/ml is for domestic market while Rabies antiserum 200IU/ml is for export only. Please clarify whether 200IU/ml (lyophilized) is available in local market in exporting country also?	200 IU/ml lyophilized as well as liquid formulation are export license product and exclusively for export market and no use in India.	The applied product is not on free sale in country of origin and registered for export purpose only, as per statement submitted by the firm.
5	Submit finished product specifications in the light of the decision of Registration Board.	Finished product specifications are attached.	The firm applied in-house specifications.

Concluding remarks: The product is not on free sale in country of origin and registered for export purpose only, as per statement submitted by the firm.

Decision

	Rejected	
	Keeping in view the non-availability of product in country of origin; Registration Board rejected the the application.	
2	Case Category	Routine (Anam Saeed)
	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	(8UB-AE7-BGRS, 2025-11-04)
	Detail of Fee Submitted	313500, 2025-09-17,
	The proposed proprietary name / brand name	RINBIO IBD (TS)
	Label Claim	RINBIO IBD (TS) - Infectious Bursal Disease Thermo-stable Vaccine, Live - Infectious bursal disease virus strain B87, virus content: $\geq 10^{4.1}$ ELD50 per dose
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 doses/Vial (10 Vials/Box)-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store at 2°C - 8°C
	For generic drugs (me-too Status)	B87 strain is not registered yet.
	Pharmacotherapeutic Group of (API)	Veterinary vaccine
	Name, address of Manufacturing site:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd-No. 793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province-China
	Name, address of Marketing Authorization Holder:	Ringpu (Baoding) Biological Pharmaceutical Co. Ltd, No. 793, Tengfei Road, Baoding Industry Area, Baoding City, Hebei Province, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	N/A Apostile copy of Letter of Authorization: Valid till 24-05-2030
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches of RINVAC IBD (TS) (20220502, 20220901, 20230301) were stored at 2-8°C and random samples were taken on the day of storage and at 3, 6, 9, 12 18 and 24 months after storage,
	Evaluation Remarks	
	B87 strain is not registered yet but the strain is already approved by the Board in its 339th meeting on the basis of recommendations of sub-committee on veterinary drugs. The recommendation of sub-committee for B87 strain which was considered in 339th meeting is as under: "After deliberation, the Sub-committee on Veterinary Drugs decided that Infectious Bursal Disease (IBD) is major challenge for Broiler segment of poultry industry in Pakistan. In China, a strict vaccine immunization program is applied to prevent and control IBD; B87 is the most widely used live-attenuated vaccine strain. Vaccine will be useful for poultry sector in Pakistan. Product is therefore Recommended."	
	Decision	
	Approved	
	Keeping in view the recommendation of Expert Working Group on Veterinary Drugs regarding B87 strain in 339th meeting of Registration Board; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
3	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	(12X-JLL-LWVD, 2025-01-30)
Detail of Fee Submitted	300000.0, 2025-01-02,
The proposed proprietary name / brand name	TETAVIN
Label Claim	Each ml contains: Enzyme Refined, Equine Tetanus Antitoxic Immunoglobulin fragments not less than 1500 I.U.
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	20 ampoules of 1 mL -As per SRO
Shelf Life (Unit)	24 Month(s)Store at 2°C-8°C.Do not freeze.
For generic drugs (me-too Status)	TETANUS ANTITOXIN ATS 1500I.U/AMPOULE MAH: RYAN PHARMA UK Manufacturer: JIANGSI INSTITUTE OF BIOLOGICAL PRODUCTS MFG. LIC. NO. S10970021 NMPA APPROVED
Pharmacotherapeutic Group of (API)	Antitoxins
Name, address of Manufacturing site:	VINS Bioproducts Limited -Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist.,509325 Telangana, India. -India
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
Name, address of Marketing Authorization Holder:	VINS Bioproducts Limited , Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist.,509325 Telangana, India. , India
Details of Certificates (CoPP/FSC/cGMP):	Ministry of Foreign Affairs attested COPP is provided.
Details of Authorization Letter :	-
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of three batches accelerated conditions 25°C±2°C and 60% + 5% RH for 6 months and long -term stability studies of three batches at 2° C-8° C for 24 months.
The status in reference regulatory authorities	Tetanus Antitoxin 1500 I.U/ml BP, MAH: Amson Vaccines & Pharma (Pvt) Ltd, Islamabad, Manufacturer: Biological E. Ltd, 18 / 1 & 3, Azamabad, Hyderabad, India
Evaluation Remarks	
Decision of 351st meeting: Registration Board directed the BE&R Division to issue a Show Cause Notice to M/s Lab Diagnostic Systems (SMC), Taxila, for rejection of their registration application of Tetavin (Tetanus Anti Toxin 1500IU) Ampoule as the authenticity of the Letter of Authorization (LoA) submitted by the applicant could not be verified. This decision was based on the communication received from M/s VINS Bioproducts Limited, India, wherein it was confirmed via email to DRAP that M/s Bristol Mayer Biotech, Pakistan, is the sole authorized entity to register, import, and market their product Tetanus Antitoxin 1500 IU Ampoule in Pakistan. Remarks of evaluator: A show cause notice was issued to the firm on 13-10-2025. The firm has requested to withdraw the registration application and submitted a reply of show cause as under; "We respectfully submit this letter to officially inform the Drug Regulatory Authority of Pakistan(DRAP) that our company is forfeiting the registration application for our product TETAVIN1500 I.U B.P) from Vins Bioproducts Limited Address: Survey	

No. 117, Thimmapur (Village),Kothur (Mandal), Ranga Reddy (Dist.),-509325, Telangana, India.After internal review and evaluation, we have decided not to proceed further with this application.We therefore request DRAP to consider the application withdrawn from our end.We appreciate your time and consideration throughout the evaluation process and remain gratefulfor your continued support and cooperation."

Decision

Rejected

Registration Board disposed off the application as withdrawn.

4	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	HealthBee Projects Private Limited Ground Floor, Momi Plaza, Plot No 43, Business Square, Phase 7, Bahria Town (01-374-0176-065437D)
	Application Form Dy. No / Tracking ID & date of submission	(DW2-YNX-HET9, 2024-07-01)
	Detail of Fee Submitted	300000.0, 2024-06-12,
	The proposed proprietary name / brand name	CTST
	Label Claim	0.1ml per human dose, containing 5U of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1.0ml/vial-As per SRO
	Shelf Life (Unit)	24 Month(s)2-8 C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	tuberculosis diagnostics
	Name, address of Manufacturing site:	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd- No.100 Fushan Road, High Tech Development Zone, Hefei City-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd, No.100 Fushan Road, High Tech Development Zone, Hefei City, China
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) bulk (Batch No.: M20171101, M20171102, and M20171201) were placed under two conditions of $\leq -70^{\circ}\text{C}$ (long-term) and $2-8^{\circ}\text{C}$ (accelerated) to observe their stability.
	The status in reference regulatory authorities	Not approved in any reference country yet
	Evaluation Remarks	
	The application was considered by the Board in 344th meeting and Board decided as under: Decision of 344th meeting: Deferred for provision of evidence of the status in reference regulatory authorities. Response of the firm: The firm submitted a reply as under; "We, M/s HealthBee Projects (Private) Limited, would like to submit the following response for your kind consideration regarding the decision made in the 344th Board Meeting. The CTST product, having a similar composition, has been approved by the European Union and registered with the European Medicines Agency (EMA). Our competitor,	

Serum Institute of India, has developed a comparable tuberculosis product named Siiltibcy (Common name: rdESAT-6 / rCFP-10). Both products share identical antigens — recombinant ESAT-6 and CFP-10 (rdESAT-6, rCFP-10). As Siiltibcy is already registered with the EMA, we respectfully request that our CTST product be considered equivalent to Siiltibcy. For your reference, please find below the relevant links: 1.<https://www.ema.europa.eu/en/medicines/human/EPAR/siiltibcy>
2.<https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-14-17-october-2024>
3.https://ec.europa.eu/health/documents/communityregister/2025/20250113164661/anx_164661_en.pdf
Furthermore, our product CTST has been reviewed and cited in the WHO Consolidated Guidelines on Tuberculosis and the WHO 2022 Report (relevant references enclosed). Please find attached the supporting documents for your review. We sincerely request your favorable consideration of our submission." Remarks of evaluator: The firm has stated in its reply that Siiltibcy is a reference product for the applied product and that both have the same composition. However, the two products are not the same. The differences between them are outlined in the table below;

Sr.No.	C-TST	Siiltibcy
1	Composition: 0.1ml per human dose, containing 5U of Recombinant Mycobacterium Tuberculosis Fusion Protein (EC).	Composition: One dose (0.1 mL) contains 0.05 microgram of rdESAT-6* and 0.05 microgram of rCFP-10**. *Recombinant dimer of Mycobacterium tuberculosis early secretory antigenic target **Recombinant culture filtrate protein of Mycobacterium tuberculosis
2	Recombinant Mycobacterium Tuberculosis Fusion Protein (EC) is expressed in Escherichia coli	Produced in Lactococcus lactis cells
3	The product comes with three different packing as mentioned, 0.3 ml/vial, 0.5 ml/vial and 1.0 ml/vial while the dosage for each human use is 0.1 ml per human dose.	Multidose vial. One vial (1 mL) contains 10 doses of 0.1 mL.
4	This product is indicated for the diagnosis of Mycobacterium tuberculosis infection, and it is recommended for infants ≥ 6 months, children, and adults ≤ 65 years.	SIILTIBCY is indicated as a diagnostic aid for detection of Mycobacterium tuberculosis infection, including disease, in adults and children aged 28 days or older.
5	Excipients disodium hydrogen phosphate, potassium dihydrogen phosphate, sodium chloride, phenol and polysorbate 80.	Excipients Disodium hydrogen phosphate dehydrate (E339), Potassium dihydrogen orthophosphate (E340), Potassium chloride (E508), Sodium chloride, Polysorbate 20 (E432), Phenol, Water for injections
6	Method of administration 2 methods: · Use this product alone or; · This product combined with TB-PPD	SIILTIBCY should be prepared and administered via intradermal injection by healthcare professionals trained for the Mantoux technique.

Decision

Deferred

Registration Board deferred the case for provision of evidence of availability of formulation in Reference Regulatory Authorities by the firm.

5	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)

Application Form Dy. No / Tracking ID & date of submission	(ABB-65L-4TBJ, 2025-12-02)
Detail of Fee Submitted	97200, 2025-11-17,
The proposed proprietary name / brand name	TERZA 10MG/0.5ML Injection in Pre-Filled Pen
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	Peptide
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
The status in reference regulatory authorities	ema approved
Detail of previous approval	
Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	

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

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

6	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(EYP-JX3-7J1V, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	TERZA 2.5MG/0.5ML Injection in Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	ema approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.		

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

7	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(NYM-ELD-2LAY, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	TERZA 12.5MG/0.5ML Injection in Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	ema approved
	Detail of previous approval	
	Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing		

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

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

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

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

8	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(TY5-LYJ-THA2, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	TERZA 5MG/0.5ML Injection syringe in Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	-
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	ema approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

9	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(Z8Z-X92-PLMH, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-17,
	The proposed proprietary name / brand name	TERZA 15MG/0.5ML Injection in Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	-
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	ema approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Not Applicable	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test	

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

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

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

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

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

10	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welcome Pakistan Trading Pharma (Pvt) Ltd Chakri Interchange, Gangawala (000987)
	Application Form Dy. No / Tracking ID & date of submission	(ZY7-3RR-8RAE, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-17,
	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-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)	-
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	ema approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
	Decision	
	Not Applicable	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
	2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration	

Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

11	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(4XX-BWG-Y2Z2, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 15mg single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Peptides
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

12	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(PJZ-BML-JPNU, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 2.5mg single dose Prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

13	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(PZ8-PW2-DA32, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 12.5mg single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		

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

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

14	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(QL4-7RR-8HG8, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 7.5mg single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		

Approved

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

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

15	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(TXM-L5R-URDR, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 10mg single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-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)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
	Evaluation Remarks	

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

Decision

Approved

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

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

16	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welwink Pharmaceuticals G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751)
	Application Form Dy. No / Tracking ID & date of submission	(YN8-DLN-V3MM, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-14,
	The proposed proprietary name / brand name	Terza 5mg single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA Approved

Detail of previous approval		
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Not Applicable		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP’s licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.		
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.		
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.		
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.		
17	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(1AA-G3S-ZL7P, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 10mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator’s Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	N/A
	Pharmaceutical Group of (API)	peptide

	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA AApproved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(47L-BEU-415N, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 2.5mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA AApproved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
19	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(4BP-Y4X-NX1S, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 12.5mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	As per SRO-As per SRO												
Shelf Life (Unit)	2 Year(s)Store at 2-8°C												
For generic drugs (me-too Status)	N/A												
Pharmacotherapeutic Group of (API)	peptide												
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-												
The status in reference regulatory authorities	EMA APproved												
Detail of previous approval													
Evaluation Remarks													
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.													
Decision													
Approved													
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.													
20	<table> <tr> <td>Case Category</td><td>Routine (Anam Saeed)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(BMJ-TQX-ST57, 2025-12-02)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>97200, 2025-11-19,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Terza 7.5mg PRefilled Pen</td></tr> <tr> <td>Label Claim</td><td>Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies</td></tr> </table>	Case Category	Routine (Anam Saeed)	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)	Application Form Dy. No / Tracking ID & date of submission	(BMJ-TQX-ST57, 2025-12-02)	Detail of Fee Submitted	97200, 2025-11-19,	The proposed proprietary name / brand name	Terza 7.5mg PRefilled Pen	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies
Case Category	Routine (Anam Saeed)												
Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)												
Application Form Dy. No / Tracking ID & date of submission	(BMJ-TQX-ST57, 2025-12-02)												
Detail of Fee Submitted	97200, 2025-11-19,												
The proposed proprietary name / brand name	Terza 7.5mg PRefilled Pen												
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies												

		Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA AApproved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
21	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(DHZ-RG9-WM8V, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 5mg sinlge dose Prefilled Pen

Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	As per SRO-De-Controlled	
Shelf Life (Unit)	2 Year(s)Store at 2-8°c	
For generic drugs (me-too Status)	N/A	
Pharmacotherapeutic Group of (API)	-	
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
The status in reference regulatory authorities	EMA APproved	
Detail of previous approval		
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.		
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.		
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.		
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.		
22	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790)
	Application Form Dy. No / Tracking ID & date of submission	(G66-UDZ-1659, 2025-12-02)

	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 15mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	EMA AApproved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
23	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)

Application Form Dy. No / Tracking ID & date of submission	(36Z-QM7-6XW9, 2025-12-02)
Detail of Fee Submitted	97200, 2025-11-19,
The proposed proprietary name / brand name	Terza 15mg single dose Prefilled Pen
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	peptide
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
The status in reference regulatory authorities	EMA Approved
Detail of previous approval	
Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
Decision	
Not Applicable	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
24	Case Category Routine (Anam Saeed)

Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
Application Form Dy. No / Tracking ID & date of submission	(D99-YSX-MRM6, 2025-12-02)
Detail of Fee Submitted	97200, 2025-11-19,
The proposed proprietary name / brand name	Terza 12.5mg single dose Prefilled Pen
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at 2-8°C
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	peptide
Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
The status in reference regulatory authorities	EMA Approved
Detail of previous approval	
Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	

25	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(L81-X6A-SUH5, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 7.5mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.		

	6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
26	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(ULY-25Y-L876, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 5mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. 5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.		

	6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
27	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(Z53-J36-33HV, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 10mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-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)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	

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

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

28	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610)
	Application Form Dy. No / Tracking ID & date of submission	(XLD-HZ1-2JWV, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Terza 2.5mg single dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	EMA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP. 4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	

5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

29	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	(7W6-3YZ-4Z85, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-21,
	The proposed proprietary name / brand name	TERZA 10mg/0.5ML single dose Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	peptide
	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	Approved in DRB M-352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions: 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. 2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT. 3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	

4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

30	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	(8UJ-M8L-RD74, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-21,
	The proposed proprietary name / brand name	TERZA 15mG/0.5ML single dose Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°c
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	peptide
	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	Approved in DRB M-352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.		
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing		

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

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

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

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

31	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	(28Q-X7L-P5BZ, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-21,
	The proposed proprietary name / brand name	TERZA 2.5MG/0.5ML single dose Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	peptide
	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	Approved in DRB M-352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
	2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

32	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	(BYW-1DY-6QD6, 2025-12-02)
	Detail of Fee Submitted	97200, 2025-11-21,
	The proposed proprietary name / brand name	TERZA 5mg/0.5ML single dose Pre-Filled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	peptide
	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	Approved in DRB M-352
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
	1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
	2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test	

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

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

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

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

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

33	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(E9T-466-1APV, 2026-01-08)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	Terza 10mg/0.5ml Single Dose Prefilled Pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	www.ema.europa.eu/en/documents/product-information/mounjaro-eparproduct-information_en.pdf
	Detail of previous approval	Terza 10mg/0.5ml Single Dose Prefilled Pen Minutes of 352nd Meeting of Registration Board
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:		
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.		

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

34	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(EX6-PN3-B5HB, 2026-01-08)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	TERZA 15mg/0.5ML single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Terza 15mg/0.5ml Single Dose Prefilled Pen Minutes of 352nd Meeting of Registration Board
	Evaluation Remarks	
	The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
	Decision	
	Approved	

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

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

35	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(GY1-MT6-6TTW, 2026-01-08)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	TERZA 12.5mg/0.5ML single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Terza 12.5mg/0.5ml Single Dose Prefilled Pen Minutes of 352nd Meeting of Registration Board
Evaluation Remarks		
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.		

Decision**Approved**

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

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.

36	Case Category	Routine (Anam Saeed)
	Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission	(LMJ-37L-EY6S, 2026-01-08)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	TERZA 2.5MG/0.5ML single dose prefilled pen
	Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	peptide
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	www.ema.europa.eu/en/documents/product-information/mounjaro-eparproduct-information_en.pdf

Detail of previous approval	TERZA 2.5MG/0.5ML Injection in PreFilled Pen 352nd Meeting of DRB
Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of Registration Board.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
37	Case Category
	Routine (Anam Saeed)
	Name, address of Applicant.
	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
	Application Form Dy. No / Tracking ID & date of submission
	(X6Y-R8Y-WHDX, 2026-01-08)
	Detail of Fee Submitted
	97200, 2026-01-02,
	The proposed proprietary name / brand name
	TERZA 7.5mg/0.5ML single dose prefilled pen
	Label Claim
	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs)
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	As per SRO-As per SRO
	Shelf Life (Unit)
	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)
	N/A
	Pharmacotherapeutic Group of (API)
	peptide

Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
The status in reference regulatory authorities	www.ema.europa.eu/en/documents/product-information/mounjaro-epar-productinformation_en.pdf
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 is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP’s licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
Case Category	Routine (Anam Saeed)
Name, address of Applicant.	Welmark Pharmaceuticals Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (000614)
Application Form Dy. No / Tracking ID & date of submission	(XV3-TJH-DEZ9, 2026-01-08)
Detail of Fee Submitted	97200, 2026-01-02,
The proposed proprietary name / brand name	TERZA 5mg/0.5ML single dose Pre-Filled Pen
Label Claim	Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator’s Specs)

Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As per SRO-As per SRO
Shelf Life (Unit)	2 Year(s)Store at 2-8°c
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	peptide
Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -
The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
Detail of previous approval	Terza 5mg/0.5ml Single Dose Prefilled Pen Minutes of 352nd Meeting of Registration Board
Evaluation Remarks	
The applied formulation is already approved in the name of proposed manufacturer in 352nd meeting of RegistrationBoard.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan with following conditions:	
1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.	
2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.	
3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract testing must be carried out at any government drug testing laboratory or DRAP’s licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.	
4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.	
5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.	
6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules.	
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	(MUB-RTU-21WW, 2025-02-13)
Detail of Fee Submitted	300000.0, 2025-01-15,

The proposed proprietary name / brand name	OSTEOPARIN		
Label Claim	Each ml contains: Recombinant Human Parathyroid Hormone (1-34) USP 250 mcg, Succinic acid USP 0.29 mg, Sodium Hydroxide USP 0.05mg, Glycerol USP 50mg, M-Cresol USP 3mg, Water for Injection USP q.s		
Reference to Finished product specifications	United States Pharmacopeia		
Proposed Pack Size	3ml (Osteoparin is s-As per SRO		
Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light. This injection is not to be frozen.		
For generic drugs (me-too Status)	FORTEO 20mcg/80mcl of M/a Eli Lilly Karachi (Reg#043009)		
Pharmacotherapeutic Group of (API)	Parathyroid hormone analogue		
Name, address of Manufacturing site:	Virchow Biotech Pvt Ltd-Sy No 172 part, Gagillapur (V), Dundigal-Gandimaisamma (M), Medchal-Malkajgiri (D), Telangana, 500043-India		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Name, address of Marketing Authorization Holder:	Virchow Healthcare Pvt. Ltd. , Sy No 172 part, Gagillapur (V), Dundigal-Gandimaisamma (M), Medchal-Malkajgiri (D), Telangana, 500043, India		
Details of Certificates (CoPP/FSC/cGMP):	COPP No of Certificate : 4309348/TS/2024 Valid UpTo : 20/05/2027 COPP is not legalized		
Details of Authorization Letter :	N/A		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of 1st batch is till 36months. 2nd batch is till 24 months and 3rd batch is till 12 months. Batch sizes are 25.8±3gm. Manufacturer informed that the API is manufactured for captive consumption not for commercial.		
The status in reference regulatory authorities	Forteo approved in Health Canada.		
Evaluation Remarks			
Decision of 352nd meeting: The Registration Board deferred the case until verification of the authenticity of the Letter of Authorization issued by the manufacturer/MA holder and submission of the following: i. Valid legalized COPP. ii. Accelerated stability data till 6 months. iii. Comparative impurity testing of applied product with innovator. iv. Letter of authorization issued by MA Holder as per COPP. The Registration Board further decided that the registration application of M/s Revive Health Care, Lahore, for ‘Osteotide Injection,’ which was deferred in the 351st meeting of the Registration Board, shall remain deferred until a decision is made on the aforementioned matter. Evaluation by BE&R:			
Sr.No.	Queries	Response of the firm	Remarks
1	The Registration Board deferred the case until verification of the authenticity of the Letter of Authorization issued by the manufacturer/MA holder.	Please verify the authenticity of LOA by emailing on the following address: regulatoryaffairs@virchowbiotech.h.com	Reply of email is received from the manufacturer as under; “We acknowledge your mail and would like to clarify that M/s Virchow Healthcare Private Limited is our sister organization and fully authorized to issue Letter of Authorization (LOA) for the registration of products manufactured by us in the territory of Pakistan. A copy of formal authorization

			letter addressed to DRAP by Virchow Biotech private Limited is enclosed for ready reference. This enclosed letter of authorization dated 15.01.2025 was issued by Virchow Healthcare Private Limited for the registration perusal under DRAP Pakistan for the Osteoparin. Hence we confirm the authenticity of both of the letter as enclosed and declare that we are proceeding our business with M/s Lab Diagnostics Systems for the product Osteoparin hence a termination letter was issued to M/s Revive Health care by our sister organization i.e Virchow Healthcare Private limited for the brand Osteotide. We realized that brand name Osteoparin was unintentionally mentioned in the termination letter, hence a revised copy of termination letter for agreed brand Osteotide is enclosed for your ready reference. Kindly consider the above clarification and revised termination letter for your kind perusal and product approval.”
2	Valid legalized COPP.	Attached	Please find the attached Apostilled COPP. Apostille COPP is not accepted from India.
3	Accelerated stability data till 6 months.	Teriparatide Injection is a biotech product i.e. recombinant DNA product and highly sensitive to temperature as slight variation may lead to degradation hence it follows the stability condition of cold chain. Upon evaluation of accelerated stability up to 3 months it is observed that it is not meeting purity criteria. It happens many instances, when biotech product are not stable at accelerated condition, in such cases shelf life is determined from real time stability study. Since product is already proven completed 36 month of shelf life (long term) when it is stored at 2-8 °C so it is acceptable to all regulatory authorities without any further justification Supporting ICH guideline: ICH Q5C QUALITY OF BIOTECHNOLOGICAL PRODUCTS: STABILITY	The product is stable up to 2 months at accelerated conditions. In-use stability data is submitted and it was concluded in the report that the product is stable in in-use condition till 28 days.

		TESTING OF BIOTECHNOLOGICAL/BIOLOGICAL PRODUCTS Q5C Please refer the text as stated from ICH Q5C : https://database.ich.org/sites/default/files/Q5C%20Guideline.pdf .3. Drug Product (Final Container Product) A minimum of 6 months data at the time of submission should be submitted in cases where storage periods greater than 6 months are requested. For drug products with storage periods of less than 6 months, the minimum amount of stability data in the initial submission should be determined on a case-by-case basis. Product expiration dating will be based upon the actual data submitted in support of the application. Since dating is based upon the real-time/real-temperature data submitted for review, continuing updates of initial stability data should occur during the review and evaluation process.	
4	Comparative impurity testing of applied product with innovator.	1-Comparative peptide-related impurity profiling of the applied product versus the innovator/reference product, preferably using LC-MS, including impurity levels expressed as % area: product is being characterized to confirm the primary amino acid sequence and structural integrity of the biosimilar product, directly comparing it to the innovator (reference) product at a molecular level. Peptide mapping of Teriparatide is performed by HPLC, specifically using a reverse-phase high-performance liquid chromatography (RP-HPLC) technique, coupled with mass spectrometry (LC-UV-MS or LC-MS/MS) for detailed analysis and confirmation of peptide fragments. This is critical factor that determine their biological activity, safety, and efficacy and the entire	Submitted

comparability has been submitted to Authority. Additional characterization of drug substance and drug product have been performed by LCMS method for the six batches of drug substance, Osteotide (our drug product) and reference biologic (Forteo). A screenshot is as below for quick reference. The primary structure by peptide mass fingerprint /peptide mapping by LC-MS of both drug substance /drug product and reference biologic have been found comparable. Peptide peptide attached. 2-Explicit confirmation that: o No individual peptide-related impurity exceeds 0.5%, and o Overall impurity levels do not exceed those of the reference product The all-individual impurities including rhPTH (1-30), Succinilnide (30) and Largest impurity in both similar biologic and reference biologic were compared as shown above. The product related substance and impurities present in six batches of the Osteotide injection complies as per specification and comparable with Forteo (Reference biologic) From the abobe tabulated presenation is is clearly depicted that No individual peptide-related impurity exceeds 0.5%, and Overall impurity levels do not exceed those of the reference product. 3-Identification and scientific justification of any new peptide-related impurities (if present), including an assessment of potential immunogenicity risk Further we would like to explain that Teriparatide is already official in USP and as per USP Teriparatide is also called rhPTH (1-34), is a single-chain peptide containing 34 amino acids identical to the 34 N-terminal amino acids of human parathyroid hormone. Our drug substance Teriparatide is produced by a recombinant DNA (rDNA)

		technology and meeting the standard and predetermined specification of Teriparatide USP. As a biotech product, its immunogenicity arises from impurities formed during synthesis, affecting immune responses like T-cell activation USP teriparatide monograph mandates tight impurity limits and we are following same standard. The host cell-derived protein content of Teriparatide produced from r DNA process is below the limit approved by the competent authority hence lower risk on immunogenicity In the reference biologic Forteo also exhibits a low immunogenicity profile. Clinical data indicate that only about 2.8% to 3% of patients develop anti-drug antibodies (ADAs) after 12 months of treatment, with minimal cross-reactivity to endogenous PTH. EMA and FDA assessments also teriparatide's overall immunogenicity as low, supporting its safety in long-term use. Similar biologics maintain comparable profiles, with impurities hence not adding significant risk Teriparatide due to homology with native PTH. Please find the attached USP Monograph.	
5	Letter of authorization issued by MA Holder as per COPP.	Please find attached the Authority Letter issued by Virchow Biotech, authorizing Virchow Healthcare to issue the Letter of Authorization (LOA) on their behalf.	No Objection on Letter of Authorization for M/s. Lab Diagnostic Systems Pvt Ltd Pakistan is provided by M/s Virchow Biotech India.
Decision			
Deferred			
Registration Board decided to issue show cause notice to M/s Revive Health care, Lahore for termination of their authorization by Product License Holder i.e. M/s Virchow Biotech Private Limited, India regarding OSTEOTIDE INJECTION 750 mcg/3mL deferred in 351st meeting of Registration Board.			
40	Case Category		Routine (M. Zubair Masood)
	Name, address of Applicant.		Vety Care (Pvt) Ltd. Plot # 77, Street 06, I-10/3 (DHO-ISB-883)

Application Form Dy. No / Tracking ID & date of submission	(H6Z-WYB-5T28, 2025-07-09)
Detail of Fee Submitted	300000.0, 2025-07-07,
The proposed proprietary name / brand name	Nobilis IB Ma5
Label Claim	Each dose (1ml) contains: Live Avian Infectious Bronchitis virus, (serotype Massachusetts) strain Ma5.....at least 3.0 log ₁₀ EID ₅₀
Reference to Finished product specifications	European Pharmacopeia
Proposed Pack Size	10000ds-De-Controlled
Shelf Life (Unit)	24 Year(s)2-8 C
For generic drugs (me-too Status)	Nobilis IB MA5 (013233)
Pharmacotherapeutic Group of (API)	Live Veterinary Vaccine
Name, address of Manufacturing site:	Batch Release & Export: M/s Intervet International-Wim de Korverstraat, 5831 AN Boxmeer-Netherlands ,Production: M/s Merck Sharp & Dohme Animal Health,-Poligono Industrial EL Montalvo I, S.Zeppelin 6, Parcela 38, 37008 Carbajosa de la Sagrada, Salamanca Spain-Spain
Name, address of Marketing Authorization Holder:	Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, Netherlands
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	Scanned copy of legalized LOA dated December, 2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: A152A1, A163B1, A176C1 Conditions: 2-8 C
Evaluation Remarks	
The firm already has registration of other packs 1000 doses, 2500 doses & 5000 doses of this product.	
Decision	
Approved	
Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
41	Case Category
	Routine (M. Zubair Masood)
	HI-TECH PHARMACEUTICALS (PVT) LTD 1-C SHADMAN CHOWK JAIL ROAD LAHORE (05-352-0063-066935D)
	Application Form Dy. No / Tracking ID & date of submission
	(85U-A59-EP75, 2025-07-17)
	Detail of Fee Submitted
	300000.0, 2025-07-15,
	The proposed proprietary name / brand name
	UltraChoice 8 (Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C&D Bacterin- Toxoid)
	Label Claim
	Each dose contains: Clostridium chauvoei Strain F..... >= 2.28

	OU* & a minimum Flagellar content of 0.6 RU** Clostridium septicum Strain A..... >= 32 L+units*** Clostridium haemolyticum Strain IRP-135.....>= 216 L+ units*** and >3.6 OU* Clostridium novyi Strain 8296.....>= 6,000 MLD**** Clostridium sordellii Strain 5918.....>= 20 L+units*** Clostridium perfringens Type C Strain PC8.....>= 300 L+units*** Clostridium perfringens Type D Strain 317.....>= 100 L+units*** *OU-Opacity Unit **RU-Relative Units ***Units of toxin, pre-inactivation ****MLD-Minimum Lethal Dose, pre-inactivation
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	10 dose (20 mL) vial-De-Controlled
Shelf Life (Unit)	24 Month(s)2 - 7 C
For generic drugs (me-too Status)	UltraChoice -8, 50 dose (Reg. No. 120487)
Pharmacotherapeutic Group of (API)	Bacterial Vaccine
Name, address of Manufacturing site:	Zoetis Inc.-279 E, White Hall Road, White Hall, IL 62092, USA-USA
Name, address of Marketing Authorization Holder:	Zoetis Inc., 279 E, White Hall Road, White Hall, IL 62092, USA
Details of Certificates (CoPP/FSC/cGMP):	Copy of Apostille CLI No. 05-01269 dated 22-04-2025
Details of Authorization Letter :	Scanned copy of Legalized Letter of Authorization dated 19-08-2020.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 554868, 557116, 654960A Storage Conditions: 2-8C
Evaluation Remarks	
The same formulation is already registered in other packaging i.e. Ultra Choice -8, 50 dose (Reg. No. 120487).	
Decision	
Approved	
Keeping in view legalized CLI indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
42	Case Category Name, address of Applicant. Application Form Dy. No / Tracking ID & date of submission Detail of Fee Submitted The proposed proprietary name / brand name
	Routine (M. Zubair Masood) jovac global pak plaza no 17 block d eme DHA Lahore (05-352-0066-072607D) (AN9-LE5-522D, 2025-08-19) 313500.0, 9400 2025-08-18, 2025-10-23 Jovac NDV La Sota Lyophilisate for Suspension

Label Claim	Each dose of vaccine contains: Live attenuated Newcastle Disease Virus strain La Sota.....at least 10 ^{6.0} EID ₅₀
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	2500 Doses Vial-De-Controlled
Shelf Life (Unit)	2 Year(s)2°C - 8°C
For generic drugs (me-too Status)	YES
Pharmacotherapeutic Group of (API)	Live Viral Veterinary Vaccines
Name, address of Manufacturing site:	Jordan Bio Industries Center (Jovac)-Amman, Yajouz road, near Yajouz Agriculture Nursery Amman Jordan-Jordan
Name, address of Marketing Authorization Holder:	Jovac "Jordan Bio Industries Center", Yajouz, near the Agriculture Nursery, Amman, Jordan
Details of Certificates (CoPP/FSC/cGMP):	Copy of Legalized CoPP No. 006703/10/5/5 dated 30-06-2025.
Details of Authorization Letter :	Copy of product specific Letter of Authorization dated 19-10-2025.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
Evaluation Remarks	
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Decision	
Approved	
Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
Case Category	Routine (M. Zubair Masood)
Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
Application Form Dy. No / Tracking ID & date of submission	(N2P-GHY-V2BB, 2025-09-12)
Detail of Fee Submitted	313500, 9400 2025-09-02, 2025-11-06
The proposed proprietary name / brand name	Medivac ND B Emulsion Inactivated vaccine for poultry
Label Claim	Each dose contains: Inactivated Newcastle Disease (ND) virus of La Sota strain.....at least 10 ^{7.0} EID ₅₀ Inactivated Newcastle Disease (ND) virus Genotype VII.2 group.....at least 10 ^{7.0} EID ₅₀
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	500ml-De-Controlled
Shelf Life (Unit)	24 Year(s)Vaccine is stored on temperature of 2 – 8°C and do not freeze, include temperature on its distribution. Vaccine is protected from heat and direct sunlight

	For generic drugs (me-too Status)	Medivac ND EDS Emulsion Vaccine by Hilton Pharma (Pvt) Ltd & Rinnovac Eli 7 by M/s. BroMed Animal Health
	Pharmacotherapeutic Group of (API)	Inactivated Veterinary Vaccine
	Name, address of Manufacturing site:	PT MEDION FARMA JAYA-Jl. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat-Indonesia
	Name, address of Marketing Authorization Holder:	PT MEDION FARMA JAYA, Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	Scanned Apostille copy of distribution agreement dated 01-02-2005 with updated product list dated 31-10-2025.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	N/A
	Evaluation Remarks	
	Expert Working Group in its 8th meeting recommended the product for grant of Registration.	
	Decision	
	Approved	
	Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
44	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(LWD-V9P-GSRB, 2024-12-02)
	Detail of Fee Submitted	300000.0, 9400 2024-11-28, 2025-11-14
	The proposed proprietary name / brand name	GUMBORO PLUS
	Label Claim	Each dose contains; Infectious Bursal Disease virus of Lukert strain $\geq 10^{2.0}$ EID50
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1000 DOSES-De-Controlled
	Shelf Life (Unit)	2 Year(s)2-8°C
	For generic drugs (me-too Status)	Not registered
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT. Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Not Submitted.
	Details of Authorization Letter :	Not submitted

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	Evaluation Remarks	
	Registration Board in its 352nd meeting deferred the case for submission of following by the firm: 1. Please submit scanned copy of valid legalized/ Apostille FSC indicating actual availability of product in country of origin instead of just mentioning permission to be sold? 2. Please submit fee of Rs. 9400/- for correction in specifications as this formulation is available in European Pharmacopoeia? The firm has submitted the requisite fee and also submitted scanned copy of legalized FSC indicating following statement: "The mentioned above product is registered in Indonesia, and produced according to the legal regulation and actual available for freely sale in the territory of Republic of Indonesia, and overseas market, and have fulfilled requirements of the quality standard of Indonesian Veterinary Pharmacopoeia. "	
	Decision	
	Approved	
	Keeping in view FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
45	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Mian Traders Railways Road, Morre Eminabad (09-341-0135-118497D)
	Application Form Dy. No / Tracking ID & date of submission	(G4W-HSV-7Z7U, 2024-12-04)
	Detail of Fee Submitted	300000.0, 2024-11-28,
	The proposed proprietary name / brand name	SANAVAC ND IB EDS K
	Label Claim	COMPOSITION : Inactivated Newcastle Disease virus La Sota strain ≥ 109.5 EID50, Infectious Bronchitis virus Massachusetts H52 strain ≥ 106.5 EID50, and Egg Drop Syndrome '76 strain FC 127 ≥ 32000 HAU before inactivation.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 DOSES-De-Controlled
	Shelf Life (Unit)	2 Year(s) 2-8°C
	For generic drugs (me-too Status)	Gallimune 302
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s PT. Sanbio Laboratories-Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat-Indonesia
	Name, address of Marketing Authorization Holder:	M/s PT. Sanbio Laboratories, Jl. Melati Desa Wanaherang RT/RW 02/09, Kecamatan Gunung Putri Kabupaten Bogor, Provinsi Jawa Barat, Indonesia
	Details of Certificates (CoPP/FSC/cGMP):	Not submitted
	Details of Authorization Letter :	Not submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	Evaluation Remarks	
	Registration Board in its 352nd meeting deferred the case for submission of valid legalized/ Apostille FSC indicating actual availability of product in country of origin instead of just mentioning permission	

to be sold. The firm has submitted the scanned copy of legalized FSC indicating following statement: "The mentioned above product is registered in Indonesia, and produced according to the legal regulation and actual available for freely sale in the territory of Republic of Indonesia, and overseas market, and have fulfilled requirements of the quality standard of Indonesian Veterinary Pharmacopeia. "

Decision

Approved

Keeping in view FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

46	Case Category	Routine (M. Zubair Masood)
	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	(HXY-ZLJ-GAM6, 2025-08-07)
	Detail of Fee Submitted	300000.0, 2025-06-20,
	The proposed proprietary name / brand name	DISRUBY
	Label Claim	One vial of 2 mL contains 6mg of monoclonal antibodies, one vial of 5 mL contains 15mg of monoclonal antibodies. Each mL of solution contains 1.5 mg of Zamerovimab and 1.5mg of Mazorelvimab.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 Months Store and transport at 2 - 8°C, protected from light.
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Synermore Biologics (Suzhou)Co., Ltd.-Building 5, No.218 Sangtian Street, Suzhou Industrial park, Sozhou, Jiangsu Province , P.R.C.-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Synermore Biologics (Suzhou)Co., Ltd., Building 5, No.218 Sangtian Street, Suzhou Industrial park, Sozhou, Jiangsu Province , P.R.C., 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	NA
	Evaluation Remarks	
	The formulation is not registered in any of the reference regulatory authorities and the firm submitted that they are the Innovator.	
	Decision	
	Rejected	Keeping in view the non-availability of formulation in Reference Regulatory Authorities; Registration Board rejected the application.

47	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(DSL-HSA-63UW, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-11-06,
	The proposed proprietary name / brand name	Semafit 1.7mg/0.75mL PFS
	Label Claim	Each PFS (0.75ml) Contains: Semaglutide.....1.7mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Refrigerate at 2°C to 8°C. Do not freeze.
	For generic drugs (me-too Status)	Seglu 1.7mg/0.75mL PFS of M/s Macter International Limited
	Pharmacotherapeutic Group of (API)	GLP- 1 Analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Name, address of Marketing Authorization Holder:	, ,
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	DRAP Clearance Certificate No. RO-64328-C dated 23-12-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 06210801, 06210901, 06210902 Conditions: 2-8 & 25 Intervals: 0, 3, 6, 9, 12, 18, 24, 36
	The status in reference regulatory authorities	Wegovy 1.7mg Injection of M/s Novo Nordisk A/S DK-2880 Bagsvaerd Denmark approved by USFDA
	Evaluation Remarks	
	The other strengths of same molecule are already registered in name of firm wherein DS manufacturer is also same.	
	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.

48	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(BQT-R49-S399, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-11-03,
	The proposed proprietary name / brand name	Semafit 2.4mg/0.75mL PFS
	Label Claim	Each PFS (0.75ml) Contains: Semaglutide.....2.4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Refrigerate at 2°C to 8°C. Do not freeze.
	For generic drugs (me-too Status)	Seglu 2.4mg/0.75mL PFS of M/s Macter International Limited
	Pharmacotherapeutic Group of (API)	GLP- 1 Analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Zhejiang Peptides Biotech Co., Ltd. Site Address: No.8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Three Batches: 088D01, 088D02, 088D03 Conditions: 2-8 & 25 Intervals: 0, 3, 6 Size: 650PFS Each

	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Clearance Certificate No. RO-64328-C dated 23-12-2024.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 06210801, 06210901, 06210902 Conditions: 2-8 & 25 Intervals: 0, 3, 6, 9, 12, 18, 24, 36
	The status in reference regulatory authorities	Wegovy 2.4mg Injection of M/s Novo Nordisk A/S DK-2880 Bagsvaerd Denmark approved by USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Scanned copy of Section Approval dated 07-05-2024.
	Evaluation Remarks	
	The other strengths of same molecule are already registered in name of firm wherein DS manufacturer is also same.	
	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.	
49	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(J8H-J7L-NLPS, 2026-01-08)

Detail of Fee Submitted	38700, 2025-12-03,
The proposed proprietary name / brand name	Semafit 1mg/0.5mL PFS
Label Claim	Each PFS (0.5ml) Contains: Semaglutide.....1mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's , 4's-As per SRO
Shelf Life (Unit)	24 Year(s)Refrigerate at 2°C to 8°C. Do not freeze.
For generic drugs (me-too Status)	Seglu 1mg/0.5mL PFS of M/s Macter International Limited
Pharmacotherapeutic Group of (API)	GLP- 1 Analogue
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Name: Zhejiang Peptides Biotech Co., Ltd. Site Address: No.8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Three Batches: 094D01, 094D02, 094D03 Conditions: 2-8 & 25 Intervals: 0, 3, 6 months Size: 1000PFS Each
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Clearance Certificate No. RO-DA8670 dated 26-02-2025.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 06210801, 06210901, 06210902 Conditions: 2-8 & 25 Intervals: 0, 3, 6, 9, 12, 18, 24, 36
The status in reference regulatory authorities	Wegovy 1mg Injection of M/s Novo Nordisk A/S DK-2880 Bagsvaerd Denmark approved by USFDA
GMP status of the firm	
Evidence of approval of manufacturing facility	Scanned copy of Section Approval dated 07-05-2024.
Evaluation Remarks	
The other strengths of same molecule are already registered in name of firm wherein DS manufacturer is also same.	
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.

50	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(N5N-QRT-N3JD, 2026-01-08)
	Detail of Fee Submitted	38700, 2025-12-03,
	The proposed proprietary name / brand name	Semafit 0.5mg/0.5mL PFS
	Label Claim	Each PFS (0.5ml) Contains: Semaglutide.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Refrigerate at 2°C to 8°C. Do not freeze.
	For generic drugs (me-too Status)	Seglu 0.5mg/0.5mL PFS of M/s Macter International Limited
	Pharmacotherapeutic Group of (API)	GLP- 1 Analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: Zhejiang Peptides Biotech Co., Ltd. Site Address: No.8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
	Detail of stability batches of drug product	Three Batches: 093D01, 093D02, 093D03 Conditions: 2-8 & 25 Intervals: 0, 3, 6 months Size: 1000PFS Each
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Clearance Certificate No. RO-DA8670 dated 26-02-2025.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 06210801, 06210901, 06210902 Conditions: 2-8 & 25 Intervals: 0, 3, 6, 9, 12, 18, 24, 36
	The status in reference regulatory authorities	Wegovy 0.5mg Injection of M/s Novo Nordisk A/S DK-2880 Bagsvaerd Denmark approved by USFDA
	GMP status of the firm	

Evidence of approval of manufacturing facility		Scanned copy of Section Approval dated 07-05-2024.
Evaluation Remarks		
The other strengths of same molecule are already registered in name of firm wherein DS manufacturer is also same.		
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.		
51	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	BF Biosciences Limited 5-KM Sundar Raiwind Road, Raiwind, Lahore (000655)
	Application Form Dy. No / Tracking ID & date of submission	(Z4J-EDB-DREV, 2025-12-02)
	Detail of Fee Submitted	38700, 2025-11-27,
	The proposed proprietary name / brand name	Semafit 0.25mg/0.5mL PFS
	Label Claim	Each PFS (0.5ml) Contains: Semaglutide.....0.25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's , 4's-As per SRO
	Shelf Life (Unit)	24 Year(s)Refrigerate at 2°C to 8°C. Do not freeze.
	For generic drugs (me-too Status)	Seglu 0.25mg/0.5mL PFS of M/s Macter International Limited
	Pharmacotherapeutic Group of (API)	GLP- 1 Analogue
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Name: Zhejiang Peptides Biotech Co., Ltd. Site Address: No.8, Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang Province, China
Detail of stability batches of drug product	Three Batches: 089D01, 089D02, 089D03 Conditions: 2-8 & 25 Intervals: 0, 3, 6 months Size: 1000PFS Each
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP Clearance Certificate No. RO-64328C dated 23-12-2024.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 06210801, 06210901, 06210902 Conditions: 2-8 & 25 Intervals: 0, 3, 6, 9, 12, 18, 24, 36
The status in reference regulatory authorities	Wegovy 0.25mg Injection of M/s Novo Nordisk A/S DK-2880 Bagsvaerd Denmark approved by USFDA
GMP status of the firm	
Evidence of approval of manufacturing facility	Scanned copy of Section Approval dated 07-05- 2024.
Evaluation Remarks	
The other strengths of same molecule are already registered in name of firm wherein DS manufacturer is also same.	
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.	

52	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	(WMN-4MW-WPZL, 2024-05-15)
	Detail of Fee Submitted	75000.0, 225000.0 2024-02-09, 2025-02-24
	The proposed proprietary name / brand name	RINVAC C RI
	Label Claim	RINVAC C RI Recombinant Canine α -Interferon, Freeze-dried - 5 Million IU/Vial
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Vials+1 Vial of 1-De-Controlled
	Shelf Life (Unit)	24 Month(s)2 - 8°C
	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	Veterinary Interferon
	Name, address of Manufacturing site:	Tianjin Ringpu Bio-Technology Co. Ltd.-Airport Economic Zone Branch, 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):	Valid legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	legalized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
53	Evaluation Remarks	
	Keeping in view the recommendations of EWG; Registration Board in its 352nd meeting deferred the case for submission of RRA status of formulation. The firm vide tracking ID: RZ4-JDE-M18R submitted response wherein they have given reference of EMA approved product Virbagen Omega which is Recombinant Omega interferon of feline which is indicated for dogs and cats. The firm submitted that their product is of same class i.e. Recombinant Interferon alfa of Dogs.	
	Decision	
	Deferred	
53	Registration Board referred the case to Expert Working Group on Veterinary Drugs for their comments regarding firm's response on availability of formulation in RRAs.	
	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. A-56, S.I.T.E, Manghopir Road, Karachi. (052)
	Application Form Dy. No / Tracking ID & date of submission	(N19-E7S-GVDR, 2025-06-25)
	Detail of Fee Submitted	300000.0, 2025-03-26,
	The proposed proprietary name / brand name	TrastuRel 440mg Combikit Trastuzumab for Injection 440mg and Bacteriostatic Water for Injection USP 20ml
53	Label Claim	Each kit contains the following: Lyophilized Vial:

	Trastuzumab for Injection..... 440mg Diluent: Bacteriostatic Water for Injection USP.....20ml
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's or As per SRO-Controlled
Shelf Life (Unit)	36 Year(s) 2°C to 8°C (36°F to 46°F)
For generic drugs (me-too Status)	Trazimera 440mg Injection by Pfizer-Pakistan, Herceptin 440mg Injection by Roche , Hertraz Injection 440mg by AGP-Pakistan
Pharmacotherapeutic Group of (API)	Monoclonal Antibody
Name, address of Manufacturing site:	M/s RELIANCE LIFE SCIENCES PVT. LTD.- DHIRUBHAI AM BANI LIFE SCIENCES CENTRE, PLANT 2 & 7 PLOT NO. R-282 TTC AREA OF MIDC, THANE BELAPUR ROAD, RABALE, NAVI MUMBAI THANE 400701 MAHARASHTRA STATE, INDIA-India
Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
Name, address of Marketing Authorization Holder:	M/s Helix Pharma (Pvt)., Ltd., A-56, S.I.T.E, Karachi, Pakistan
Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of Apostille CoPP No. COPP/CERT/KD/139484/2024/11/51102/244487 DATED 01-08-2024.
Details of Authorization Letter :	Scanned copy of LOA dated 5-12-2024.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches (Plant 2): TRMDS18009, TRMDS19001, TRMDS19002 Realtime at -20+-5 for 24 months Accelerated at 5+-2 for 6 months Four batches (Plant 7): 7TRDS19001, 7TRDS19002, 7TRDS19003, 7TRDS19004 Realtime at -20+-5 for 24 months Accelerated at 5+-2 for 6 months
The status in reference regulatory authorities	herceptin® 440mg approved by USFDA for Roche
Evaluation Remarks	
Registration Board in its 352nd meeting deferred the case for submission of Scientific Rationale/ Justification of performing Open Label clinical studies while WHO recommends at least observer blind approach. The firm in response vide tracking ID: WZQ-R1Y-S855 submitted the following: The primary endpoint, Objective Response Rate (ORR) and other secondary efficacy endpoints were objective parameters; hence, observational bias was limited to none. The site radiologist was blinded to the treatment arm during CT scan (with contrast) assessment as per RECIST criteria. Additionally, an independent assessor blinded to the treatment arm verified the tumour response assessment performed by site radiologist and his/ her final assessment was considered for evaluation of efficacy. Hence, even though the treatment allocation was done in an open-label manner, the important objective assessment of efficacy parameters were performed by an independent assessor who was blinded to the treatment allocation. Moreover, The submitted administrative documents are Apostilled, however, Apostille convention is not applicable for India as per decision of DRAP Authority. The diluent is manufactured in Plant 9 of manufacturer as per CoPP, however, the firm has not submitted separate Module of diluent.	
Decision	
Approved	

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 and submission of 2.3.P part of accompanying diluent and legalized CoPP.

54	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Helix Pharma (Pvt)., Ltd. A-56, S.I.T.E, Manghopir Road, Karachi. (052)
	Application Form Dy. No / Tracking ID & date of submission	(Z1Z-7S3-UDTD, 2025-06-25)
	Detail of Fee Submitted	300000.0, 2025-03-26,
	The proposed proprietary name / brand name	TrastuRel® 150mg for Injection
	Label Claim	Each kit contains the following: Lyophilized Vial: Trastuzumab for Injection 150mg Diluent: Sterile Water for Injection BP.....10ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's or As per SRO-Controlled
	Shelf Life (Unit)	36 Year(s) 2°C to 8°C (36°F to 46°F)
	For generic drugs (me-too Status)	Trazimera® by Pfizer-Pakistan; Hertraz 150mg by AGP-Pakistan
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	M/s RELIANCE LIFE SCIENCES PVT. LTD.- DHIRUBHAI AM BANI LIFE SCIENCES CENTRE, PLANT 2 & 7 PLOT NO. R-282 TTC AREA OF MIDC, THANE BELAPUR ROAD, RABALE, NAVI MUMBAI THANE 400701 MAHARASHTRA STATE, INDIA-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity data submitted.
	Name, address of Marketing Authorization Holder:	M/s RELIANCE LIFE SCIENCES PVT. LTD., DHIRUBHAI AM BANI LIFE SCIENCES CENTRE, PLANT 2 & 7 PLOT NO. R-282 TTC AREA OF MIDC, THANE BELAPUR ROAD, RABALE, NAVI MUMBAI THANE 400701 MAHARASHTRA STATE, India
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of Apostille CoPP No. COPP/CERT/KD/139484/2024/11/51102/244486 DATED 01-08-2024.
	Details of Authorization Letter :	Scanned copy of LOA dated 5-12-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three batches (Plant 2): TRMDS18009, TRMDS19001, TRMDS19002 Realtime at -20+-5 for 24 months Accelerated at 5+-2 for 6 months Four batches (Plant 7): 7TRDS19001, 7TRDS19002, 7TRDS19003, 7TRDS19004 Realtime at -20+-5 for 24 months Accelerated at 5+-2 for 6 months
	The status in reference regulatory authorities	herceptin® 150mg approved by USFDA for Genentech, Inc.
Evaluation Remarks		

Registration Board in its 352nd meeting deferred the case for submission of Scientific Rationale/ Justification of performing Open Label clinical studies while WHO recommends at least observer blind approach. The firm in response vide tracking ID: WZQ-R1Y-S855 submitted the following: The primary endpoint, Objective Response Rate (ORR) and other secondary efficacy endpoints were objective parameters; hence, observational bias was limited to none. The site radiologist was blinded to the treatment arm during CT scan (with contrast) assessment as per RECIST criteria. Additionally, an independent assessor blinded to the treatment arm verified the tumour response assessment performed by site radiologist and his/ her final assessment was considered for evaluation of efficacy. Hence, even though the treatment allocation was done in an open-label manner, the important objective assessment of efficacy parameters were performed by an independent assessor who was blinded to the treatment allocation. Moreover, The submitted administrative documents are Apostilled, however, Apostille convention is not applicable for India as per decision of DRAP Authority. The diluent is manufactured in Plant 9 of manufacturer as per CoPP, however, the firm has not submitted separate Module of diluent.

Decision

Approved

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 and submission of 2.3.P part of accompanying diluent and legalized CoPP.

55	Case Category	Contract Manufacturing (M. Zubair Masood)
	Name, address of Applicant.	PHARMEVO (PVT) LTD. A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (000504)
	Application Form Dy. No / Tracking ID & date of submission	(U89-HLS-U9VJ, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-19,
	The proposed proprietary name / brand name	Sematide 0.25mg/0.188ml Injection
	Label Claim	Each 0.188ml contains: Semaglutide.....0.25mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s) 2°C to 8°C
	For generic drugs (me-too Status)	Ozempic by Novo Nordisk Pakistan
	Pharmacotherapeutic Group of (API)	GLP-1 Analogue
	Name, address of Manufacturing site:	BF Biosciences Limited-5-KM Sunder Raiwind Road, Opposite Ijtima Chowk, Raiwind, Lahore – Pakistan-
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	336th Meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	336th Meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	336th Meeting
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	336th Meeting
	The status in reference regulatory authorities	Ozempic Injection approved by US FDA
	GMP status of the firm	

Evidence of approval of manufacturing facility		336th Meeting
Evaluation Remarks		
The same product is already registered in name of proposed manufacturer in light of data approved in 336th meeting of Registration Board.		
Decision		
Approved		
The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore 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.		
56	Case Category	Contract Manufacturing (M. Zubair Masood)
	Name, address of Applicant.	PHARMEVO (PVT) LTD. A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (000504)
	Application Form Dy. No / Tracking ID & date of submission	(PDN-LD6-XQ1U, 2026-01-09)
	Detail of Fee Submitted	97200, 2025-12-19,
	The proposed proprietary name / brand name	Sematide 0.5mg/0.375ml Injection
	Label Claim	Each 0.375ml contains: Semaglutide.....0.5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s) 2°C to 8°C

	For generic drugs (me-too Status)	Ozempic by Novo Nordisk Pakistan
	Pharmacotherapeutic Group of (API)	GLP-1 Analogue
	Name, address of Manufacturing site:	BF Biosciences Limited-5-KM Sunder Raiwind Road, Opposite Ijtima Chowk, Raiwind, Lahore – Pakistan-
	Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
	Detail of stability batches of drug product	336th Meeting
	Documents for the procurement of API with approval from DRAP (in case of Import)	336th Meeting
	Pharmaceutical Equivalence and Comparative Dissolution Profile	336th Meeting
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	336th Meeting
	The status in reference regulatory authorities	Ozempic Injection approved by US FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	336th Meeting
	Evaluation Remarks	
	The same product is already registered in name of proposed manufacturer in light of data approved in 336th meeting of Registration Board.	
	Decision	
	Approved	
	The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore 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.	
57	Case Category	Contract Manufacturing (M. Zubair Masood)

Name, address of Applicant.	PHARMEVO (PVT) LTD. A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (000504)
Application Form Dy. No / Tracking ID & date of submission	(TDX-GX5-JRSA, 2026-01-09)
Detail of Fee Submitted	97200, 2025-12-19,
The proposed proprietary name / brand name	Sematide 1mg/0.75ml
Label Claim	Each 0.75ml contains: Semaglutide.....1mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 C
For generic drugs (me-too Status)	Ozempic by Novo Nordisk Pakistan
Pharmacotherapeutic Group of (API)	GLP-1 Analogue
Name, address of Manufacturing site:	BF Biosciences Limited-5-KM Sunder Raiwind Road, Opposite Ijtima Chowk, Raiwind, Lahore – Pakistan-
Name & address of API manufacturer	Zhejiang Peptides Biotech Co., Ltd.
Detail of stability batches of drug product	336th Meeting
Documents for the procurement of API with approval from DRAP (in case of Import)	336th Meeting
Pharmaceutical Equivalence and Comparative Dissolution Profile	336th Meeting
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	336th Meeting
The status in reference regulatory authorities	Ozempic Injection approved by US FDA
GMP status of the firm	
Evidence of approval of manufacturing facility	336th Meeting
Evaluation Remarks	
The same product is already registered in name of proposed manufacturer in light of data approved in 336th meeting of Registration Board.	
Decision	
Approved	
The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore 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.

58	Case Category	Routine (M. Zubair Masood)
	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	(2YG-ZZ5-4WE6, 2024-05-08)
	Detail of Fee Submitted	300000.0, 2024-03-08,
	The proposed proprietary name / brand name	Rituxiver 500mg Injection Concentrate solution for infusion
	Label Claim	Each vial (50ml) contains: Rituximab.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)	MabThera 500mg/vial Manufactured by Roche
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Actoverco Biotech Pharmaceutical Company -4th Golestan Blv.,Baharestan Industrail Zone, Karaj,Iran.-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity provided.
	Name, address of Marketing Authorization Holder:	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran., Iran
	Details of Certificates (CoPP/FSC/cGMP):	CoPP No. 665/60346 dated 15-10-2023.
	Details of Authorization Letter :	Copy of Distribution certificate dated 29-05-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 30221001, 30221002, 30221003 Real time at -20C and Accelerated at 2-8C
	The status in reference regulatory authorities	MabThera By Roche USFDA Approved
	Evaluation Remarks	
	Registration Board in its 352nd meeting deferred the product for submission of complete biosimilarity data performed by finished product manufacturer. The firm has submitted the data which was evaluated and following are the observations: 1. The firm has not submitted quality comparison of finished product manufactured by M/s Actoverca with Innovator product. However, quality comparison of ready-to-fill bulk is submitted. 2. Quality Target Profile of finished product performed by M/s Mabxience is not submitted. However, the firm has submitted biosimilarity data of finished product	

manufactured by M/s Mabxience in comparison with Innovator product. 3. The firm has not submitted any Technology Transfer document instead a general quality agreement is submitted.

Decision

Approved

Keeping in view legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of Analytical comparability data of finished product conducted by Actoverco with Innovator/ Reference product.

59	Case Category	Routine (M. Zubair Masood)
	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	(YGN-7HQ-2MH7, 2024-05-14)
	Detail of Fee Submitted	300000.0, 2024-03-08,
	The proposed proprietary name / brand name	Rituxiver vial 10mg/1ml Concentrate for solution for infusion
	Label Claim	Each vial (10ml) contains: Rituximab.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's vial packing-As per SRO
	Shelf Life (Unit)	24 Month(s)Store at 2-8°C, protecting from light.
	For generic drugs (me-too Status)	MabThera 100mg/vial Manufactured by Roche
	Pharmacotherapeutic Group of (API)	Monoclonal Antibody
	Name, address of Manufacturing site:	Actoverco Biotech Pharmaceutical Company -4th Golestan Blv.,Baharestan Industrail Zone, Karaj,Iran.-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Biosimilarity provided.
	Name, address of Marketing Authorization Holder:	Actero Middle East, On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial Zone, Karaj, Iran., Iran
	Details of Certificates (CoPP/FSC/cGMP):	CoPP No. 665/60349 dated 15-10-2023.
	Details of Authorization Letter :	Copy of Distribution certificate dated 29-05-2024.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: 30221001, 30221002, 30221003 Real time at -20C and Accelerated at 2-8C
	The status in reference regulatory authorities	MabThera By Roche USFDA Approved

Evaluation Remarks

Registration Board in its 352nd meeting deferred the product for submission of complete biosimilarity data performed by finished product manufacturer. The firm has submitted the data which was evaluated and following are the observations: 1. The firm has not submitted quality comparison of finished product manufactured by M/s Actoverca with Innovator product. However, quality comparison of ready-to-fill bulk is submitted. 2. Quality Target Profile of finished product performed by M/s Mabxience is not submitted. However, the firm has submitted biosimilarity data of finished product manufactured by M/s Mabxience in comparison with Innovator product. 3. The firm has not submitted any Technology Transfer document instead a general quality agreement is submitted.

Decision

Approved

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 and submission of Analytical comparability data of finished product conducted by Actoverco with Innovator/ Reference product.

60	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Abbott Laboratories (Pakistan) Limited Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (056/2023)
	Application Form Dy. No / Tracking ID & date of submission	(WQT-8T9-XTEE, 2025-04-21)
	Detail of Fee Submitted	300000.0, 2025-04-10,
	The proposed proprietary name / brand name	RESYNIV
	Label Claim	Each pre-filled syringe contains 60mg of denosumab in 1ml of solution (60mg/1ml)
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 Single pre-filled -De-Controlled
	Shelf Life (Unit)	36 MonthsStore in a refrigerator at +2°C to +3°C. Do not freeze. Do not shake. Keep the syringe in the outer carton in order to protect from light.
	For generic drugs (me-too Status)	PROLIA DRAP registration no. 077527
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Universal Farma, S.L.-C/EL Tejido, No.2, 19200 Azuqueca de Henares, Guadalajara, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Abbott Laboratories (Pakistan) Limited., Opposite Radio Pakistan Transmission Center Hyderabad Road, Landhi, Karachi-75120, Pakistan., 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	US-FDA & MHRA-UK Approved
	Evaluation Remarks	
	The Registration Board in its 347th meeting deferred the case for the submission of the following documents: ☐ Hard copy of original or notarized LOA of the applied strength. ☐ The COPP states that provided is neither licensed nor available in the jurisdiction of certifying authority. Justification is required. ☐ Complete contents of COPP are required as per WHO as only COPP till point 2.B.1 has been submitted. ☐ QOS is not on WHO template. ☐ The batch analysis section 3.2.S.4.4 contains COA of Denosumab 70mg/ ml. Clarification is required. ☐ Submit stability data of drug product commercial batches till claimed shelf life ☐ Submit complete bio similarity studies in line with WHO requirements in comparison of applied product with innovator product Prolia.The submitted data in some places is with Xgevia. ☐ MB09 PFS DP manufacturing was firstly established at Universal Farma, S.L. (Process 1) andconsequently transferred to Farmalan, S.A. (Process 2) for clinical batch manufacture.Therefore,Clarification is required w.r.t manufacturing site. The firm submitted the requisite documents on 13th June 2025 and CoPP No. 01/25/012781 dated 10-12-2025 issued by EMA	

on 22-12-2025 vide tracking ID: XUQ-XZT-9VS4. The submitted CoPP is also indicating batch release site which was not included in Module I. Hence, fee is required for pre registration variation.

Decision

Approved

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.

61	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Abbott Laboratories (Pakistan) Limited Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (056/2023)
	Application Form Dy. No / Tracking ID & date of submission	(ZQG-2J7-V1WT, 2025-04-21)
	Detail of Fee Submitted	300000.0, 2025-04-10,
	The proposed proprietary name / brand name	DNOCLAST
	Label Claim	Each vial contains 120mg of Denosumab in 1.7ml of Solution
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	1 Single use vial-De-Controlled
	Shelf Life (Unit)	36 MonthsStore at +2°C to +3°C. Do not freeze. Keep the vial in outer carton in order to protect from light.
	For generic drugs (me-too Status)	XGEVA (Denosumab) 120 mg/1.7 mL, DRAP Registration No: 077528
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Universal Farma, S.L.-C/EL Tejido, No.2, 19200 Azuqueca de Henares, Guadalajara, Spain-Spain
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Name, address of Marketing Authorization Holder:	Abbott Laboratories (Pakistan) Limited., Opposite Radio Pakistan Transmission Center Hyderabad Road, Landhi, Karachi-75120, Pakistan., 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	US-FDA & MHRA-UK Approved

Evaluation Remarks

The Registration Board in its 347th meeting deferred the case for the submission of the following documents: ☐ Hard copy of original or notarized LOA of the applied strength. ☐ The COPP states that provided is neither licensed nor available in the jurisdiction of certifying authority. Justification is required. ☐ Complete contents of COPP are required as per WHO as only COPP till point 2.B.1 has been submitted. ☐ QOS is not on WHO template. ☐ The batch analysis section 3.2.S.4.4 contains COA of Denosumab 70mg/ ml. Clarification is required. ☐ Submit stability data of drug product commercial batches till claimed shelf life ☐ Submit complete bio similarity studies in line with WHO requirements in comparison of applied product with innovator product Prolia.The submitted data in some places is with Xgevia. ☐ MB09 PFS DP manufacturing was firstly established at Universal Farma, S.L. (Process 1) andconsequently transferred to Farmalan, S.A. (Process 2) for clinical batch

manufacture. Therefore, Clarification is required w.r.t manufacturing site. The firm submitted the requisite documents on 13th June 2025 and CoPP No. 01/25/012786 dated 10-12-2025 issued by EMA vide tracking ID: XUQ-XZT-9VS4 on 22-12-2025. The submitted CoPP is also indicating batch release site which was not included in Module I. Hence, fee is required for pre registration variation.

Decision

Approved

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.

62	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, 2025-07-22,
	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

An autogenous (or herd-autogenous) vaccine is a bacterin/toxoid/viral preparation made from pathogens isolated from the same herd, flock or client population and returned to that herd (or a defined group) to help control a disease when no suitable licensed vaccine exists. Autogenous are not a first-line intervention but are indispensable for controlling specific, persistent infectious diseases caused by pathogens with significant strain variation or for which no commercial alternative exists. The application has already been reviewed, and the deficiencies/ shortcomings were communicated to the applicant. However, the applicant has not yet submitted response which pending since September 11, 2025 for ANIVAC Mg, Ms. Moreover, the matter of Autogenous vaccines was referred to M/s National Food Security and their response is as under: "The disease burden in Pakistan indicates a genuine clinical need for effective vaccines against MG/MS and FAdV; however, the specific autogenous products under review cannot be supported in their present form. These vaccines are neither licensed in the country of origin nor accompanied by essential safety, efficacy, or strain-matching data. Approving such unverified products would entail regulatory and biosafety risks. Therefore, the Registration Board may not support approval at this stage and may advise the applicant to submit complete safety and

efficacy data, including controlled field-trial results, along with antigenic-similarity evidence demonstrating alignment with Pakistani field isolates. Only upon fulfilment of these fundamental requirements may the applications be processed further."

Decision

Deferred

Keeping in view the recommendations of Ministry of National Food Security & Research; Registration Board deferred the product for submission of following by the firm:

1. Complete safety and efficacy data including controlled field-trial results
2. Antigenic-similarity evidence demonstrating alignment with Pakistani field isolates.
3. Free Sale Certificate indicating quantitative composition issued by regulatory authority of country of origin instead of issued by the firm.
4. Clarification of submitted Contract Agreement as the supplier is M/s San Vet Holding GmbH, Austria while GMP submitted is of M/s San Group Biotech Germany GmbH, Germany?
5. Fee of Rs. 9400/- along with details of foreign MAH.
6. Scanned legalized/ Apostille GMP certificate issued by Regulatory Authority of Germany.
7. Clarification of monograph to be used for testing of product or In-house specs.
8. Clarification of address at which the product shall be stored.
9. Clarification of not performing assay test during stability studies.

63	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 > 1x10 ^{6.5} TCID ₅₀ Fowl Adenovirus Serotype 4 > 1x10 ^{6.5} TCID ₅₀ Fowl Adenovirus Serotype 8a > 1x10 ^{6.5} TCID ₅₀ Fowl Adenovirus Serotype 8b > 1x10 ^{6.5} TCID ₅₀ Fowl Adenovirus Serotype 11 > 1x10 ^{6.5} TCID ₅₀
	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		
An autogenous (or herd-autogenous) vaccine is a bacterin/toxoid/viral preparation made from pathogens isolated from the same herd, flock or client population and returned to that herd (or a defined group) to help control a disease when no suitable licensed vaccine exists. Autogenous are not a first-line intervention but are indispensable for controlling specific, persistent infectious diseases caused by pathogens with significant strain variation or for which no commercial alternative exists. The application has already been reviewed, and the deficiencies/ shortcomings were communicated to the applicant. However, the applicant has not yet submitted response which pending since August 29, 2025 for ANIVAC FAdV 5. Moreover, the matter of Autogenous vaccines was referred to M/s National Food Security and their response is as under: "The disease burden in Pakistan indicates a genuine clinical need for effective vaccines against MG/MS and FAdV; however, the specific autogenous products under review cannot be supported in their present form. These vaccines are neither licensed in the country of origin nor accompanied by essential safety, efficacy, or strain-matching data. Approving such unverified products would entail regulatory and biosafety risks. Therefore, the Registration Board may not support approval at this stage and may advise the applicant to submit complete safety and efficacy data, including controlled field-trial results, along with antigenic-similarity evidence demonstrating alignment with Pakistani field isolates. Only upon fulfilment of these fundamental requirements may the applications be processed further."		
Decision		
Deferred		
Keeping in view the recommendations of Ministry of National Food Security & Research; Registration Board deferred the product for submission of following by the firm: 1. Complete safety and efficacy data including controlled field-trial results 2. Antigenic-similarity evidence demonstrating alignment with Pakistani field isolates. 3. Free Sale Certificate indicating quantitative composition issued by regulatory authority of country of origin instead of issued by the firm. 4. Clarification of submitted Contract Agreement as the supplier is M/s San Vet Holding GmbH, Austria while GMP submitted is of M/s San Group Biotech Germany GmbH, Germany? 5. Scanned legalized/ Apostille GMP certificate issued by Regulatory Authority of Germany. 6. Clarification of specifications either Manufacturer's or As per Innovator's. 7. Clarification of address at which the product shall be stored. 8. Clarification of not performing assay test during stability studies.		
64	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	PharmEvo Private Limited Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi (057/2023.)

Application Form Dy. No / Tracking ID & date of submission	(HJH-Y5T-2GPH, 2025-04-14)
Detail of Fee Submitted	300000.0, 2025-03-21,
The proposed proprietary name / brand name	Pembro Injection 100mg/4ml
Label Claim	One vial of 4 mL contains: Pembrolizumab.....100mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1 vial-De-Controlled
Shelf Life (Unit)	2 Year(s)Store vials under refrigeration at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	L01FF02 : PD-1/PD-L1 (Programmed cell death protein 1/death ligand 1) inhibitors
Name, address of Manufacturing site:	M/s Limited Liability Company "PK-137"-LLC PK-137, Russia 124460, Moscow, Intracity, Territory of the Silino Municiple District ,Zelenograd, Proyezed 5557-y, d.2-Russia
Pharmaceutical Equivalence and Comparative Dissolution Profile	(NA)
Name, address of Marketing Authorization Holder:	M/s Limited Liability Company "PK-137", LLC PK-137, Russia 124460, Moscow, Intracity, Territory of the Silino Municiple District ,Zelenograd, Proyezed 5557-y, d.2, Russia
Details of Certificates (CoPP/FSC/cGMP):	Scanned Apostille CoPP Certificate no. 05/2024/0007537 Certifying Authority: Ministry of Industry and Trade of the Russian Federation The COPP specifies that the product is licensed for sale in country of origin. GMP status confirmed: Yes Validity:
Details of Authorization Letter :	Scanned Letter of Authorization Validity :2, April 2026 JSC "BIOCAD" company authorize Anabion Pharmaceutical Trading Ltd
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	DS BCD-201 batches were stored at the long-term condition of $5 \pm 3^{\circ}\text{C}$ for 12 months and at the accelerated storage condition of $25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%$ RH for 6 months. Based on the results of long-term, accelerated, stress stability and photostability studies, the shelf life and storage conditions of DS BCD-201 were established. Shelf life of DS BCD-201 is 12 months. Storage conditions: protected from light from 2 to 8 °C. Do not freeze.
The status in reference regulatory authorities	EMA Approved. Keytruda Marketing Authorisation Holder Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem The Netherlands
Evaluation Remarks	
Registration Board in its 352nd meeting deferred the product for submission of following by the firm: Revised CoPP indicating actual Market Authorization Holder and all the manufacturing sites. NOC from Product License Holder for proposed brand name. Revised product specific LOA indicating complete relationship between Product License Holder, JSC BIOCAD and Importer. Evidence of	

registration of product in other countries. Assessment report of product from regulatory authority of country of origin. The response of the firm was evaluated and following are the observations: 1. In quality comparison under biosimilarity studies, in multiple tests, results of multiple batches are at borderline or outside the result range of Innovator? The firm submitted that this difference is insignificant as in Phase-III immunogenicity studies, the results of applied product are comparable with Innovator product.

Decision

Approved

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.

65	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd 115, Industrial Triangle Kahuta Road (017/DSL(D)/PS&DC-ICT/2025)
	Application Form Dy. No / Tracking ID & date of submission	(3VJ-L7B-9JU9, 2025-01-23)
	Detail of Fee Submitted	300000.0, 2024-09-18,
	The proposed proprietary name / brand name	GC FLU Pre-filled syringe injection 0.5 ml.
	Label Claim	1 Pre-filled Syringe (0.5ml) contains: Purified Inactivated Influenza Virus Antigen Type A [A/Victoria/4897/2022 IVR-238 (H1N1)] ----- -----15µg Purified Inactivated Influenza Virus Antigen Type A [A/Thailand/8/2022 IVR-237 (H3N2)] -----15µg Purified Inactivated Influenza Virus Antigen Type B [B/Austria/1359417/2021 BVR-26] -----15µg Sodium chloride (as a buffer) ----- ----- 4mg Potassium chloride (as a buffer) ----- -- 0.1mg Disodium hydrogen phosphate dihydrate (as a buffer) ----- 0.6mg Potassium dihydrogen phosphate (as a buffer) ----- 0.1mg Water for injection ----- q.s. Needle (Sterilized disposable needle) (25G x 5/8 (0.5 x 16mm)) ----- ----- 1 ea
	Reference to Finished product specifications	European Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	12 MonthsStore at 2 – 8 °C
	For generic drugs (me-too Status)	Brand name: Influvac Suspension for Injection Manufacturer: Abbott Laboratories (Pakistan)Limited Registration No: 028437
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	GC Biopharma Corp.-Name: GC Biopharma Corp. Address: 40, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea. Contact details: Tel No.: +82-61-379-2100, Fax No.: +82-61-379-2166-South Korea
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

Name, address of Marketing Authorization Holder:	AMSON VACCINES & PHARMA (PVT.) LTD, DISTRIBUTOR, Plot no. 115, Industrial Triangle, Kahuta Road, Islamabad Pakistan., 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	Brand name: GC FLU injection 0.5 ml Responsible NRA: Ministry of Food and Drug Safety Country: Republic of Korea URL :http://www.mfds.go.kr/eng/index.do Reference authorities: WHO PQ
Evaluation Remarks	
Decision of 345th Meeting: The Registration Board deferred the case for the submission of the following documents: i. Hard copy of Original, legalized and valid COPP mentioning the composition of vaccine. ii. Hard copy of original or notarized copy of letter of authorization. iii. Documents/evidence for acceptable shipping conditions for both finished product and drug substance and formulated bulk (for importing bulks for filling and domestic production) & proof of shipping validation. iv. List of RRA where the product is already licensed and the date of approval. v. Evidence of approval / registration / marketing status of the applied formulation in the same composition and dosage form in one of the reference regulatory authority specified by Registration Board. vi. Drug substance part of each monovalent virus bulk containing data of recommended strains for the year 2024-2025 northern hemisphere influenza seasons as per (EMA/CHMP/BWP/99698/2007 Rev. 2). vii. Drug product part (Final bulk Filling) as per WHO recommended strains for the year 2024-2025 containing data of recommended strains for the year 2024-2025 northern hemisphere influenza season as per (EMA/CHMP/BWP/99698/2007 Rev. 2). viii. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3. ix. Justification for not performing non-clinical studies pertinent to recommended strains and for not performing complete pharmacodynamics studies like protective studies, passive immune transfer studies, safety pharmacology, safety studies, development and reproductive toxicity studies. x. Submit single dose/repeat dose toxicity and local tolerance studies of WHO recommended strains 2024-2025. xi. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for non-clinical study reports. xii. Complete Clinical study reports along with raw data for the WHO recommended strains for the year 2024-2025 as per international guidelines or justification is required in the light of reference guidelines. xiii. Proper justification with evidence of reference guidelines were “Not applicable” has been mentioned for clinical study reports. xiv. Risk Management Plan (RMP) for the WHO recommended strains for the year 2024-2025. xv. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) for the WHO recommended strains for the year 2024-2025. xvi. Adverse event following immunization report (summary of annual reports) in the country of origin. The firm has submitted the requisite documents along with Periodic Benefit Risk Assessment Report from July, 2024 to July, 2025. Moreover, their application for Tetravalent vaccine was deferred in 352nd meeting for Pharmacovigilance data of applied product available on Uppsala Monitoring Centre from Pharmacy Services Division of DRAP. Moreover, the trivalent vaccine of same manufacturer is WHO Prequalified in vial presentation available @ https://extranet.who.int/prequal/vaccines/p/gc-flu-inj	
Decision	
Approved	
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 with updated strains of NH 2025-2026.	

66	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)..... $\geq 10^{6.5}$ TCID ₅₀ Fowl Adenovirus (Group I, Serotype 8b)..... $\geq 10^{7.0}$ TCID ₅₀ Fowl Adenovirus (Group I, Serotype 11)..... $\geq 10^{7.0}$ 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
67	Evaluation Remarks	
	1. The product is not available in country of origin and firm submitted that it is registered for export purpose only. 2. Initially the firm submitted stability data of 100ml, the firm was asked to submit relevant data and they submitted the same data and changed the batch size and batch number. 3. The formulation was considered in 8th meeting of EWG and following are the recommendations: "The Committee recommended the product for grant of registration.	
	Decision	
67	Deferred	
	Registration Board 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.	
67	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	HI-TECH PHARMACEUTICALS (PVT) LTD 1-C SHADMAN CHOWK JAIL ROAD LAHORE

		(05-352-0063-066935D)
	Application Form Dy. No / Tracking ID & date of submission	(6BW-6PH-47LG, 2024-06-12)
	Detail of Fee Submitted	300000.0, 2024-06-12,
	The proposed proprietary name / brand name	QXK ND+IB+EDS
	Label Claim	Each 0.1ml contains; Inactivated Newcastle Disease Virus Strain LaSota... $\geq 3 \times 10^8.0$ EID50 before inactivation Inactivated Infectious Bronchitis Virus Strain M41.... $\geq 3 \times 10^6.0$ EID50 before inactivation Inactivated Egg Drop Syndrome Virus Strain HE02... $\geq 3 \times 10^6.0$ TCID50 before inactivation
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	250 ml / bottle-De-Controlled
	Shelf Life (Unit)	18 Month(s)2-8°C
	For generic drugs (me-too Status)	Jova Zeit 1, 2,4 vaccine (Jovac, Jordan) Reg. No. 111181
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	M/s Qixiang Biological Technology Co., Ltd.- No.5333, Heshuo Avenue, Wuzhi County, Henan Province, P.R. China-China
	Name, address of Marketing Authorization Holder:	M/s Qixiang Biological Technology Co., Ltd., No.5333, Heshuo Avenue, Wuzhi County, Henan Province, P.R. China, China
	Details of Certificates (CoPP/FSC/cGMP):	Valid Legalized FSC & GMP certificate has been submitted.
	Details of Authorization Letter :	Legalized LOA from MAH has been submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
	Evaluation Remarks	
	The Registration Board in its 347th meeting endorsed the recommendations of sub-committee on veterinary drugs and deferred the case for the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. The EWG in its 8th meeting provided the following recommendation: "The Committee recommended the product for grant of registration."	
	Decision	
	Approved	
	Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of revised Legalized/ Apostille FSC indicating actual availability of product in country of origin.	
68	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	(L5P-4BW-T2LJ, 2024-05-15)
	Detail of Fee Submitted	75000.0, 2024-05-15,

The proposed proprietary name / brand name	RINBIO TFOS
Label Claim	Each ml contains; Polypeptide...1mg, D-Ribose...30mcg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	500ml/Bottle-De-Controlled
Shelf Life (Unit)	24 Month(s)2° - 8°C
For generic drugs (me-too Status)	New Registration in Pakistan
Pharmacotherapeutic Group of (API)	Veterinary Immunomodulator
Name, address of Manufacturing site:	Tianjin Ringpu Bio-Technology Co. Ltd.-Airport Economic Zone Branch, 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):	Valid legalized FSC & GMP certificate has been submitted.
Details of Authorization Letter :	Legalized LOA from MAH has been submitted.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies data of three batches has been submitted.
Evaluation Remarks	
Keeping in view the recommendations of EWG that the data submitted by the firm was not satisfactory; Registration Board in its 352nd meeting did not accede to request of the firm for grant of registration. However, while issuing Letter it was observed that scientific reason for rejection should be recorded. Accordingly, the case was placed in 8th meeting of EWG wherein following are the recommendations: "The Committee revisited decision of its 7th meeting and deliberated that Poultry Farms have closed environment wherein there are chances of poorly developed Immune System and these polypeptides are useful in enhancing the Immune Function of chicken. Hence, recommended the product for grant of registration."	
Decision	
Approved	
Keeping in view the recommendations of EWG in its 8th meeting ; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
69	
Case Category	New Molecule/Formulation (Muneeb Ahmed Cheema)
Name, address of Applicant.	Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006-118530D)
Application Form Dy. No / Tracking ID & date of submission	(P93-TJE-3EH5, 2026-01-09)
Detail of Fee Submitted	313500, 2025-11-17,
The proposed proprietary name / brand name	CECOLIN 9®
Label Claim	Each dose (0.5 mL) contains: Recombinant Human Papillomavirus Type 6 L1 protein 30 µg Recombinant Human Papillomavirus Type 11 L1 protein 40 µg Recombinant Human Papillomavirus Type 16 L1 protein 60 µg Recombinant Human Papillomavirus Type 18 L1 protein 40 µg

	Recombinant Human Papillomavirus Type 31 L1 protein 20 µg Recombinant Human Papillomavirus Type 33 L1 protein 20 µg Recombinant Human Papillomavirus Type 45 L1 protein 20 µg Recombinant Human Papillomavirus Type 52 L1 protein 20 µg Recombinant Human Papillomavirus Type 58 L1 protein 20 µg
Reference to Finished product specifications	Any Other
Proposed Pack Size	10's-As per SRO
Shelf Life (Unit)	18 Year(s)Store at 2-8°C, protecting from light.
For generic drugs (me-too Status)	Not Applicable
Pharmacotherapeutic Group of (API)	Recombinant Human Papillomavirus 9-Valent (Types 6, 11, 16, 18, 31, 33, 45, 52, 58) Vaccine
Name, address of Manufacturing site:	Xiamen Innovax Biotech Co., Ltd.-No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China-China
Pharmaceutical Equivalence and Comparative Dissolution Profile	NA
Name, address of Marketing Authorization Holder:	Xiamen Innovax Biotech Co., Ltd., No. 60, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province, China, China
Details of Certificates (CoPP/FSC/cGMP):	
Details of Authorization Letter :	NA
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data of all 9 monovalent antigen bulks at accelerated and real time are provided.
The status in reference regulatory authorities	Gardasil 9 (9-valent HPV vaccine) Merck & Co. USFDA Approved
Evaluation Remarks	
.	
Decision	
Deferred	
Registration Board deferred the case for comments of Expanded Program on Immunization (EPI) regarding need of product for Pakistan.	
70	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	.
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):	
Details of Authorization Letter :	.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
The status in reference regulatory authorities	Mounjaro-FDA
Evaluation Remarks	
The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required. Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale. In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced. The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy. In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation. Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China. Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	
Decision	
Deferred	
Registration Board deferred the case for fulfillment of abovementioned deficiencies/ shortcomings.	
71	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	.
	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):	
	Details of Authorization Letter :	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	The status in reference regulatory authorities	Mounjaro-FDA
	Evaluation Remarks	
	The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required. Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale. In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced. The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy. In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation. Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China. Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	
	Decision	
	Deferred	
	Registration Board deferred the case for fulfillment of abovementioned deficiencies/ shortcomings.	
72	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	.
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):	
Details of Authorization Letter :	.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
The status in reference regulatory authorities	Mounjaro-FDA
Evaluation Remarks	
The Innovator proposes identification of the drug substance using a cell-based bioassay; however, this test is not included in your drug substance specifications. A justification for its omission is required. Please submit the Certificate of Analysis for drug substance batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025), along with clarification on whether this batch was produced at laboratory or pilot scale. In the formulation development section, Tirzepatide batch No. ZG27230701 (manufactured on 03/08/2023 and expiring on 03/08/2025) has been referenced. The same batch number has also been cited as the API batch in the finished product batch analysis data. However, according to the drug substance manufacturer, both laboratory-scale and pilot-scale batches were produced in 2024. Please provide clarification regarding this discrepancy. In Section 3.2.P.5.4, the batch analysis data for the applied strengths shows identical pilot-scale batch numbers with varying manufacturing dates and batch sizes. Please explain this observation. Please provide the purchase invoice for API Lot No. ZG27230701 supplied by Zhejiang Peptides Biotech Co., Ltd., China. Kindly submit details of the production line used for manufacturing, including information on other products manufactured on the same line.	
Decision	
Deferred	
Registration Board deferred the case for fulfillment of abovementioned deficiencies/ shortcomings.	

Item No. VI Supplementary Minutes

Registration I&V-II Section

Case.No.01: REGISTRATION OF DRUGS UNDER DRUGS ACT, 1976.

Registration Board in its 350th meeting considered and approved the following product of M/s Forward Solutions, Plot No.19-B, Qazalbash, Abdul Sattar Edhi Road, Lahore.

Name of Importer/Manufacturer	Name of Product and Composition
M/s Forward Solutions, Plot No.19-B, Qazalbash, Abdul Sattar Edhi Road, Lahore. Product License Holder & Manufacturer: M/s Shandong Soocom Animal Remedy Co., Ltd.- Agricultural High and New Technology Development Zone of Changqing District Jinan City-China	Doxycom Each gram contains: Doxycycline hyclate 500mg
Decision:	

Virtual inspection of manufacturer abroad was conducted on 4th November, 2025 and not recommended on by nominate panel Madam Saima, Deputy Director PE&R Division DRAP, Islamabad and Mr. Farooq Aslam, Deputy Director PE&R Division DRAP, Islamabad Conclusion of the panel of experts is as under:

Conclusion

The virtual inspection was conducted to the extent of the activities mentioned in the preceding paragraphs. There is a difference between conducting a physical inspection and a virtual inspection, as the depth of a virtual inspection remains limited. It is therefore recommended that whenever the policy for foreign inspections is revised to allow physical inspections, the site in question should also be inspected physically. However, keeping in view the current policy of virtual inspections and based on the virtual inspection conducted including the individuals interviewed, areas observed, records reviewed and on the basis of following observations noted during the inspection:

1. The firm does not have established a quarantine area within the raw material store which is being used for sampling area as well but there was no sampling both available at the time of inspection. When it was inquired, the representative of the firm answered that there no designated sampling area having a sampling booth installed, instead the samples were drawn for QC testing directly using a sampling rod by opening the containers in quarantine area.
2. No mechanism was existed for control of temperature and humidity, no HVAC system was installed, no air conditions were installed. Glass windows were provided in the area and curtains were installed to protect the materials from sunlight. Moreover, the windows were not properly cleaned, and visible dust and fungal growth were observed. Furthermore, direct sun light can lead to degradation of the material stored.
3. There was no segregation of excipients and APIs stored in raw material store.
4. No dispensing area was provided. When question was asked, the representative of the firm replied that

- the process of dispensing is carried out in the same raw material store. No dispensing booth was installed.
5. The firm could not provide the evidence of availability of FTIR at the time of inspection.
 6. Documents confirming validation of analytical procedures could not be presented by the firm.
 7. The firm could not produce cleaning validation documents at the time of inspection.
 8. The firm could not answer to the question of controlling the cross contamination.
 9. Windows in the warehouse allow direct sunlight to enter. Sunlight exposure can cause temperature fluctuations and increases in storage area temperature. There is no system for temperature control, such as an HVAC system or air conditioner. Without such a system, maintaining appropriate storage temperatures, particularly during summer.
 10. At the entrance of manufacturing unit, personnel were observed not wearing gloves according to standard protocol.
 11. No air curtain was installed at the entrance of the manufacturing unit.

The panel is of the view **not to recommend** Doxycom Powder (**Doxycycline**) for the grant of marketing authorization applied for, by M/s Forward Solutions, plot no. 19-B, Qazalbash, Abdul Sattar Edhi Road Lahore to be manufactured by M/s Shandong Soocom Animal Remedy Co., Ltd. Agricultural High & New Technology Development Zone of Changqing District Jinan City, China.

Decision 353:

The Registration Board, in its 350th meeting, considered the application for grant of marketing authorization of Doxycom (Doxycycline Powder). In view of the outcome of the virtual inspection of the manufacturing site conducted on 4th November 2025 and the observations of the nominated inspection panel, the product is not recommended for approval at this stage due to major GMP deficiencies. The Board decided to grant a personal hearing to the applicant before taking a final decision on the application.

Case.No.02: REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Searle Pakistan Limited, Section E, 2nd Floor One IBL Centre, Plot No.1, Block 7&8, DMCHS, Tipu Sultan Road, Off Shahrah-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.	Candidas 50mg Powder for concentrate for solution for Infusion Each Vial Contains: - Caspofungin (as acetate)...50mg (As per Innovator's Specification)*	115691	This is in reference to the supply, promotion and distribution agreement dated 21 st May 2018, and amendment no. 6 dated 29 th July 2025 (hereinafter referred to as the "Agreement"), executed between Merck Sharp & Dohme Asia Pacific Services Pte Ltd (MSD) and Searle Pakistan Private Limited (Searle),	Caspogin by M/s AJM Pharma, Karachi. Caspofungin Normon 70mg Powder for concentrate by Mirixil Pharma, Islamabad.
2.	Candidas 70mg Powder for concentrate for solution for Infusion	115692		

Each Vial Contains: - Caspofungin (as acetate)...70mg (As per Innovator's Specification)*		concerning the withdrawal of certain products from the market.	

Firm has submitted following supporting documents:

- Copy of Registration letter issued on 28-09-2023.
- Fee of Rs.12,500/- for above product.
- List of alternative brands as mentioned above.
- Justification as mentioned above.
- An Undertaking.

Decision 353: Registration Board acceded the firm's request for de-registration of following imported product:

S. No	Product(s) Name	Reg. No.
1.	Cancidas 50mg Powder for concentrate for solution for Infusion Each Vial Contains: - Caspofungin (as acetate)...50mg (As per Innovator's Specification)*	115691
2.	Cancidas 70mg Powder for concentrate for solution for Infusion Each Vial Contains: - Caspofungin (as acetate)...70mg (As per Innovator's Specification)*	115692

Case.No.03: REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.

M/s Searle Pakistan Limited, Section E, 2nd Floor One IBL Centre, Plot No.1, Block 7&8, DMCHS, Tipu Sultan Road, Off Shahrah-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	This is in reference to the supply, promotion and distribution agreement dated 21 st May 2018, and amendment no. 6 dated 29 th July 2025 (hereinafter referred to as the "Agreement"), executed between Merck Sharp & Dohme Asia Pacific Services Pte Ltd (MSD) and Searle Pakistan Private Limited (Searle), concerning the withdrawal of certain products from the market.	No alternate brands

Firm has submitted following supporting documents:

- Copy of Registration letter issued on 17-01-2024.
- Fee of Rs.12,500/- for above product.

- c. Justification as mentioned above.
- d. An Undertaking.

Decision 353: Registration Board decided to refer the case to availability committee.

Case.No.04: DEFERRED VETERINARY CASE OF 297TH MEETING OF M/S POUL MED ENTERPRISES 9-C, AMBER ESTATE BUILDING, BALOUCH COLONY, MAIN SHAHRAH-E-FAISAL, KARACHI FOR PRODUCT HIDROCOL SOLUTION FOR USE IN DRINKING WATER.

The subject case was presented in 297th meeting and deferred as per following details:

1.	Name and address of Applicant	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarragona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarragona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26822 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	HIDROCOL Solution for use in drinking water
	Composition	Each ml contains: Colistin 4.000.000 IU
	Finished Product Specification	In house
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 1L, 5L
	Me-too status	COLISER WATER SOLUBLE POWDER of M/s ATTABAK PHARMACEUTICALS, ISLAMABAD.
	Stability studies	Firm has submitted long term (24 months) at 30oC 65±5%RH & accelerated (06 months) stability data at 40oC, 75±5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP dated 11th May 2018 by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarragona) Spain
	Remarks of the Evaluator	Firm submitted accelerated stability data conclusion shows that product store at 250C and fulfil specification for 24 months.
	Decision of 292nd meeting of Registration Board: Deferred for clarification of submitted accelerated stability data conclusion shows that product store at 250C and fulfil specification for 24 months. M/s Poul Med submitted that due to error the conclusion wrongly mentions product storage at 250C while conclusion should mention the findings of product storage at 40oC, 75±5% RH.	

Decision of 293rd meeting: Registration Board deferred the case and decided that Secretary Registration Board will contact (email) to M/s S.P. VETERINARIA, S.A. Spain (Marketing Authorization Holder) for submission of applied product stability data throughout shelf life as per Zone IVa.

Evaluation by PEC:

Secretary Registration Board had sent an email to M/s S.P. VETERINARIA, S.A. Spain (Marketing Authorization Holder) for submission of applied product stability data throughout shelf life as per Zone IVa. In response to the query, the said firm has submitted real time stability data of 03 batches for 24 months as per the conditions of zone IVA. The firm has not clarified the ambiguity regarding already submitted accelerated stability data. The conclusion from stability results is hereby reproduced before the Board received via email.



s.p.® veterinaria, s.a.

Ctra. Reus-Vinyols, km. 4,1
Apartado 60
43330 - RIUDOMS (Tarragona)
Tel. 977 85 01 70
Fax 977 85 04 05

CONCLUSIONS

The stability tests show that the product COLISTIN 4000000 UI/ml ORAL SOLUTION stored at 25±2°C and 60% relative humidity fulfils the specifications for the 24 months tested in batches manufactured in SP VETERINARIA, S.A.

Therefore:

- a) There are no signs of degradation of the active substance, which can be corroborated in the tabulated results
- b) No tendencies are observed in the physical-chemical specifications of the product
- c) The microbiological specifications have been completely satisfactory

However, an important increase of the active substance impurities is observed when the product COLISTIN 4000000 UI/ml ORAL SOLUTION is stored at 30±2°C and 75% de relative humidity and at 40±2°C and 75% relative humidity. Therefore, and taking into account such conclusions, the following shelf-life is proposed:

The shelf-life proposed is 24 months.

Do not store at temperatures over 25°C.

Decision 297: The Board deferred the case as the results of stability testing conducted according to the conditions of zone-IVA are not satisfactory. The applicant is required to submit clarification regarding the increase of the active substance impurity.

Reply:

Firm has submitted revised stability data as per zone Iva.

Decision 353: Approved as per policy of import for inspection of manufacturer abroad.

Case.No.05: DEFERRED HUMAN IMPORT CASE OF 284TH MEETING OF M/S PHARMATECH PAKISTAN (PVT) LTD, KARACHI FOR PRODUCT RANEXA PROLONGED RELEASE TABLET 500MG.

The subject case was presented in 284th meeting and deferred as per following details: -

Name and address of Applicant	M/s Pharmatech Pakistan (Pvt.) Ltd. D-86/A. Manghopir road, SITE, Karachi
Detail of Drug Sale License	Address: Pharmatech Pakistan (Pvt.) Ltd. Pharmatech Pakistan (Pvt.) Ltd.

	Validity: 22/06/2019 Status: Drug sale license by the way of wholesale
Name and address of manufacturer	M/s Menairi-Von Heyden GmbH Leipziger Strabe 7-13 01097 Dresden, Federal republic of German.
Name and address of marketing authorization holder	M/s Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, l-1611 Luxembourg, Germany
Name of exporting country	Germany
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No.4043 Dated 26/05/2017
Fee including differential fee	Rs. 50,000/- Dated 26/05/2017 Rs. 50,000/- Dated 19/07/2018
Brand Name+Dosage Form+Strength	RANEXA prolonged release tablet 500 mg
Composition	Each Prolonged Release Tablet contains: Ranolazine..... 500mg
Finished Product Specification	In House
Pharmacological Group	Anti anginal cardiac preparation
Shelf life	2 years
Demanded Price	Rs. 1821/- per pack of 30's(blisters) Rs. 3642/- per pack of 60's Rs. 6000/- per Pack of 100's
Pack size	30's, 60's, 100's
International availability	Ranexa, MHRA Approved Approved in Germany as per CoPP
Me-too status	(500mg and 1000mg XR tablets are approved)
Detail of certificates attached	• <u>Original legalized CoPP</u> Certificate No. 78/2015 Certified by: Landesdirektion Sachsen Dienststelle Dresden, Germany , Issued on: 10/08/2015 Confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO. • <u>GMP certificate</u> • <u>Copy of agreement</u> Menarini asia pacific, Singapore Validity:29-03-2019
Remarks of the Evaluator.	• The firm has claimed for In House manufacturing specifications and the product is not present in USP/BP.
Decision 284th: Deferred for submission of documented evidence for relationship between Menarini Asia Pacific, Singapore and “M/s Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, l-1611 Luxembourg, Germany” as the submitted agreement is between Menarini Asia Pacific, Singapore and Pharmatech Pakistan (Pvt.) Ltd. Pharmatech Pakistan (Pvt.) Ltd. Reply: Firm clarify that Menarini Asia Pacific, Singapore is subsidiary of M/s Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, l-1611 Luxembourg, Germany and has permission from parent firm for authorization (letter dated 18-04-2019)	

Decision 353: Approved as per the policy of inspection of manufacturers abroad; however, the firm shall submit an updated LOA and CoPP before issuance of the registration letter.

Case.No.06: DEFERRED HUMAN IMPORT CASE OF 351ST MEETING OF M/S HIMMEL

**PHARMACEUTICALS (PVT.) LTD, LAHORE FOR PRODUCTS ABENIX 100MG
& 200MG TABLETS**

The subject case was presented in 351ST meeting and deferred as per following details: -

Name, address of Applicant.		HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)	
Application Form Dy. No / Tracking ID & date of submission		(YSJ-68H-6VT4, 2025-05-12)	
Detail of Fee Submitted		300000.0, 2025-03-14,	
The proposed proprietary name / brand name		Abenix 200mg Tablet	
Label Claim		Each film coated tablet contains..... Abemaciclib 200mg	
Reference to Finished product specifications		As per Innovators Specification	
Proposed Pack Size		60's-As per SRO	
Shelf Life (Unit)		2 Year(s)Store below 30°C.	
For generic drugs (me-too Status)		Not Applicable	
Pharmacotherapeutic Group of (API)		Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03	
Name, address of Manufacturing site:		Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh	
Pharmaceutical Equivalence and Comparative Dissolution Profile		PE and CDP performed against the innovator product VERZENIO 200 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 200 TABLET	
Name, address of Marketing Authorization Holder:		Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh	
Details of Certificates (CoPP/FSC/cGMP):		Firm submit GMP CERTIFICATE NO. DA/6-110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val	
Details of Authorization Letter :		NA	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability data submitted	
The status in reference regulatory authorities		Verzenio 200mg Film-coated Tablet (USA)	
Evaluation Remarks			
Sr.no.	Observations	Response of the Firm	
1.	Submit specification and detailed analytical procedure that has actually been for the quality analysis of the drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure that has been used for the quality analysis of the drug substance by drug product manufacturer.	

2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit batch analysis report of drug substance performed by drug product manufacturer.	Firm submit batch analysis report of drug substance performed by drug product manufacturer.
4.	Submit the pharmaceutical equivalence report against the innovator/reference product, including all quality tests that are part of the finished product specifications.	Firm submit Pharmaceutical equivalence report.
5.	Justify the omission of the Uniformity of Weight test and Water Content test in the batch analysis of the drug product, since the results of these tests have not been included in the batch analysis report.	Firm submit revised batch analysis report of drug product.
6.	Submit the stability data (three batches) of the drug product manufactured at commercial batch size, as the submitted data pertains only to a batch size of 400 tablets.	The firm has resubmitted the same stability data sheets that were previously provided, with the only change being the batch size, which is now stated as 6666 tablets, whereas the previously submitted data indicated a batch size of 400 tablets.
7.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	The firm submitted the unfilled Batch Manufacturing Records (BMR) for all three batches, indicating that 1000 g of active ingredient was dispensed for the manufacturing of a batch size of 6666 tablets. However, the theoretical calculation shows that 1333.2 g of active ingredient is required to manufacture 6666 tablets of 200 mg strength.

Deferred 351st meeting

Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life.

Reply:

Firm has submitted stability data as per zone IVA.

Decision: Approved as per the policy of inspection of manufacturers abroad.

Name, address of Applicant.	HIMMEL PHARMACEUTICALS (PVT.) LTD Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Zazaria e Pakistan Lahore (05-352-0065)
Application Form Dy. No / Tracking ID & date of submission	(6UM-YEY-JUPT, 2025-06-04)
Detail of Fee Submitted	300000.0, 2025-03-14,
The proposed proprietary name / brand name	Abenix 100mg Tablet
Label Claim	Each film-coated tablet contains.....Abemaciclib

	100mg	
Reference to Finished product specifications	As per Innovators Specification	
Proposed Pack Size	60's-As per SRO	
Shelf Life (Unit)	24 Month(s)Store below 30°C.	
For generic drugs (me-too Status)	Not Applicable	
Pharmacotherapeutic Group of (API)	Anti-neoplastic (Protein kinase inhibitor) ATC Code: L01EF03	
Name, address of Manufacturing site:	Beacon Pharmaceuticals PLC.-Kathali, Bhaluka , Mymensingh, -Bangladesh	
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP performed against the innovator product VERZENIO 100 MG TABLETS® (abemaciclib; manufactured by –Eli Lilly USA) & ABENIX 100 TABLET	
Name, address of Marketing Authorization Holder:	Beacon Pharmaceuticals PLC., Kathali, Bhaluka , Mymensingh, , Bangladesh	
Details of Certificates (CoPP/FSC/cGMP):	Firm submit GMP CERTIFICATE NO. DA/6-110/06/ 896 dated 08-Jan-2024 of M/s. Beacon Pharmaceuticals PLC. : Kathali, Bhaluka, Mymensingh, Bangladesh certifying authority: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka -1212 val	
Details of Authorization Letter :	NA	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability data submitted	
The status in reference regulatory authorities	Verzenio 100mg Film-coated Tablet (USA)	
Evaluation Remarks		
CoPP of certificate no. DA/6-110 /2016/975 dated 22.01.2025 certifying authority: Directorate General of Drug Administration, Mohakhali, Dhaka-1212, Bangladesh. valid for 2 years from the date of issuance.Letter of Authorization dated 02-October,2024 did not specify the name of products is submitted by the firm.		
S.NO.	Observations	Response of the Firm
1.	Submit specification and detailed analytical procedure that has actually been for the quality analysis of the drug substance by drug product manufacturer.	Firm submit specification and detailed analytical procedure that has been used for the quality analysis of the drug substance by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit batch analysis report of drug substance performed by drug product manufacturer.	Firm submit batch analysis report of drug substance performed by drug product manufacturer.
4.	Submit the pharmaceutical equivalence report against the innovator/reference product, including all quality tests that are part of the finished product	Firm submit Pharmaceutical equivalence report.

	specifications.	
5.	Justify the omission of the Uniformity of Weight test and Water Content test in the batch analysis of the drug product, since the results of these tests have not been included in the batch analysis report.	Firm submit revised batch analysis report of drug product.
6.	Submit the stability data (three batches) of the drug product manufactured at commercial batch size, as the submitted data pertains only to a batch size of 400 tablets.	The firm has resubmitted the same stability data sheets that were previously provided, with the only change being the batch size, which is now stated as 6666 tablets, whereas the previously submitted data indicated a batch size of 400 tablets.
7.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	The firm submitted the unfilled Batch Manufacturing Records (BMR) for all three batches, indicating that 1000 g of active ingredient was dispensed for the manufacturing of a batch size of 6666 tablets. However, the theoretical calculation shows that 666.6g of active ingredient is required to manufacture 6666 tablets of 100 mg strength.
Deferred 351st meeting. Deferred for submission of stability data of commercial batches of the drug product, performed under Zone-IV conditions up to the claimed shelf life. Reply: Firm has submitted stability data as per zone IVA.		

Decision 353: Approved as per the policy of inspection of manufacturers abroad.

Case No 7: REGISTRATION OF ZUVIDOX-50 OF M/S LAB DIAGNOSTIC SYSTEMS (SMC) PVT. LTD. 36-A, PSIC, SIE, TAXILA.

The Registration Board in its 345th meeting considered and approved the following product of M/s Lab Diagnostic Systems (SMC) Private Limited, 36-A, PSIC, SIE, Taxila:

Name of Importer / Manufacturer	Name of Product and Composition	Demanded Price & Pack Size
M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. Product License Holder & Manufacturer: Zuvius Lifesciences Pvt. Ltd., At[1]Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)173205 India.	Zuvidox-50 Each vial contains: Doxorubicin Hydrochloride USP 50mg Mannitol USNF 250mg United States Pharmacopeia.	1 Vial Packing As per SRO Essential
Decision: Approved. Registration letter will be issued upon submission of analytical record including chromatograms and raw data sheets for the drug product stability studies.		

Inspection exemption abroad granted on the basis of manufacturing facility GMP certificate issued by ANVISA Brazil. M/s Zuvius Lifesciences (Pvt.) Limited has a loan license in India as per following details:

Manufacturer address as per CoPP	Manufacturer address as per ANVISA Brazil Official website
M/s Zuvius Life Sciences (Pvt.) Limited, Kharuni Lodhimajra Road, Vill. Nandpur Baddi, Distt. Solan, Himachal Pradesh, India.	M/s Beta Drugs Limited, Kharuni Lodhimajra Road, Vill. Nandpur Baddi, Distt. Solan, Himachal Pradesh, India.

The Registration Board, in its 351st meeting held on 23rd – 24th September 2025, referred the case to Legal Affairs Division to opine in the matter.

In India, a loan license is granted under rule 69A of the Drugs Rules, 1945. A loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee. As per rule 69A, before the grant of a loan licence, the licensing authority satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence. Hence, the concept of loan licence has a legal backing in the country of origin and loan licence holder is also MA holder of the product.

The Registration Board may proceed with the registration of drug if it fulfills requirements of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Decision 353: After detailed examination of the case and deliberation by the Registration Board, it is observed that although the concept of a loan licence has legal backing in the country of origin (India) under Rule 69A of the Drugs Rules, 1945, However, under the existing “the Drug (Licensing, Registering & Advertising) Rules, there is no provision of loan licensing in Pakistan for local manufacturers. Same practices are required to be followed for imported products to provide level playing field.

Since the subject product, Zuvidox-50, is manufactured under a loan-licence arrangement, the Registration Board is not inclined to grant registration in the present case on loan-licence basis. Therefore, the case is not approved for registration.

Furthermore, any pharmaceutical product(s) previously granted registration on a loan-licence basis to importers, if any, shall be reviewed and show cause shall be issued with the approval of Chairman, RB before placing the Case in the Board.

Case no 8. Suspected Use of Toxic Solvents in Veterinary Medicines

On 7 January 2026, the World Health Organization (WHO) received information alleging the use of toxic solvents in the manufacturing of certain veterinary medicines marketed in Pakistan. As the competent regulatory authority for veterinary products, this information is being shared with DRAP for awareness, assessment, and further investigation. WHO is unable to independently verify the information at this stage; however, if confirmed, the alleged substitution may pose serious toxicological risks to both animal and human health.

The information suggests that some manufacturers may have substituted pharmaceutical-grade solvents with methanol in specific veterinary injectables and oral solutions. It is alleged that methanol levels in some suspect products may exceed 20% (200,000 ppm).

The basis for suspicion appears to be the market pricing of the identified products, which may be inconsistent with the economic feasibility of manufacturing using approved excipients.

Buparvaquone Injections (Suspected NMP/DMA Substitution) Buparvaquone Injection (5% w/v) is a lipophilic formulation requiring N-Methyl-2-Pyrrolidone (NMP) or Dimethylacetamide (DMA) as solvents. The current retail prices of certain products appear incompatible with the cost of these solvents (approximately PKR 4,000 per liter), suggesting possible substitution with methanol (approximately PKR

350 per liter).

Oral Solutions (Suspected Propylene Glycol/Ethanol Substitution) Information further suggests that methanol may have been used in place of propylene glycol or ethanol as solvents in certain oral liquid formulations. The current market prices of these products appear inconsistent with the cost of approved solvents (approximately PKR 1,300 per liter), again suggesting possible substitution with methanol.

In the light of received information, it is submitted that the Board may please issue advisory to all the veterinary pharmaceutical manufacturers to revise their formulations containing methanol in urgent basis.

Decision 353:

In view of the information shared by the World Health Organization (WHO) regarding the alleged use of toxic solvents, particularly methanol, in certain veterinary medicines marketed in Pakistan, the matter was deliberated and decided that:

1. An advisory shall be issued to all manufacturers of veterinary medicines, emphasizing that the use of methanol is strictly prohibited in pharmaceutical and veterinary products.
2. The Quality Assurance (QA) Division is directed to examine the identified/suspected manufacturers for possible use of methanol in veterinary injectables and oral liquid formulations.
3. The QA Division may undertake inspection, sampling, and laboratory testing of suspected products, where required, to verify compliance with pharmacopeial standards.

Registration I&V-I Section

1.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Levox drench 100ml
	Composition	Each ml contains: Levamisole HCl...1.5gm
	Diary No. Date of R& I & fee	Dy.No 495 dated 08-01-2024 Rs 30,000/- dated 03-01-2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Arch Leva 1.5% Drench of M/s Archard Pharmaceuticals Pvt Ltd., AJK. (Reg. No. 121894)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator	Oral Liquid (Veterinary) Section confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 Shortcomings: • Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
Decision M-343: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter.		

Remarks: During processing of registration letter it was observed that applied composition mentioned in minutes is not same as per generic, now firm has submit pre-registration variation fee for correction of composition as per generic.i.e. Each 100ml contains: Levamisole HCl...1.5gm																													
Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.																													
2.	<table border="1"> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s Alina Combine Pharmaceuticals (Pvt.) LTD, Karachi.</td></tr> <tr> <td>Brand Name +Dosage Form + Strength</td><td>FLORLINA PLUS Solution</td></tr> <tr> <td>Composition</td><td>Each 1000ml contains: Florfenicol.....230gm Colistine Sulphate.....50MIU</td></tr> <tr> <td>Diary No. Date of R& I & fee</td><td>Dy. No.11; 1-7-2015 ; Rs.20,000/- (30-6-2015)</td></tr> <tr> <td>Pharmacological Group</td><td>Antibacterial</td></tr> <tr> <td>Type of Form</td><td>Form-5</td></tr> <tr> <td>Finished product Specification</td><td>Manufacturer's</td></tr> <tr> <td>Pack size & Demanded Price</td><td>100ml, 200ml, 500ml, 1000ml, 2.5liter, 5liter</td></tr> <tr> <td>Approval status of product in Reference Regulatory Authorities.</td><td>N/A</td></tr> <tr> <td>Me-too status</td><td>Maxiflor-Plus Liquid of Biogen Pharma</td></tr> <tr> <td>GMP status</td><td>Last inspection report 15-12-2016 The management is putting all efforts to bring a team of qualified staff together and putting resource together for continuous improvement of their system.</td></tr> <tr> <td>Previous remarks of the Evaluator.</td><td>•</td></tr> <tr> <td>Previous decision</td><td>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. (M-277)</td></tr> <tr> <td>Evaluation by PEC</td><td>The firm has submitted copy of GMP inspection conducted on 08-01-2018 which concluded as "The overall GMP compliance level is rated as Satisfactory." The submitted me-too reference is of different strength.</td></tr> </table> Decision M-287: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Firm has submitted full fee (via tracking challan no. 66369081826)of registration along with generic details LISTOFLO LIQUID Registration No.078238 And revised formulation as per generic: Each 100ml contains: Florfenicol.....23gm Colistine Sulphate.....50MIU Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals (Pvt.) LTD, Karachi.	Brand Name +Dosage Form + Strength	FLORLINA PLUS Solution	Composition	Each 1000ml contains: Florfenicol.....230gm Colistine Sulphate.....50MIU	Diary No. Date of R& I & fee	Dy. No.11; 1-7-2015 ; Rs.20,000/- (30-6-2015)	Pharmacological Group	Antibacterial	Type of Form	Form-5	Finished product Specification	Manufacturer's	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml, 2.5liter, 5liter	Approval status of product in Reference Regulatory Authorities.	N/A	Me-too status	Maxiflor-Plus Liquid of Biogen Pharma	GMP status	Last inspection report 15-12-2016 The management is putting all efforts to bring a team of qualified staff together and putting resource together for continuous improvement of their system.	Previous remarks of the Evaluator.	•	Previous decision	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. (M-277)	Evaluation by PEC	The firm has submitted copy of GMP inspection conducted on 08-01-2018 which concluded as "The overall GMP compliance level is rated as Satisfactory." The submitted me-too reference is of different strength.
Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals (Pvt.) LTD, Karachi.																												
Brand Name +Dosage Form + Strength	FLORLINA PLUS Solution																												
Composition	Each 1000ml contains: Florfenicol.....230gm Colistine Sulphate.....50MIU																												
Diary No. Date of R& I & fee	Dy. No.11; 1-7-2015 ; Rs.20,000/- (30-6-2015)																												
Pharmacological Group	Antibacterial																												
Type of Form	Form-5																												
Finished product Specification	Manufacturer's																												
Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml, 2.5liter, 5liter																												
Approval status of product in Reference Regulatory Authorities.	N/A																												
Me-too status	Maxiflor-Plus Liquid of Biogen Pharma																												
GMP status	Last inspection report 15-12-2016 The management is putting all efforts to bring a team of qualified staff together and putting resource together for continuous improvement of their system.																												
Previous remarks of the Evaluator.	•																												
Previous decision	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. (M-277)																												
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3.	<table border="1"> <tr> <td>Name and address of Applicant</td><td>M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacy, 30-km Multan Road, Lahore</td></tr> <tr> <td>Detail of Drug Sale License</td><td>Address: 26 abbot road Lahore (godown: Plot NO. 5, Pharmacy 30 KM, Multan Road Lahore. Validity: 12-06-2020 Status: License to Sell Drug as Distributor</td></tr> <tr> <td>Name and address of manufacturer</td><td>Name: M/s Von Franken S.A.I.C. Address: N° 941, Laval 2247/49, Florida, PCIA, De</td></tr> </table>	Name and address of Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacy, 30-km Multan Road, Lahore	Detail of Drug Sale License	Address: 26 abbot road Lahore (godown: Plot NO. 5, Pharmacy 30 KM, Multan Road Lahore. Validity: 12-06-2020 Status: License to Sell Drug as Distributor	Name and address of manufacturer	Name: M/s Von Franken S.A.I.C. Address: N° 941, Laval 2247/49, Florida, PCIA, De																						
Name and address of Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacy, 30-km Multan Road, Lahore																												
Detail of Drug Sale License	Address: 26 abbot road Lahore (godown: Plot NO. 5, Pharmacy 30 KM, Multan Road Lahore. Validity: 12-06-2020 Status: License to Sell Drug as Distributor																												
Name and address of manufacturer	Name: M/s Von Franken S.A.I.C. Address: N° 941, Laval 2247/49, Florida, PCIA, De																												

	Buenos Aires, Argentina"
Name and address of marketing authorization holder	Name: M/s Von Franken S.A.I.C. Address: Lavalle 2247/49, Florida, PCIA, De Buenos Aires, Argentina
Name of exporting country	Argentina
Type of Form	Form 5A
Diary No. & Date of R& I	Dy. No. 20216; Dated 04-06-2018,
Fee including differential fee	Rs.50,000/-; Dated 04-06-2018
Brand Name +Dosage Form + Strength	DISPOCEL MAX IVD
Composition	Each Device contains: Progesterone.....1.20g Complete composition includes excipients: Silicone: q.s.p. 23.20g
Finished Product Specification	Manufacturer specifications
Pharmacological Group	Hormones
Shelf life	24 months
Demanded Price	As per SRO
Pack size	As per SRO
International availability	Could not be confirmed
Me-too status	Could not be confirmed
Detail of certificates attached	Applicant has submitted the following documents stating following information on it: <u>Free sale and Registration certificate of Veterinary Product.</u> Registration number: 07-057 Registration expiration date: 03-28/27 The firm has submitted original, legalised free sale and Registration certificate of veterinary product alongwith translation issued by Ministry of Agro-industry, National service of Agri-Food Health and Quality (SENASA), National Animal Health office, Veterinary products office, Buenos Aires, Argentina. It confirms the availability of product in the exporting country and endorses the facilities and operations conform to GMP as recommended by the World Health Organisation. <u>GMP certificate:</u> The firm has submitted original, legalised GMP certificate alongwith English translation issued by Ministry of Agro-Industry, National Food Safety and Quality Service (SENASA) dated 03-02-2021. Certified manufacturing process/es include: General procedure for the manufacture, conditioning and storage of veterinary products. Procedure for the manufacture of sterile and non-sterile solutions, suspensions and semi-solid products including those that contain beta-lactamic and hormonal ingredients. Procedure for the manufacture of intravaginal devices containing hormonal ingredients. <u>Letter of authorization:</u> The firm has submitted copy of sole agency agreement whereby M/s. Von Franken S.A.I.C authorizes M/s prix pharmaceutica, Lahore as sole distributor for registrations and sales of Von Franken's pharmaceutical products for

		veterinary use in Pakistan.			
Remarks of the Evaluator		The firm has submitted stability study data of following 3 batches as per Zone IVA conditions:			
		Presentation	Lot / Batch No.	Mfg date	Lot size
		Bag × 10	27 / 2014	July, 2014	1084
		Bag × 10	28 / 2014	July, 2014	1100
		Bag × 10	09 / 2014	July, 2014	1084
Evaluation by PEC:					
Sr. No.	Decision of 295 th meeting of RB	Response by the firm			
1.	Submit Sole agency agreement.	The firm has submitted copy of sole agency agreement whereby M/s. Von Franken S.A.I.C authorizes M/s prix pharmaceutica, Lahore as sole distributor for registrations and sales of Von Franken’s pharmaceutical products for veterinary use in Pakistan.			
2.	Submit copy of valid DSL of the applicant	The firm has submitted copy of application receipt for renewal of DSL dated 09-06-2020.			
3.	Submit FPP Specifications.	The firm has submitted copy of finished product specifications of applied formulation			
4.	Mention type of primary packaging material of applied formulation.	Final container check is bag containing 10 devices with white-colored little tail, 1 large card and 10 orange-colored little tails in pocket.			
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting. <u>Reply of firm:</u> They have applied for the Registration of subject product in 2018 alongwith one reproductive hormone “Estradiol Benzoate”. The two products are used together, These product were discussed in meeting ref. meetings no. 275,295,307. • GMP inspection of Fatro Von Franken was conducted twice and approved. • After which “Estradiol Benzoate” was registered Reg No.125912 “ 100ml dated June 05,2025. • The use of this produt “ Estradiol Benzoate” is limited without Dispolcel Max. • They has provided all the relevant information required. Therefor you are kindly requested to allow the Registration of the product as Dispolcel Max in public interest as is is vial for breeding of animals in Pakistan and is facing severe shortages.					
Recommendations of sub-committee on veterinary drugs (M-7th) The sub-committee on veterinary drugs decided to ask the firm to submit safety and efficacy data of applied product and registration status in RRA. Remarks: Safety data is submitted by the firm EMA data base shows 0.35gm in sheeps and from 1to 1.35gm in cattles https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=progesterone&sort by=prod search upd product name&pg=3					
Recommendations of sub-committee on veterinary drugs (M-8th).					
Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.					
4.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.			
	Brand Name, Dosage Form, Strength	SAM-E VET Oral Liquid			
	Composition	Each 100ml contains:-			

		Silymarin 2100mg Vitamin E 1500mg
Diary No., Date of R & I & Fee	Dy. 19055, 30-09-2019, Rs.20,000, 27-09-2019,	
Pharmacological Group	Hepato-protective agent, Vitamin	
Type Of Form	Form 5	
Finished product Specification	Manufacturers Specification	
Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled	
Me-Too Status	Hepato Care (Attabak Pharma) 062167	
GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.	
Remarks of Evaluator		
Decision M-292: Deferred for further deliberation. sub-committee on veterinary drugs recommended such type of formulations		
Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.		
5.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Eva 250ml Injection
	Composition	"Each ml Contains: L-arginine HCL...1.44mg L-cysteine HCL...3.20mg L-glutamine...3.20mg Glycine...3.20mg L-histidine...1.32mg L-isoleucine HCL...3.60mg L-leucine HCL...4.28mg L-lysine HCL...5.44mg L-methionine...3.20mg L-threonine...3.20mg L-tryptophan...0.86mg L-phenylalanine...5mg L-valine...3.60mg Thiamine HCL...4mg Riboflavin Sod. Phosphate...0.171mg Pyridoxine HCL...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg"
	Diary No. Date of R & I & fee	Dy. No 10008 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Vitamins, amino acids & mineral supplement.
	Type of Form	Form
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass container
	Me-too status (with strength and dosage form)	AMI-VICOM INJECTION by M/s SELMORE AGENCIES LAHORE (Reg.#016294)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator ^{II}	Evidence of Me-too status in applied fill volume is required.
	Decision: (M-289) Deferred for evidence of me-too status in applied fill volume. Firm reply:	

	EVA Injection 50ml & 100ml Reg. No. 088085 & 101961 are our already Registered Products Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
6.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Florosel-30 Oral Solution
	Composition	Each ml contains: Florfenicol...300mg
	Diary No. Date of R& I & fee	Dy No. 15744: 27.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Antibiotic (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	The firm has submitted pictures of label and packing of me-too product Florofen oral solution by Leads Pahrma (Reg. No. 43160), which is registered in the me-too data as injection.
	Decision: (M-290): Deferred for confirmation of me-too product. Remarks: Me-too is confirmed Florofen oral solution by Leads Pahrma (Reg. No. 43160) Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	

7.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Hepavit Oral Suspension
	Composition	Each 100ml Contains: Silymarin...2100mg Vitamin E...1500mg
	Diary No. Date of R & I & fee	Dy. No. 32756; 02.10.2018 PKR. 20,000/-; 02.10.2018
	Pharmacological Group	Liver therapy + Vitamin E
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml 1litre, 2.5litre; Decontrolled
	Me-too status	Hepatocare Oral Suspension by M/s attabak, reg. no. 62167
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator	
	Decision: (M-295) Deferred for opinion of HOTC Division as it contains Silymarin. Remarks: Sub-committee on veterinary drugs recommended such combinations on the basis of already registered product in veterinary. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
8.	Name and address of manufacture / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form and Strength	Amino-vet Injection 100ml
	Composition	Each 100ml contains:

	L-Arginine HCl.....85mg L-Cysteine HCl.....34mg L-Histidine HCl.....34mg DL-Isoleucine HCl.....68mg L-Lysine HCl.....102mg DL-Methionine.....34mg L-Threonine.....68mg DL-Tryptophan.....34mg DL-Phenylalanine.....102mg DL-Valine.....170mg L-Leucine.....136mg Monosodium Glutamate.....136mg Thiamine HCl (Vit B1).....10mg Riboflavin 5 phosphate (Vit B2)....4mg Pyridoxine HCl (Vit B6).....10mg Cyanocobalamin (Vit B12).....5µg Niacinamide.....150mg Dextrose.....5.5mg Calcium chloride.....15mg Potassium chloride.....20mg Magnesium sulphate.....20mg Sodium acetate.....250mg Benzyl alcohol.....1.5g Water for Injection.....100ml
Dairy No. date of R &I fee	Form-5 Dy.No 8773 dated 18-06-2019 Rs.20,000/- Dated 17-06-2019
Pharmacological Group	Vitamins, amino acids & mineral supplements
Type of form	Form 5
Finished product specifications	Manufacturer's specifications
Pack size and Demand Price	100ml; As per SRO
Me-too-status	
GMP Status	The firm was inspected on 05-03-2018,17-08-2018 & 16-10-2018 and conclusion of inspection was: In the light of the inspection conducted by the panel and based on the findings the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Selmore Pharma Lahore for following sections: 1- Veterinary Bolus 2- Veterinary Aerosol 3- Veterinary Oral powder 4- Veterinary Oral Liquid 5- Veterinary Liquid Injection 6- Veterinary Penicillin oral powder 7- Veterinary Penicillin dry powder for injection 8- Veterinary Penicillin liquid injection 9- Veterinary Hormone Liquid injection 10- Human Penicillin capsule 11- Human Penicillin dry powder suspension 12- Human Penicillin dry powder injection.
Previous Remark of Evaluator ^{XI}	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status)

		alongwith registration number, brand name and name of firm The firm have submitted that they did not perform terminal sterilization due to vitamins and amino acids and filter the final solution and perform aseptic filling
	Previous Decision (297-DRB)	Deferred for the 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 provided evidence of Aminoplex forte injectable solution by M/s Mustafa Brothers (Reg#053953). However, the applied label claim is different from available me-too product when verified from registration letter.
	Decision M-307: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Aminoplex Forte Injection (Reg. No. 053953) by M/S Mustafa Brothers Faisalabad Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
9.	Name and address of manufacture / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form and Strength	Amino-vet Injection 250ml
	Composition	Each 100ml contains: L-Arginine HCl.....85mg L-Cysteine HCl.....34mg L-Histidine HCl.....34mg DL-Isoleucine HCl.....68mg L-Lysine HCl.....102mg DL-Methionine.....34mg L-Threonine.....68mg DL-Tryptophan.....34mg DL-Phenylalanine.....102mg DL-Valine.....170mg L-Leucine.....136mg Monosodium Glutamate.....136mg Thiamine HCl (Vit B1).....10mg Riboflavin 5 phosphate (Vit B2).....4mg Pyridoxine HCl (Vit B6).....10mg Cyanocobalamin (Vit B12).....5µg Niacinamide.....150mg Dextrose.....5.5mg Calcium chloride.....15mg Potassium chloride.....20mg Magnesium sulphate.....20mg Sodium acetate.....250mg Benzyl alcohol.....1.5g Water for Injection.....100ml
	Dairy No. date of R &I fee	Form-5 Dy.No 8774 dated 18-06-2019 Rs.20,000/- Dated 17-06-2019
	Pharmacological Group	Vitamins, amino acids & mineral supplements
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	250ml; As per SRO

	Me-too-status	
	GMP Status	The firm was inspected on 05-03-2018, 17-08-2018 & 16-10-2018 and conclusion of inspection was: In the light of the inspection conducted by the panel and based on the findings the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Selmore Pharma Lahore for following sections: 1- Veterinary Bolus 2- Veterinary Aerosol 3- Veterinary Oral powder 4- Veterinary Oral Liquid 5- Veterinary Liquid Injection 6- Veterinary Penicillin oral powder 7- Veterinary Penicillin dry powder for injection 8- Veterinary Penicillin liquid injection 9- Veterinary Hormone Liquid injection 10- Human Penicillin capsule 11- Human Penicillin dry powder suspension 12- Human Penicillin dry powder injection.
	Previous Remark of Evaluator ^{xi}	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • The firm have submitted that they did not perform terminal sterilization due to vitamins and amino acids and filter the final solution and perform aseptic filling
	Previous Decision (297-DRB)	Deferred for the 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 provided evidence of Aminoplex forte injectable solution by M/s Mustafa Brothers (Reg#053953). However, the applied label claim is different from available me-too product when verified from registration letter.
	Decision M-307: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Aminoplex Forte Injection (Reg. No. 053953) by M/S Mustafa Brothers Faisalabad. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
10.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Utecine Pessaries.
	Composition	Each Pessary Contains: Sulphathiazole 1750mg Penicillin G 100,000 IU Streptomycin Sulphate 50mg Ethinylestradiol 0.5mg
	Diary No. Date of R & I & fee	Dy. No 26579 dated 09-10-2020; Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Combination of three bactericidal and estrogen hormone.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specifications.

	Pack size & Demanded Price	10's, 20's, 50's, 100's & Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Utenol Pessaries, Star Labs Lahore, Reg. No. 017942.
	GMP status	Same as above.
	Remarks of the Evaluator	Firm was asked to provide evidence of approval of manufacturing facility/section approval for the applied formulation. In response the firm replied that the applied formulation will be manufactured in Bolus veterinary section.
	Decisionm-312: Deferred for confirmation of required manufacturing facility / section from Licensing Division. Reply: Firm has submitted relevant manufacturing facility. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
11.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore (Veterinary Liquid Injection).
	Brand Name + Dosage Form + Strength	Eva Injection 10ml
	Composition	Each ml Contains: L-Arginine HCl 1.44mg L-Cysteine HCl 3.20mg L-Glutamine 3.20mg Glycine 3.20mg L-Histidine 1.32mg L-Isoleucine 3.60mg L-Leucine 4.28mg L-Lysine HCl 5.44mg L-Methionine 3.20mg L-Threonine 3.20mg L-Tryptophan 0.86mg L-Phenylalanine 5mg L-Valine 3.60mg Thiamine HCl 4mg Riboflavin Sod. Phosphate 0.17mg Pyridoxine HCl 0.34mg Nicotinamide 8mg Ascorbic Acid 4mg Glucose 33mg Calcium Chloride 0.08mg Potassium Chloride 0.21mg Magnesium Sulphate 0.08mg
	Diary No. Date of R & I & fee	Dy. No 26575 dated 09-10-2020; Rs.20,000/- dated 08-10-2020.
	Pharmacological Group	Vitamins, amino acids & mineral supplement.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Ami-Vicom Injection (10ml, 50ml, 100ml), Imported by Selmore Agencies from Korea, Reg. No. 016294. Could not be confirmed/ database have no composition.
	GMP status	Same as above.

	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-312: 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. Firm reply: EVA Injection 50ml & 100ml Reg. No. 088085 & 101961 are our already Registered Products Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
12.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Eva Injection 500ml
	Composition	Each ml Contains: L Arginine HCl 1.44mg L Cysteine HCl 3.20mg L Histidine 1.32mg Glycine 3.20mg L Isoleucine HCl 3.60mg L Lysine HCl 5.44mg L Threonine 3.20mg L Leucine HCl 4.28mg L Tryptophan 0.86mg L Phenylalanine 5mg L Valine 3.60mg Ascorbic Acid 4mg Glucose 33mg L Glutamine 3.20mg Thiamine HCl 4mg Riboflavin Sodium Phosphate 0.17mg Pyridoxine HCl 0.34mg Nicotinamide 8mg Calcium Chloride 0.08mg Potassium Chloride 0.21mg Magnesium Sulphate 0.08mg
	Diary No. Date of R & I & fee	Dy. No 8770 dated 18-06-2019; Rs.20,000/- dated 17-06-2019.
	Pharmacological Group	Vitamins, amino acids & mineral supplement.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Ami-Vicom Injection (10ml, 50ml, 100ml), Imported by Selmore Agencies from Korea, Reg. No. 016294. Could not be confirmed/ database have no composition.
	GMP status	Same as above.
	Remarks of the Evaluator	- First page of form 5 is unsigned. - Different fill volumes are mentioned. Clarification is required? - Evidence of applied formulation/drug already approved by DRAP with applied fill volume (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-312: 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. Firm reply: EVA Injection 50ml & 100ml Reg. No. 088085 & 101961 are our already Registered Products Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
13	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Sterivit Injection 500ml.
	Composition	Each ml Contains: DI-Acetylmethionine 200mg Cyanocobalamin 0.2mg L-Carnitine HCl 61.3mg Eq. To L-Carnitine 50mg Alpha-Tocopherol Acetate 32.9mg Eq. To Alpha-Tcopherol 30mg
	Diary No. Date of R & I & fee	Dy. No 10344 dated 02-07-2019; Rs.20,000/- dated 01-07-2019
	Pharmacological Group	Vitamin & amino acid.
	Type of Form	Form-5.
	Finished product Specification	Innovator's specification.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Metabolase Forte Injectable Solution (50, 100, 250ml), Imported by Prix pharma from Italy, Reg. No. 043109.
	GMP status	Same as above.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP in applied fill volume (generic / me-too status) along with registration number, brand name and name of firm.
	Decision M-312: Deferred for Evidence of applied formulation/drug already approved by DRAP in applied fill volume (generic / me-too status) along with registration number, brand name and name of firm. Firm reply: Sterivit Injection 10ml, 50ml, 100ml & 250ml Reg. No. 122631, 095650, 109968 & 109969 are our already Registered Products. Decision 353: Approved.	
14.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore."
	Brand Name +Dosage Form + Strength	CEFAPEN INJECTION 50ml.
	Composition	Each ml contains : Cephalexin Monohydrate 157.8mg. equivalent to Cephalexin 150mg.
	Diary No. Date of R& I & fee	Rs.30,000/- (20989/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Me-too status	Cephalexine 15% Injection, Registration No: 085727.by M/s. Mustafa Brothers Faisalabad.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too granted 50ml
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Cefapen Injection 100ml Reg. No. 114798 is our already Registered product. Decision 353: Approved.	

15.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Clofenac Injection 10ml
	Composition	Each ml contains: Aceclofenac Sodium eq. to Aceclofenac...25mg
	Diary No. Date of R& I & fee	Dy.No 26574 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Afonac Injection (10ml) of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 095656)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
Remarks of the Evaluator ^x		Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. Shortcomings: - Firm has mentioned salt form while the reference formulation is Each ml contains: Aceclofenac.....25mg - Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
Decision: (M-326) Referred to EWG on veterinary drugs to review environment safety requirements Remarks: Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.		
16.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Fospho-AV Injection 10ml
	Composition	Each ml Contains: Butaphosphan...100mg Cyanocobalamin...0.05mg Taurine...37.3mg Nicotinamide...23.0mg DL-Methionine...18.7mg
	Diary No. Date of R& I & fee	Dy.No. 26447 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Phosphorus/Supplement6/Vitamis/Aminoacids
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10ml,:Decontrolled
	Me-too status	Not found in 10ml
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good

		level of GMP compliance."
	Remarks of the EvaluatorIV	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply: Fospho-AV Injection 50ml, 100ml, 250ml & 500ml Reg. No. 088084, 099370, 109966 & 109967 are our already Registered Products. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
17.	Name and address of manufacturer / Applicant	M/s. D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Bem-Cool Water Soluble Powder
	Composition	Each 100g contains:- Vitamin C.....20g Aspirin.....6.7g
	Diary No. Date of R& I & fee	Dy.No 2066 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Anti-oxidant, Analgesic, Antipyretic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10Kg ; Decontrolled
	Me-too status	049778; Bursa Gold Water Soluble Powder
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator	
	Previous Decision:	Registration Board referred the case to expert working group on veterinary drugs for review of formulation.
	Deferred for further deliberation by Expert Working Group on Veterinary Drugs. Decision of EWGVD: The EWGVD deliberated the cases of aspirin with vit. C and similar combinations with their dosage form at length and decided to obtain scientific rationale of combination and pharmacokinetics with examples of such products registered at scientifically developed countries for use in variety of animal species as applied by the firms in their applications for product registration. Decision:- (M-320) Registration Board endorsed the decision of Expert Working Group on Veterinary Drugs. Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
18.	Name and address of manufacturer / Applicant	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amino Hans Injection (100ml)
	Composition	Each 100ml contains:- L-Carnitine 500mg Thiotic acid 20mg Pyridoxine HCl 15mg DL-Acetylmethionine 2000mg L-Arginine 240mg L-Ornithine 120mg L-Citruline 120mg L-Lysine 50mg

		Glycine 150mg Taurine 150mg Aspartic acid 150mg Glutamic acid 150mg Fructose 5000mg Sorbitol 8000mg
	Diary No. Date of R& I & fee	Dy No. 21816: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
	Decision: (M-321) Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation. Reply: Firm has submitted testing facility for above formulation. Decision 353: Approved.	
19.	Name and address of manufacturer / Applicant	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amino Hans Injection (250ml)
	Composition	Each 100ml contains:- L-Carnitine 500mg Thiotic acid 20mg Pyridoxine HCl 15mg DL-Acetylmethionine 2000mg L-Arginine 240mg L-Ornithine 120mg L-Citruline 120mg L-Lysine 50mg Glycine 150mg Taurine 150mg Aspartic acid 150mg Glutamic acid 150mg Fructose 5000mg Sorbitol 8000mg
	Diary No. Date of R& I & fee	Dy No.21815: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	250ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
	Decision: (M-321) Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation. Reply: Firm has submitted testing facility for above formulation. Decision 353: Approved.	

20.	Name and address of manufacturer / Applicant	M/s. D-HAANS PHARMACEUTICALS of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Amino Hans Injection (500ml)
	Composition	Each 100ml contains:- L-Carnitine 500mg Thiotic acid 20mg Pyridoxine HCl 15mg DL-Acetylmethionine 2000mg L-Arginine 240mg L-Ornithine 120mg L-Citruline 120mg L-Lysine 50mg Glycine 150mg Taurine 150mg Aspartic acid 150mg Glutamic acid 150mg Fructose 5000mg Sorbitol 8000mg
	Diary No. Date of R& I & fee	Dy No. 21814; 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Amino acids, Multi Vitamins
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	500ml/Decontrolled
	Me-too status (with strength and dosage form)	Multimino-V Injection (Selmore Pharma) Reg # 058712
	Remarks of the Evaluator	
Decision: (M-321) Deferred for evidence of availability of testing facility required for the analysis of amino acid ingredients of the applied formulation. Reply: Firm has submitted testing facility for above formulation. Decision 353: Approved.		
21.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Hascoli-600 W/S Powder
	Composition	"Each g Contains: Colistin Sulphate...600,000IU"
	Diary No. Date of R&I &fee	Dy.No 1878 dated 19-02-2020 Rs.20,000/- (17-02-2020)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Imhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	089855; Neflorex 60 Water Soluble Powder M/s. Breeze Pharma (Pvt) Ltd., Kahuta Road, Islamabad.
	GMP status	CLB in its 273 rd meeting held on 15 th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator	
Decision: (M-294) Referred to expert working group for rationalization of colistin formulations.		

	Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved.	
22.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Neo-Hans 72% W/S Powder
	Composition	"Each 100g Contains: Neomycin Sulphate...72g"
	Diary No. Date of R&I &fee	Dy.No 1885 dated 19-02-2020 Rs.20,000/- (17-02-2020)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	078297; N-72 Water Soluble Powder "M/s. Nawal Pharmaceuticals, Rawalpindi"
	GMP status	CLB in its 273 rd meeting held on 15 th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator	
	Decision: (M-294) Deferred for scientific rational for neomycin 72% water soluble powder, since neomycin 70% water soluble powder is already approved. Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
23.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Sulpamed-60 W/S Powder
	Composition	"Each 100g Contains: Oxytetracycline Hcl...20g Colistin Sulphate...20g Neomycin Sulphate...20g"
	Diary No. Date of R&I &fee	Dy.No 2060 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	075659; NCO-60 "Each Gm Contains:- Oxytetracycline Hcl 20% W/V Colistin Sulphate..... 20% W/V Neomycin..... 20% W/V "M/S. Breeze Pharma (Pvt.) Ltd., Kahuta Road, Islamabad."
	GMP status	CLB in its 273 rd meeting held on 15 th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator	The drug already approved by DRAP (generic / me-too status) provided by you mentions "Neomycin" whereas, you have applied for "Neomycin Sulphate".

Decision: (M-294) Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Reply: Applied formulation is same as generic but with corrected unit. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.																											
24.	<table border="1"> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s. Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur.</td></tr> <tr> <td>Brand Name +Dosage Form + Strength</td><td>ASPER FAM POWDER</td></tr> <tr> <td>Composition</td><td>Each kg contains: Acetylsalicylic Acid.....67gm Ascorbic Acid.....200gm Citric Acid.....125gm Sodium Bicarbonate.....250gm</td></tr> <tr> <td>Diary No. Date of R& I & fee</td><td>Dy. No 16297 Dated 03-05-2018, Rs. 20,000/-</td></tr> <tr> <td>Pharmacological Group</td><td>Antipyretic, analgesic</td></tr> <tr> <td>Type of Form</td><td>Form-5</td></tr> <tr> <td>Finished product Specifications</td><td>In-house</td></tr> <tr> <td>Pack size & Demanded Price</td><td>10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; Decontrolled</td></tr> <tr> <td>Me-too status</td><td>S.B. Asper-C effervescent granules of m/s s.b.pharma Islamabad</td></tr> <tr> <td>GMP status</td><td>Last GMP inspection conducted on 16-03-2017 and report concludes that firm was considered to be operating at good level of GMP Compliance.</td></tr> <tr> <td>Remarks of the Evaluator</td><td></td></tr> <tr> <td>Previous Decision</td><td>Registration Board deferred as formulation is under review of expert working group on veterinary drugs (M-293).</td></tr> <tr> <td colspan="2"> (M-316) Deferred for further deliberation by Expert Working Group on Veterinary Drugs. Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO. </td></tr> </table>	Name and address of manufacturer / Applicant	M/s. Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur.	Brand Name +Dosage Form + Strength	ASPER FAM POWDER	Composition	Each kg contains: Acetylsalicylic Acid.....67gm Ascorbic Acid.....200gm Citric Acid.....125gm Sodium Bicarbonate.....250gm	Diary No. Date of R& I & fee	Dy. No 16297 Dated 03-05-2018, Rs. 20,000/-	Pharmacological Group	Antipyretic, analgesic	Type of Form	Form-5	Finished product Specifications	In-house	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; Decontrolled	Me-too status	S.B. Asper-C effervescent granules of m/s s.b.pharma Islamabad	GMP status	Last GMP inspection conducted on 16-03-2017 and report concludes that firm was considered to be operating at good level of GMP Compliance.	Remarks of the Evaluator		Previous Decision	Registration Board deferred as formulation is under review of expert working group on veterinary drugs (M-293).	(M-316) Deferred for further deliberation by Expert Working Group on Veterinary Drugs. Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.	
Name and address of manufacturer / Applicant	M/s. Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur.																										
Brand Name +Dosage Form + Strength	ASPER FAM POWDER																										
Composition	Each kg contains: Acetylsalicylic Acid.....67gm Ascorbic Acid.....200gm Citric Acid.....125gm Sodium Bicarbonate.....250gm																										
Diary No. Date of R& I & fee	Dy. No 16297 Dated 03-05-2018, Rs. 20,000/-																										
Pharmacological Group	Antipyretic, analgesic																										
Type of Form	Form-5																										
Finished product Specifications	In-house																										
Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; Decontrolled																										
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Remarks of the Evaluator																											
Previous Decision	Registration Board deferred as formulation is under review of expert working group on veterinary drugs (M-293).																										
(M-316) Deferred for further deliberation by Expert Working Group on Veterinary Drugs. Sub-committee on veterinary drugs recommended such formulations. Decision 353: Approved. The firm shall submit the fee for specification correction as per SRO.																											

Registration I Section

Case No.1. Clarification Regarding Status of Sodium Hyaluronate Eye Drops 0.2% in Reference Regulatory Authorities

Registration Board in different meetings approved the following products containing Sodium Hyaluronate Eye Drops 0.2%:

M-293 (Held on 6 th , 7 th & 8 th January 2020)	
Name and address of manufacturer / Applicant	M/s Polyfine Chem Pharma, 51- Industrial Estate, Hayatabad, Peshawar.
Brand Name +Dosage Form + Strength	Tier Eye Drop 2mg/ ml (0.2%)
Composition	Each ml contains : Purified Sodium Hyaluronate 2mg
Diary No. Date of R& I & fee	Dy. No.352;03-01-2018; Rs.20,000/- (03-01-2018)
Pharmacological Group	Ophthalmic surgical agents
Type of Form	Form- 5
Finished product Specification	JP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Could not be confirmed in the applied strength (1mg/ ml is approved in TGA, Australia)
Me-too status	Hylo Eye Drop 2mg/ ml of M/s Helix (Reg. # 067031)
GMP status	Last GMP inspection was conducted on 07-02-2018 and report concludes an acceptable level of GMP compliance.

Previous remarks of the Evaluator	- General eye drops section is available in the firm as mentioned in the GMP inspection report. - International availability could □□□□be confirmed in the applied strength as 1mg/ ml is approved in TGA, Australia.
Previous decision	Deferred in 288 th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting.
Evaluation by PEC-XIII	- Firm has claimed proposed volume of 5ml and 10ml while in TGA; Australia, it is 2ml, 10ml and 7.5ml. - In TGA public summary document of reference product i.e. Hylo- forte eye drops, strength is not mentioned. However, on the website of manufacturer, 2mg/ml strength is verified.
Decision of M-293: Approved.	

M-292 (Held on 1ST – 2ND October, 2019)	
Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi.
Brand Name +Dosage Form + Strength	Dronate 2mg/ml Eye Drops
Composition	Each ml of solution contains: Sodium Hyaluronate.....2mg
Diary No. Date of R& I & fee	Dy.No.20327; 05-06-2018; Rs.20,000 (05-06-2018)
Pharmacological Group	Lubricant
Type of Form	Form- 5
Finished product Specification	Innovators specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	MHRA Approved
Me-too status	Hylo 2mg/ ml Eye Drops of M/s Helix (Reg. # 067031)
GMP status	Last GMP inspection was conducted on 09-10-2018 and the report concludes good level of GMP compliance.
Remarks of the Evaluator XIII	- Eye Drops (General) section is available in the firm as mentioned in the submitted section approval letter. - The official monograph is available in JP.
Decision of M-292: Approved with JP specifications	

While processing for issuance of registration letter, it was observed that Sodium Hyaluronate Eye Drops have been categorized as a “Medical Device” by TGA, Australia.

Furthermore, a similar case of “Sodium Hyaluronate Ophthalmic Solution 1mg/ml (0.1%w/v) has been discussed in 323rd meeting of Registration Board where opinion of MDMC Division was also sought. Opinion of MDMC Division and decision of 323rd meeting of Registration Board is as under:

Opinion/Response of MDMC Division:

Reference pre paras, the undersigned searched the GMDN Agency for the said case, and the molecule/formulation 0.1% w/v Sodium Hyaluronate solution is not found in it. Furthermore, after examination of the case as per the attached documents and provided online link, it is submitted that:-

- The intended use of the product as per manufacturer’s claim is for the treatment of Keratoconjunctival epithelial disorder and the mechanism of action is that it promotes corneal injury healing by binding to fibronectin and promoting adhering/repairing corneal epithelial cells and not just physiological action.
- Also the product is a drug in the country of origin i.e. Japan which is one of the stringent regulatory authorities. Therefore, in the light of above stated position, it is proposed that the case may be dealt under the existing rules pertaining to drug.

Decision of 323rd Meeting of Registration Board:

Registration Board after thorough deliberation and considering the response of the MDMC Division and

the fact that the applied product is approved as a drug product by PMDA Japan which is a reference regulatory authority, decided to approve the applied product as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

Proceedings of 331st Meeting of Registration Board (held on 31st Oct- 02nd Nov, 2023):

Foregoing in view, placed below is the comparison of products approved by TGA and PMDA:

S.No.	Properties	PMDA	TGA
1.	Strength	0.1% & 0.3%	0.2%
2.	Status	Drug	Medical Device Included Class III
3.	Indication/ Use	Treatment of Keratoconjunctival epithelial disorder and the mechanism of action is that it promotes corneal injury healing by binding to fibronectin and promoting adhering/repairing corneal epithelial cells and not just physiological action.	To improve the lubrication of the eye in eyes that are experiencing severe or persistent dryness

Decision of 331st Meeting of Registration Board:

Registration Board deferred the case and advised to reconfirm status of Sodium Hyaluronate containing ophthalmic solutions in reference regulatory authorities adopted by the Registration Board in its 275th meeting.

Now, approval status of '**Hyalistil 0.2% Eye Drops Solution**' has been confirmed from AIFA Italy [<https://medicinali.aifa.gov.it/it/#/it/dettaglio/0000028973> accessed on 12.01.2026] with following detail:

Product Name	Hyalistil 0.2% Eye Drops Solution
Composition	Each ml of Eye Drop Solution contains: Hyaluronic Acid Sodium Salt.....2mg
Pharmaceutical Form	Eye drops, solution
Therapeutic Indication	Symptomatic treatment of dry eye syndrome.
MA Holder	SIFISpA – Via Ercole Patti, 36 – 95020 Lavinaio – Aci S. Antonio (CT)
Available CCS & Pack size	LDPE Container of 5ml, 10ml, 0.25ml (single dose container).
Shelf life	The shelf life after first opening the bottle is 28 days.

Decision: Keeping in view the approval granted by AIFA Italy, Registration Board decided to grant registration letters of above-mentioned products.

Miscellaneous

Task identified to be accomplished in light of WHO consultant workshop dated 15-17th December, 2025.

Case No. 1.

S. No.	Task to be done	Status/Roadmap	Remarks
SmPC and PIL			
I.	Notification for submission of SmPC and PIL	Implemented w.e.f 15 th October, 2025.	-
II.	Roadmap for publishing and Developing	All new registration letters of new vaccines and MABs since 353 rd meeting	The matter has been discussed and agreed

	SmPC/PSUR/PBER/PILS (Starting from Innovator, brands, vaccines, EPI vaccines)	onward will be issued alongwith SmPC and same will be upload on the website through an exclusive tab developed for submission and processing of SmPC and PIL. All new registration applications for pharmaceutical drugs are received alongwith SmPC and PIL w.e.f 15 th October, 2025. These application will be evaluated and processed for consideration on their turn by the RB. On getting approval, SmPC will be issued alongwith registration letter.	upon in a meeting with PPMA representative on 12-01-2026.
III.	Roadmap for submission, approval and uploading of SmPCs & PIL of already registered products.	All registration holders will submit the renewal application along with SmPC and PIL w.e.f 01 st April, 2026.	-do-
IV.	Delegation of powers to the Chairman, RB for approval of SmPC and PIL.		
V.	Drafting of SOP for conduct of meeting of RB.		
VI.	Declaration of conflict of interest by evaluator and members before evaluating any application or meeting, respectively.		

Relevant guidelines i.e. PRV guidelines, guidelines for submission of CTD (Form-F) and SOPs will be accordingly amended to incorporate the decision and requirements in this regard.

Decision:

The Registration Board deliberated on the matter and decided as under:

- I. Approved the roadmap for submission and approval of SmPCs & PIL as per following timelines:**

S.No.	Task to be done	Status/Roadmap
a)	Notification for submission of SmPC and PIL	Implemented w.e.f 15 th October, 2025.
b)	Roadmap for publishing and Developing SmPC/PSUR/PBER/PILS (Starting from Innovator, brands, vaccines, EPI vaccines)	All new registration letters of new vaccines and MABs since 353 rd meeting onward will be issued alongwith SmPC and same will be upload on the website through an exclusive tab developed for submission and processing of SmPC and PIL. All new registration applications for pharmaceutical drugs are now received alongwith SmPC and PIL w.e.f 15 th October, 2025. These application will be evaluated and processed for consideration on their turn by the RB. On getting approval, SmPC will be issued alongwith registration letter.
c)	Roadmap for submission, approval and uploading of SmPCs & PIL of	All registration holders will submit the renewal application along with SmPC and

	already registered products.	PIL w.e.f 01 st April, 2026.

- II. Endorsed the amendments in the relevant guidelines i.e. PRV guidelines, guidelines for submission of CTD (Form-F), SOPs and relevant checklists regarding incorporation of the decision and requirements in this regard.
- III. Delegated the powers for approval of SmPC and PIL to the Chairman, Registration Board.
- IV. Approved / endorsed the SOP for conduct of meeting of RB.
- V. Approved the proposal of obtaining declaration of conflict of interest by evaluator and members before evaluating any application or meeting, respectively.

Case No 2: Mandatory Submission of Risk Management Plan (RMP) as a Part of Registration Application Dossier and initiation of active surveillance by registration holders.

Pharmacy Services Division of DRAP informed vide letter dated 10.07.2024 and 12.07.2024 that Drug Regulatory Authority of Pakistan (DRAP) has notified the Pharmacovigilance Rules, 2022, vide S.R.O 540 (I) /2022, dated 22nd April 2022. Rule 11 (11) of said rules requires the mandatory submission of Risk Management Plans (RMPs) as a part of the registration dossier to the Registration Board for all new drug products. Moreover, the World Health Organisation (WHO) team at the time of formal benchmarking of the DRAP developed the Institutional Development Plans (IDPs) related to active surveillance and submission of Risk Management plans (RMPs).

Accordingly, in order to streamline the procedure with the aforementioned rules and IDPs, the Divisions of Pharmaceutical Evaluation & Registration and Biological Evaluation & Research were requested by the Pharmacy Services Division to take the necessary measures as per the following details:

- a. The RMP should be made a mandatory part of the CTD (Form-5F) application dossier for new drug products, including biological and vaccines, as per the Pharmacovigilance Rules, 2022.
- b. Submission of approved RMP by registration holders for new drug products, biologicals and vaccines to the National Pharmacovigilance Centre (NPC) before the sale of the drug product should be kept as a condition of registration;
- c. Provision of registration letter of new drug products, biologicals and vaccines to NPC, Pharmacy Services Division for further coordination with registration holders related to pharmacovigilance activities such as submission of Periodic Benefit-Risk Evaluation Report (PBRER) and RMPs, etc.; and
- d. Share a list of new drug products, including biological and vaccines registered since 1st January 2022, so that NPC can identify high-risk products for submission of RMP and implementation of active surveillance and benefit-risk assessment.

The case was discussed in the 339th meeting of the Registration Board held on 6th August to 8th August, 2024. The Board decided as under:

The Registration Board considered the proposal of the Pharmacy Services Division, DRAP, regarding the mandatory submission of the Risk Management Plan (RMP) as part of the registration dossier for all new drug products. The Board deliberated that the submission of RMP by the registration holders needs to be in line with the requirements laid down by the Reference Regulatory Authorities. Therefore, the Board decided that the PE&R Division shall frame a guidance document in consultation with the Pharmacy Services Division regarding the submission of RMP by registration holders for new drug/ biological products.

Risk Management Plan (RMP) is a detailed description of the risk management system, which includes a set of pharmacovigilance activities and interventions that are designed to identify, characterise, prevent or minimise risks relating to a drug, including the assessment of the effectiveness of these activities and interventions. The RMP consists of a safety overview of the medicinal product (Safety Specification), proposed pharmacovigilance activities (Pharmacovigilance Plan), and risk minimisation activities (Risk Minimisation Plan).

The National Pharmacovigilance Centre (NPC), Division of Pharmacy Services, has already issued the

Guidelines on Good Pharmacovigilance Practices (GVP) for Registration Holders, dated 14th April 2022. Module 4 of these guidelines provides detailed requirements pertaining to the Risk Management Plan, including its prescribed format in line with ICH guidelines and references regulatory authorities. Furthermore, it is submitted that three virtual meetings of the WLA Level 3 status of DRAP have been conducted, during which the submission of RMPs was emphasised by the WHO assessors. The next virtual assessment visit of DRAP for World Listed Authority (WLA) level 3 status is scheduled for the first quarter of 2026.

Additionally, during a visit by a WHO Pharmacovigilance Consultant in November 2025, it was advised that, since DRAP applies a reliance-based approach in the registration of medicines in Pakistan, a similar reliance approach should also be adopted for Risk Management Plans. Accordingly, it was recommended that RMP versions approved by reference regulatory authorities should be submitted to DRAP as part of the reliance pathway, rather than Core RMPs, as the latter reflect the Marketing Authorisation Holder's (MAH's) internal assessment and are not suitable for regulatory reliance.

Moreover, it was also informed by the Division of Pharmacy Services that during the formal benchmarking of DRAP, the WHO assessor also developed an Institutional Development Plan (IDP) focusing on the implementation of active surveillance under sub-indicator VL04.01. The IDP emphasises the conduct of active surveillance through Marketing Authorisation Holders (MAHs) as well as through other relevant pharmacovigilance stakeholders.

It was informed that the National Pharmacovigilance Centre (NPC) has also developed Guidelines on the National Pharmacovigilance System, wherein Chapter 5, Section 5.7 outlines the criteria for the initiation of active surveillance. In addition, the medicines and vaccines that may be subject to active surveillance or additional monitoring have been defined, which is reproduced as under:

- Introduction of new vaccine or biological, including monoclonal antibodies;
- New active substance;
- New drugs for the treatment of HIV, tuberculosis, malaria and hepatitis;
- Orphan drugs for the treatment of rare diseases.
- If active surveillance is a condition of registration, and
- Medicine was authorised under exceptional circumstances or emergency conditions or EUA.

In view of the above, the matter is submitted for the consideration of the Registration Board:

- a) To issue a notification for mandatory submission of the Risk Management Plan (RMP) approved by reference regulatory authorities as part of the registration dossier for all new drug products; and
- b) Issue a notification regarding the initiation and/or implementation of active surveillance by Registration Holders (MAHs), in accordance with the above-defined criteria and accordingly submit the data to the National Pharmacovigilance Centre, DRAP.
- c) To report any newly identified risk alongwith complete RMP for already registered drugs to National Pharmacovigilance Centre, DRAP

Decision:

The Registration Board considered the proposal of the Pharmacy Services Division, DRAP and decided to:

- a) **issue a notification for mandatory submission of the Risk Management Plan (RMP) approved by reference regulatory authorities as part of the registration dossier for all new drug products; and**
- a) **issue a notification regarding the initiation and/or implementation of active surveillance by Registration Holders (MAHs), in accordance with the above-defined criteria and accordingly submit the data to the National Pharmacovigilance Centre, DRAP.**
- b) **direct Registration Holders to report any newly identified risk alongwith complete RMP for already registered drugs to National Pharmacovigilance Centre, DRAP**

Miscellaneous Decision:-

In order to ensure the quality of manufactured products on contract manufacturing basis, the Board decided that comprehensive inspection of top five Contract Acceptors shall be conducted by a panel constituted by the Chairman Registration Board to evaluate their GMP Compliance level, operational capacities and quality control testing facilities to meet the requisite standards and reports shall be presented before the Board.

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Pharmaceutical Evaluation Cell (PEC)

1.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	K-Zole Shampoo 2%.
	Composition	Each mL contains: Ketoconazole... 20 mg
	Diary No. Date of R & I & fee	(Duplicate Dossier) dated 04/06/2011 Rs. 8000/- (Photocopy fee challan) Differential fee (photocopy) Rs. 12000/- submitted on 28/10/2015 (Date of STO stamp) Receipt of application verified from R&I.
	Pharmacological Group	Azole Antifungals.
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's Specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA (Ketoconazole 2%w/w shampoo)
	Me-too status	Conaz of M/s Acto, Pakistan.
	GMP status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	☐ Approved formulation in MHRA contain: <i>Each gram of shampoo contains 20 milligrams of Ketoconazole. Each 1 ml of shampoo contains 20.84 milligrams of Ketoconazole.</i> ☐ While the applied formulation is different i.e. Each ml contains 20mg of KETOCONAZOLE. ☐ Further firm claimed Manufacturer's specification while official monograph of applied formulation is present in BP.
	Decision of 308 th meeting	Deferred for the followings: ☐ Revision of formulation as per the reference product i.e. Each gram of shampoo contains 20 milligrams of Ketoconazole. Each 1 ml of shampoo contains 20.84 milligrams of Ketoconazole along with submission of applicable fee, revise Form-5, master formula, manufacturing method. ☐ Confirmation of requisite manufacturing facility for medicated shampoo (external preparation section) from Licensing Division.
	Remarks of the Evaluator	The vide letter No. nil dated nil has submitted a copy of inspection report dated 24.11.2022 (Renewal of DML inspection) wherein Topical Section (General) (Cream/ointment/lotions/gels etc) is mentioned. The firm has not stated anything regarding label claim in their reply.

	Decision of M-333: The Board decided to defer the case and give last chance to the firm for submission of complete reply. Remarks: The firm has shared DRAP R&I evidence of submission of duplicate dossier dated 25.10.2024 and Fee of Rs.37000/- vide challan No. 92426260039 dated 25.10.2024 vide General Request Form TID GXX-Q3G-HBA3, wherein the firm submitted duplicate dossier with the label claim as follows: <i>Each gram contains: Ketoconazole.....20mg. 1mL contains 20.84mg of ketoconazole (BP Specifications)</i> Decision: Approved with B.P specifications. The firm shall submit applicable fee for revision of label claim and change of specifications.	
2.	Name and Address of Manufacturer /Applicant	Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Duofil Topical Solution.
	Diary No. Date of R&I & fee	(Duplicate Dossier) Dy. No. dated 04/06/2011 Rs. 8000/- (Photocopy fee challan) Differential fee (photocopy) of Rs. 12000/- submitted on 28/10/2015 Receipt of application has verified from R&I
	Composition	Each ml contains: Lactic Acid 167mg. Salicylic Acid....167mg. (with the excipient flexible collodion “Flexible collodion works by forming a protective coating over the treated area. It helps to keep the area clean and also keeps the salicylic acid and moisture in contact with the skin.”)
	Pharmacological group	Wart and anti-corn preparations.
	Type of Form	Form-5
	Finished Product specification	Manufacturer’s Specifications.
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Duofilm of M/s GSK (MHRA), Approved. (<i>Salicylic acid 16.7% w/w Lactic acid 15% w/w) Flexible Collodion is used as an excipient</i>
	Me-too Status	Duofilm of M/s GSK, Pakistan.
	GMP Status	Last GMP inspection was conducted on 08-02-2021 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	In MHRA approved formulation is (<i>Salicylic acid 16.7% w/w Lactic acid 15% w/w) while the applied formulation is different.</i>
	Decision of M-308: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting. Remarks: The firm has shared DRAP R&I evidence of submission of duplicate dossier dated 25.10.2024 and Fee of Rs.37000/- vide challan No. 97445081853 dated 25.10.2024 vide General Request Form TID GXX-Q3G-HBA3, wherein the firm has not provided evidence of approval in RRAs but mentioned the strength under point 4 of the duplicate dossier as following:	

	<i>Each mL contains: Lactic Acid 150mg.</i> <i>Salicylic Acid.....167mg.</i> <i>(Innovator's Specifications)</i> Decision: Approved with B.P specifications and following label claim:- <i>Each gram contains:</i> <i>Lactic Acid 167mg.</i> <i>Salicylic Acid.....167mg.</i> The firm shall submit applicable fee for revision of label claim and change of specifications.	
3.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat
	Brand Name +Dosage Form + Strength	Vorizole 200mg tablet
	Composition	Each film coated tablet contains: Voriconazole 200mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 6452 dated 27-06-2024 (Duplicate dossier) Fee 8000/- dated 20-12-2010 (Photocopy) Fee 12000- dated 28-10-2015 (photocopy)
	Pharmacological Group	Triazole antifungal agent
	Finished product Specifications	Innovator's specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Vfend UK
	Me-too status	Vorif of M/s Ferozsans
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	Submitted after the deadline Shortcomings: • verification is required from R&I • section Section approval from CLB is required????
	Decision of M-344: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted General Request form TID JRW-T87-G8MY in which they have provided Form 5. Since the DRAP Authority in its 206th meeting decided as follows: "The Authority, in light of the agenda presented and upon deliberation, directed the Division of Pharmaceutical Evaluation and Registration to review and process all remaining cases of duplicate dossiers submitted by the companies till 31st December 2024." Accordingly, the case is presented for consideration of the Board. Decision: Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	
4.	Name and address of manufacturer / Applicant	M/s Panacea pharmaceuticals Plot No 4 Street No.S-6 , National industrial Zone Rawat

	Brand Name +Dosage Form + Strength	Post Eye Drops 0.004%
	Composition	Each ml ophthalmic Solution contains: Travoprost 0.04mg
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No. 6451 dated 27-06-2024 (Duplicate dossier) Fee 20000- dated 07-03-2019 (photocopy)
	Pharmacological Group	Antiglaucoma preparations and miotics prostaglandin analogues
	Finished product Specifications	USP specs
	Pack size & Demanded Price	As per SRO, As per SRO
	RRA status	Travatan USFDA UK
	Me-too status	Travost of M/s Sante Pvt. Ltd., Karachi
	GMP status	GMP certificate dated 28-04-2023 based on evaluation conducted on 24-11-2022
	Remarks of the Evaluator	Submitted after the deadline Shortcomings: • verification is required from R&I section • Section approval from CLB is required????
	Decision of M-344: The Board was apprised that the decision of Authority regarding timelines for submission of duplicate dossier has not been notified. Hence, Board decided to defer the instant application and referred it to Authority for further directions in this regard. Remarks: The firm has submitted General Request form TID JRW-T87-G8MY in which they have provided Form 5. Since the DRAP Authority in its 206th meeting decided as follows: “The Authority, in light of the agenda presented and upon deliberation, directed the Division of Pharmaceutical Evaluation and Registration to review and process all remaining cases of duplicate dossiers submitted by the companies till 31st December 2024.” Accordingly, the case is presented for consideration of the Board. Decision: Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	
5.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	GOPAIN Injection 20mg (2%)
	Composition	Each 1ml injection contains: Lignocaine (as hydrochloride) 20mg
	Diary No. Date of R & I & fee	Dy. No.21 dated 20-04-2011, Rs: 8000/- dated 20-04-2011 (Challan photocopy dated 20-04-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535880 dated 24-02-2016. “Duplicate dossier, R & I record of initial submission is verified only. R & I record of differential fee submission not verified.”
	Pharmacological Group	anesthetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2ml glass ampoule, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Lidocaine 2 % with preservative Injection, Lidocaine 2% w/v solution for injection

Me-too status	Adcaine Injection (Each 1ml injection contains Lidocaine HCl....20mg) of M/s Ameer & Adnan pharmaceuticals, Lahore. Registration No. 078638
GMP status	Routine GMP inspection report dated 05 th & 06 th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
Remarks of the Evaluator ^(PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. • R & I record of initial submission is verified only. R & I record of differential fee submission could not be verified as communicated by the R & I section. However, differential fee challan (No.0535880) photocopy dated 24-02-2016 submitted. • Revise label claim as: Each 2ml of solution for injection contains: Lidocaine hydrochloride.....40mg • Lidocaine 2% with preservative Injection is used as a local anaesthetic when injected subcutaneously. This solution is not intended for use intravenously. Solutions of lidocaine, which contain preservatives, should not be used for spinal, epidural, caudal or intravenous regional anaesthesia. Lidocaine solution for injection is indicated for use in infiltration anaesthesia, intravenous regional anaesthesia and nerve blocks. In MHRA, variety of route of administration are given depending upon the intended purpose. Such as in ventricular arrhythmias both IV bolus and IV infusion are mentioned. While the IM route is also given in specific circumstances (in case ECG monitoring is not available). For local anesthesia (local infiltration, spinal, epidural or caudal, paracervical block for obstetric analgesia (including abortion). The preservative-free injection label given as “For infiltration and Nerve block including caudal and epidural use”

		The injection containing preservative, label is given as "For injection and nerve block" Not for epidural and caudal use. Contains preservative. • Revise finished drug product specifications as per official monograph. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision of M-323: Deferred for: • Verification of differential fee submission. • Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021. • Revision of label claim as: Each 2ml of solution for injection contains: Lidocaine hydrochloride.....40mg • Revision of finished drug product specifications as per official monograph. Evidence of approval of requisite manufacturing facilities by Licensing Division. 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), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. <u>Remarks:</u> The firm has shared submission to DRAP R&I dated 19.12.2024 and shared the information vide General Request Form TID 179-MM3-GMEE. The firm has submitted the following response: - Attested photocopy of Rs.12000/- challan from Allied Bank - Resumption of production letter dated 5th December, 2023 • Revision of label claim on Covering letter Revision of label claim as: Each 2ml of solution for injection contains: Lidocaine hydrochloride.....40mg - Finished product specification as per USP monograph - Approval of LOP dated 6th October, 2021 - Copy of paid challan of Rs. 37000/- vide challan number 200571267193 dated 19.12.2024 Decision: Approved with USP specifications subject to verification of fee challans in light of decision of 285th meeting of RB.	
6.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	TRAXOFIN 250mg Injection (IM)
	Composition	Each vial contains: Ceftriaxone (as Sodium) 250mg
	Diary No. Date of R & I & fee	Dy. No. dated 21-05-2011, Rs: 8000 /- dated 20-05-2011 (Challan photocopy dated 20-05-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535881 dated 24-02-2016. "Duplicate dossier, R & I record of initial application submission and differential fee submission could not be verified."
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Getofin 250mg IM injection Getz Pharma, Karachi. Registration No. 024628

	GMP status	Routine GMP inspection report dated 05 th & 06 th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
	Remarks of the Evaluator ^(PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. • R & I record of initial submission of application form and differential fee submission could not be verified as communicated by the R & I section.
		• However, differential fee challan (No.0535881) photocopy dated 24-02-2016 provided. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision M-323: Deferred for: • Verification of R & I record of initial submission of registration application and differential fee submission. • Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021. • Revision of finished drug product specifications as per official monograph (USP). • Evidence of approval of requisite manufacturing facilities by Licensing Division. • Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. <u>Remarks:</u> The firm has shared submission to DRAP R&I dated 19.12.2024 and shared the information vide General Request Form TID 179-MM3-GMEE. The firm has submitted the following response: - Attested photocopy of Rs.12000/- challan from Allied Bank - Resumption of production letter dated 17th April 2024 - Finished product specification as per USP monograph - Copy of paid challan of Rs. 9000/- vide challan number 38462625343 dated 19.12.2024 Decision: : Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	
7.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	TRAXOFIN 500mg Injection (IM)
	Composition	Each vial contains: Ceftriaxone (as Sodium) 500mg

Diary No. Date of R & I & fee	Dy. No. dated 21-05-2011, Rs: 8000 /- dated 20-05-2011 (Challan photocopy dated 20-05-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535883 dated 24-02-2016. “Duplicate dossier, R & I record of initial application submission and differential fee submission could not be verified.”
Pharmacological Group	Cephalosporin antibiotic
Type of Form	Form-5
Finished product Specification	USP specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	MHRA approved
Me-too status	Novaxone 500mg Injection IM of M/s NovaMed Pharmaceuticals, Ferozepur Road Lahore. Registration No. 100875
GMP status	Routine GMP inspection report dated 05 th & 06 th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
	• R & I record of initial submission of application form and differential fee submission could not be verified as communicated by the R & I section. • However, differential fee challan (No.0535883) photocopy dated 24-02-2016 submitted. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Decision: Deferred for: • Verification of R & I record of initial submission of registration application and differential fee submission. • Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021. • Revision of finished drug product specifications as per official monograph (USP). • Evidence of approval of requisite manufacturing facilities by Licensing Division. • Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. <u>Remarks:</u> The firm has shared submission to DRAP R&I dated 19.12.2024 and shared the information vide	

General Request Form TID 179-MM3-GMEE. The firm has submitted the following response: - Attested photocopy of Rs.12000/- challan from Allied Bank - Resumption of production letter dated 17th April 2024 - Finished product specification as per USP monograph - Copy of paid challan of Rs. 9000/- vide challan number 5563717837 dated 19.12.2024 Decision: : Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	
8.	Name and address of manufacturer/ Applicant
	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength
	TRAXOFIN 1gm Injection (IM)
	Composition
	Each vial contains: Ceftriaxone (as Sodium) 1gm
	Diary No. Date of R & I & fee
	Dy. No.22 dated 20-04-2011, Rs: 8000 /- dated 20-04-2011 (Challan photocopy dated 20-04-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535878 dated 24-02-2016. “Duplicate dossier, R & I record of initial application submission is verified only. R & I record of differential fee submission not verified.”
	Pharmacological Group
	Cephalosporin antibiotic
	Type of Form
	Form-5
	Finished product Specification
	USP specifications
	Pack size & Demanded Price
	As per SRO
	Approval status of product in Reference Regulatory Authorities
	MHRA approved
	Me-too status
	Sweet Injection 1gm IM of M/s Avensis, Karachi. Registration No. 100346
	GMP status
	Updated cGMP compliance status is required.
	Remarks of the Evaluator ^(PEC-XVII)
	- Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. - Provide most recent GMP inspection report conducted within last 03 years. - R & I record of initial submission of application is verified only. - R & I record of differential fee submission could not be verified as communicated by the R & I section. - Specify finished drug product specifications as per official monograph (USP). - For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Decision: Deferred for: - Verification of differential fee submission - Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021. - Revision of finished drug product specifications as per official monograph (USP). - Evidence of approval of requisite manufacturing facilities by Licensing Division. - Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. <u>Remarks:</u> The firm has shared submission to DRAP R&I dated 19.12.2024 and shared the information vide General Request Form TID 179-MM3-GMEE. The firm has submitted the following response: - Attested photocopy of Rs.12000/- challan from Allied Bank - Resumption of production letter dated 17th April 2024 - Finished product specification as per USP monograph	

	iv. Copy of paid challan of Rs. 9000/- vide challan number 85550923 dated 19.12.2024	
	Decision: : Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	
9.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	CD-3 Injection 5mg/ml (oral)
	Composition	Each 1ml injection contains: Cholecalciferol 5mg
	Diary No. Date of R & I & fee	Dy. No.641 dated 13-07-2012, Rs: 8000 /- dated 13-07-2012 (Challan copy not available). Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535882 dated 24-02-2016. “Duplicate dossier, R & I record of initial application submission is verified only. R & I record of differential fee submission not verified.”
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Sweet Injection 1gm IM of M/s Avensis, Karachi. Registration No. 100346
	GMP status	Updated cGMP compliance status is required.
	Remarks of the Evaluator ^(PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years. • R & I record of initial submission of application is verified only. • R & I record of differential fee submission could not be verified as communicated by the R & I section. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • Verification of differential fee submission. • Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021. • Revision of finished drug product specifications as per official monograph (USP). • Evidence of approval of requisite manufacturing facilities by Licensing Division. • Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. Remarks: The firm has shared submission to DRAP R&I dated 19.12.2024 and shared the information vide General Request Form TID 179-MM3-GMEE . The firm has submitted the following response: i. Attested photocopy of Rs.12000/- challan from Allied Bank ii. Resumption of production letter dated 05th December, 2023	

iii.	Finished product specification as per USP monograph
iv.	Copy of paid challan of Rs. 9000/- vide challan number 9636019292 dated 19.12.2024
Decision: : Approved subject to verification of fee challans in light of decision of 285th meeting of RB.	

Old Form 5 Cases

S. No.	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Decision	Remarks
10.	Servaz Sachet Each sachet contains: Azithromycin dehydrate eq. to Azithromycin base.....1 gm (Macrolides)	1's 3's 5's 10's	As per PRC	28-01-2013 Dy.No.56 Form-5 Rs.20,000/-	M-237 Deferred for confirmation of me-too	The firm has replied on 20.03.2025 which is after the due date. Also the firm has provided reference of a product approved in 340 th meeting on Form 5F.
Decision: Rejected as the firm failed to submit the reply within the notified time i.e. 31-12-2024.						

Form 5-F deferred cases

11.	Name, address of Applicant / Marketing Authorization Holder	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Name, address of Manufacturing site.	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Status of the applicant	☒ Manufacture ☐ r Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18432 dated 21-07-2023
	Details of fee submitted	Rs.75,000/- dated 20-12-2022
	The proposed proprietary name / brand name	Emazone 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Empagliflozin.....25mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Empozin tablet of Macter
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Sr.#	Section#	Observation

			Firm's response
1.	1.5.2	Label claim shall be revised for the name of drug, as firm has mentioned brand name in the label claim.	
2.	3.2.S.1.3	Declaration of solubility of Empagliflozin in water as "practically insoluble" shall be justified with reference to the innovator drug product literature.	
3.	3.2.S.4.4	COA of Empagliflozin from M/s Jiangsu Yongan declares as "Insoluble in water", while COA of Empagliflozin from M/s Medizan declares solubility "very slightly soluble in water". Justification shall be submitted for this variation.	
4.	3.2.P.5.1	Justification shall be submitted for not including test of Uniformity of dosage unit by way of content uniformity, in the drug product specifications.	
5.	3.2.P.8.3	- Documents confirming import of drug substance shall be submitted with the approval of DRAP I&E office shall be submitted. - Analytical record of drug product stability studies shall be submitted.	

Decision of M-340: Deferred for submission of reply to above cited shortcomings.

Remarks:

The firm has submitted replies vide General Request form TID H1H-EUU-ZU17 dated 24th June 2024 wherein the firm has submitted the following:

Revised label claim

1. Empagliflozin is very slightly soluble and revised COA from DS manufacturer is attached.
2. In Medizan's COA mentioned solubility "very slightly soluble in water as per Innovators' but this was a mistake from manufacturer which is rectified and revised COA and procedure of Drug Substance is attached.
3. Revised testing method is attached.
4. ADC & form-6 of Empagliflozin

Decision: Approved.

12.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Emplina 10/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin...10mg Linagliptin...5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 39668 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs.
	Type of Form	Form 5.
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	10's; 20's; 14's; 30's; As per SRO

Approval status of product in Reference Regulator Authorities		GLYXAMBI (USFDA Approved)	
Me-too status			
GMP status		Not submitted.	
Remarks of the Evaluator		Decision 296 th meeting: Deferred for following: Submission of application on Form-5D alongwith applicable fee. Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
STABILITY STUDY DATA			
Drug		Emplina 10/5mg Tablets.	
Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition		Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%	
Time Period		Real time: 6 months	
		Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)	
Batch No.		TEM-055	TEM-056 TEM-056
Batch Size		1350 Tablets	1350 Tablets 1350 Tablets
Manufacturing Date		01-2022	01-2022 01-2022
Date of Initiation		06-01.2022	06-01.2022 06-01.2022
No. of Batches		03	
Date of Submission		Dy. No. 39308 dated 29-12-2022.	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
4.	Stability study data of API from both API manufacturer shall be submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	

7.	Protocols followed for conduction of stability study shall be submitted.	
8.	Method used for analysis of Finished Product shall be submitted.	
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
10.	Complete batch manufacturing record of three stability batches shall be submitted..	
11.	Record of comparative dissolution data shall be submitted.	
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

Decision of M-344: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks:

Sr. No.	Observation	Reply by the firm
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Not provided
2.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	Provided
3.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Provided
4.	Stability study data of API from both API manufacturer shall be submitted.	Provided
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Provided for DS manufacturer of Empagliflozin but not for DS manufacturer of Linagliptin
6.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.	For Empagliflozin DHL
7.	Protocols followed for conduction of stability study shall be submitted.	--
8.	Method used for analysis of Finished Product shall be submitted.	Provided
9.	Drug-excipients compatibility studies (where applicable) shall be submitted.	--
10.	Complete batch manufacturing record of three stability batches shall be submitted..	Provided
11.	Record of comparative dissolution data shall be submitted.	Provided
12.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Provided
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided however peak area in all chromatograms is same.

Decision: The Board was apprised that the firm has submitted similar chromatograms in the

follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

13.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Emplina 25/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin...25mg Linagliptin...5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 39669 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs.
	Type of Form	Form 5.

	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulator Authorities	GLYXAMBI (USFDA Approved)
	Me-too status	
	GMP status	Not submitted.
	Remarks of the Evaluator	Decision 296 th meeting: Deferred for following: Submission of application on Form-5D alongwith applicable fee. Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.
STABILITY STUDY DATA		
Drug		Emplina 25/5mg Tablets.
Manufacturer of API		

API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TEM-055	TEM-056	TEM-056
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	06-01.2022	06-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39309 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.	
7.	Protocols followed for conduction of stability study	Submitted.	
8.	Method used for analysis of FPP	Not submitted.	
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.	

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

Remarks of Evaluator:

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

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

Remarks:																																			
Sr. No.	Observation	Reply by the firm																																	
1.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	Not provided																																	
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13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided however peak area in all chromatograms is same.																																	
Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications. <table border="1"> <thead> <tr> <th>Sr. No.</th><th>General Request Tracking ID</th><th>Brand Name</th></tr> </thead> <tbody> <tr><td>1</td><td>ELU-1NU-X52A</td><td>Rexira 1mg Tablets</td></tr> <tr><td>2</td><td>3MN-8SZ-VDU8</td><td>Rexira 2mg Tablets</td></tr> <tr><td>3</td><td>H4G-48T-Z3JL</td><td>Daplo 5mg Tablets</td></tr> <tr><td>4</td><td>H4G-48T-Z3JL</td><td>Daplo 10mg Tablets</td></tr> <tr><td>5</td><td>5W6-51X-LJQP</td><td>Empline 10mg/5mg</td></tr> <tr><td>6</td><td>DY5-1Y4-WD7J</td><td>Emplina 25mg/5mg</td></tr> <tr><td>7</td><td>XUX-TUU-AB63</td><td>Gliem-M 5/500mg Tablet</td></tr> <tr><td>9</td><td>H6E-HZP-1NGQ</td><td>Gliem-M 5/1000mg Tablet</td></tr> <tr><td>10</td><td>1N3-Q2P-EHQS</td><td>Gliem-M 12.5/500mg Tablet</td></tr> <tr><td>11</td><td>JPW-R7J-6QVD</td><td>Gliem-M 12.5/1000mg Tablet</td></tr> </tbody> </table>			Sr. No.	General Request Tracking ID	Brand Name	1	ELU-1NU-X52A	Rexira 1mg Tablets	2	3MN-8SZ-VDU8	Rexira 2mg Tablets	3	H4G-48T-Z3JL	Daplo 5mg Tablets	4	H4G-48T-Z3JL	Daplo 10mg Tablets	5	5W6-51X-LJQP	Empline 10mg/5mg	6	DY5-1Y4-WD7J	Emplina 25mg/5mg	7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet	9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet	10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet	11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet
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The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

Agenda of Adil Saeed DD-PEC-IX

Deferred cases of Form-5

14.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Rulcer 500mg Tablet
	Composition	Each Tablet Contains: Sucralfate.....500mg
	Diary No. Date of R& I & fee	Dy. No 24869 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's; As per leader price
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Sucralif Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg#054695)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Previous remarks of the Evaluator.	☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
15.	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 12Z-QJM-2PGY Initial reply submitted on 25.11.2024 Firm has not submitted any RRA reference. Firm has submitted reference of Saudi FDA approved GastroFait Tab 500mg.
	Decision: Deferred for policy decision for products with me-too reference but does not have RRA reference.	
	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, Karachi.
	Brand Name +Dosage Form + Strength	Budicap rotacaps
	Composition	Each capsule contains: Budesonide.....400mcg Formoterol Fumarate.....6mcg
	Diary No. Date of R& I & fee	Dy. No.167; 25-1-2017; Rs.20,000/- (24-1-2017)

	Pharmacological Group	Anti-inflammatory and bronchodialator
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30s as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Combivair of M/s Highnoon labs
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate
	Previous remarks of the Evaluator.	International availability in RRA could not be confirmed.
	Previous Decision 279 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities /agencies which were declared/approved by Registration Board in 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 17N-ESX-MQHA Initial reply submitted on 20.12.2024 Firm has not submitted any RRA reference. Firm has submitted me-too reference (Combivair 400 Rotacap) instead of RRA reference.
	Decision: Deferred for policy decision for products with me-too reference but does not have RRA reference.	
16.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vedagon XR 1.5mg Tablet
	Composition	Each extended release tablet contains: Paliperidone.....1.5mg
	Diary No. Date of R& I & fee	Dy.No. 40506 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	INVEGA of USFDA approved.
	Me-too status	Paliris-XR Tablets 1.5mg of M/s Genome Pharmaceuticals
	GMP status	Copy of inspection report dated 10-8-2022 concludes good level of compliance
	Previous remarks of the Evaluator.	Reference product is capsule-shaped tablet in appearance, consists of an osmotically active trilayer core surrounded by a subcoat and semipermeable membrane. The trilayer core is composed of two drug layers containing the drug and excipients, and a push layer containing osmotically active components. There are two precision laser-drilled orifices on the

		drug-layer dome of the tablet. submit of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.
	Previous Decision 324 th meeting	Deferred for confirmation of manufacturing requirements as per reference product.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 1R3-E1T-DV7G Initial reply submitted on 30.12.2024 Firm has submitted manufacturing method, which is of manufacturing a sustained release tablet (Use of HPMC). The firm is not following innovator product manufacturing method i.e. of OROS Push Pull technology.
	Decision: The board rejected the case due to the fact that firm had applied for a product that is qualitatively dissimilar to innovator product.	
17.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vedagon XR 3mg Tablet
	Composition	Each extended release tablet contains: Paliperidone.....3mg
	Diary No. Date of R& I & fee	Dy.No. 40507 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	INVEGA of USFDA approved.
	Me-too status	Avega 6mg Tablets of M/s Biogen Pharma
	GMP status	Copy of inspection report dated 10-8-2022 concludes good level of compliance
	Previous remarks of the Evaluator.	Reference product is capsule-shaped tablet in appearance, consists of an osmotically active trilayer core surrounded by a subcoat and semipermeable membrane. The trilayer core is composed of two drug layers containing the drug and excipients, and a push layer containing osmotically active components. There are two precision laser-drilled orifices on the drug-layer dome of the tablet. submit of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.
	Previous Decision 324 th meeting	Deferred for confirmation of manufacturing requirements as per reference product.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 1R3-E1T-DV7G

		Initial reply submitted on 30.12.2024 Firm has submitted manufacturing method, which is of manufacturing a sustained release tablet (Use of HPMC). The firm is not following innovator product manufacturing method i.e. of OROS Push Pull technology.
	Decision: The board rejected the case due to the fact that firm had applied for a product that is qualitatively dissimilar to innovator product.	
18.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Daypime 250mg I.M/ I.V Injection 5ml
	Composition	Each vial contains: Cefepime (as HCl) with sterile Arginine 250mg
	Diary No. Date of R& I & fee	Dy. No. 5348; 08-06-2017; Rs.20,000/- (08-06-2017)
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's x 5ml & as per leader price
	Approval status of product in Reference Regulatory Authorities	Not confirmed
	Me-too status	Cefstar 250mg powder for solution for injection of M/s Barrett Hodgson
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	Section approval letter needs to be submitted by firm. • QCM's sign is not original. • Powder for injection is not mentioned in Form-5. • Strength is not completely mentioned. • The availability of the applied drug could not be confirmed in the reference regulatory authorities. • Letter has been issued on 19-04-2018 and still no reply has been received by the firm.
	Previous Decision 284 th meeting	Deferred due to following reasons: • Section approval letter needs to be submitted by firm. • QCM's sign is not original. • Powder for injection is not mentioned in Form-5. • Strength is not completely mentioned. • The availability of the applied drug could not be confirmed in the reference regulatory authorities. • Letter has been issued on 19-04-2018 and still no reply has been received by the firm.
	Submission of the firm	Firm has provided revised form-5 with signatures. Firm has also provided Maxipime as reference product approved by USFDA. However, Maxipime has strengths of 500mg, 1gm & 2 gm
	Remarks of the Evaluator PEC-XIII	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th

	meeting. • Current GMP status could not be confirmed. • Manufacturing facility/ Section approval letter could not be confirmed.
Decision of 307 th meeting	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Current GMP status could not be confirmed. • Manufacturing facility/ Section approval letter for applied formulation.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 35W-GS3-RPP1 Initial reply submitted on 20.12.2024 Firm has not submitted any RRA reference. Instead, me-too details are submitted Cefstar Injection IV/IM 250mg
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
19.	
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Coxibex (Celecoxib) 400mg Capsule
Composition	Each capsule contains: Celecoxib B.P.....400mg
Diary No. Date of R& I & fee	Dy. No 20066 Dated 04-06-2018, Rs. 20,000/- 01-06-2018
Pharmacological Group	NSAID
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	10's, 20's, 30's & As per SRO
Approval status of product in Reference Regulatory Authorities	CELEBREX (USFDA)
Me-too status	
GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
Previous remarks of the Evaluator.	
Previous Decision 291 st meeting	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 5V4-E8V-RSQA Initial reply submitted on 17.12.2024 Firm has submitted me-too reference of Celbexx plus 400mg Capsule M/s Getz Reg No. 053369

	Decision: Deferred for verification of submission of reply from R&I.	
20.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Itoper XR Tablet 150mg
	Composition	Each extended-release tablet contains: Itopride HCl.....150mg
	Diary No. Date of R& I & fee	Dy. No.20886; 11-06-2018;Rs.20,000 (11-06-2018)
	Pharmacological Group	Propulsive; drugs for GIT disorders
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Ganaton OD Tablet of M/s Abbott Labs (Reg. # 058549)
	GMP status	Last GMP inspection was conducted on 10-04-2018 and the report concludes acceptable level of GMP compliance.
	Previous remarks of the Evaluator.	☐ Firm has General Tablet Section as mentioned in the submitted GMP report. ☐ International availability of the applied formulation could not be confirmed.
	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 62M-N9Q-VS8P Initial reply submitted on 20.12.2024 Firm has not submitted RRA reference, instead, have submitted me-too reference (ganaton-OD)
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
21.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Qutec 75 Tablet
	Composition	Each Tablet Contains: Diclofenac sodium.....75mg Misoprostol.....200mcg
	Diary No. Date of R& I & fee	Dy. No 24874 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	NSAID, Prostaglandin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Misocot 50 Tablet by M/s Nabiqasim, Karachi (R#074965)

GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
Previous remarks of the Evaluator.	☐ The submitted master formulation does not include ingredients for enteric coating. ☐ It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. ☐ Manufacturing method has not been submitted. ☐ In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
Previous Decision 291 st meeting	Deferred for following: ☐ The submitted master formulation does not include ingredients for enteric coating. ☐ It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. ☐ Manufacturing method has not been submitted. ☐ In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 62Q-P3P-BMPN Initial reply submitted on 20.12.2024 Fee of Rs. 9000/- vide slip No. 37690646 Firm has submitted detailed manufacturing method. As per submitted manufacturing method product is Diclofenac enteric coated core and misoprostol is added as active coating (immediate release). Label claim needs to be revise as under; Each film coated modified release tablet contains; Diclofenac sodium.....75mg (Enteric coated core) Misoprostol.....200mcg
Decision: Approved with following label; Each film coated modified release tablet contains; Diclofenac sodium.....75mg (Enteric coated core) Misoprostol.....200mcg	
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Acelof SR 200mg Capsule
Composition	Each Capsule contain Aceclofenac (60% sustained release pellets) .200mg
Diary No. Date of R& I & fee	Dy.No.9806; 24-07-2017; Rs.20,000/- (24-07-2017)
Pharmacological Group	NSAID
Type of Form	Form-5
Finished product Specifications	MS

Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Could not found
Me-too status	Acelonac-SR 200mg Of M/S Maple Pharmaceuticals
GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate
Previous remarks of the Evaluator.	1st letter: 04th June, 2018 ☐ Reminder letter: 9th October, 2018 ☐ Latest GMP inspection report (conducted within the period of last one year). ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. ☐ Source of pellets (In case of imported source remaining Rs: 80000/- fee) ☐ GMP certificate of source of pellets ☐ Stability study of 3 batches of pellets ☐ Certificate of analysis of pellets.
Previous Decision 291 st meeting	Registration Board deferred the case for: ☐ Latest GMP inspection report (conducted within the period of last three year). ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. ☐ Source of pellets (In case of imported source remaining Rs: 80000/- fee) ☐ GMP certificate of source of pellets, stability data and COA of pellets.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 6H4-26U-SEQX Initial reply submitted on 26.12.2024 i. GMP certificate issued on basis of inspection dated 26.02.2025 is submitted. ii. Instead of RRA reference, me-too reference of Acenac SR 200mg Capsule is submitted. iii. Fee of Rs. 17000/- vide slip No. 917972035 is submitted. iv. Pellets intended to be used are of M/s Vision, GMP of DS manufacturer is submitted.
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
23. Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Oxytrol 3mg Tbalet
Composition	Each Tablet Contains: Oxybutynin HCl.....3mg
Diary No. Date of R& I & fee	Dy.No 16197 dated 07-03-2019 Rs.20,000/- dated 06-03-2019

Pharmacological Group	Drugs for urinary frequency and incontinence
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	Bunin tablets of M/s Libra Pharmaceuticals (Reg.# 030317)
GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
Previous remarks of the Evaluator.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. ☐ Reference for drug product specifications.
Previous Decision 323 rd meeting	Deferred for following: ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 8A8-AHW-Y4HN Initial reply submitted on 12.09.2024 i. Me-too: Taivor Tab 3mg Reg 029390 M/s Raazee ii. MHRA Approved. (uncoated tablet)
Decision: Approved.	
24. Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Oxytrol 5mg Tablet
Composition	Each Tablet Contains: Oxybutynin HCl.....5mg
Diary No. Date of R& I & fee	Dy.No 16198 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
Pharmacological Group	Drugs for urinary frequency and incontinence
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	Bunin tablets of M/s Libra Pharmaceuticals (Reg.#

	030317)
GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
Previous remarks of the Evaluator.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. ☐ Reference for drug product specifications.
Previous Decision 323 rd meeting	Deferred for following: ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 8A8-AHW-Y4HN Initial reply submitted on 12.09.2024 i. Me-too: Urobutin Tablet 049304 M/s Focus&Rulz ii. MHRA Approved. (uncoated tablet)
Decision: Approved.	
25.	
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Stomacol-C Suspension
Composition	Each 5ml Contains: Domperidone as Maleate.....5mg Cinnarizine.....10mg
Diary No. Date of R& I & fee	Dy. No 24870 dated 18-07-2018 Rs.20,000/- 16-07-2018
Pharmacological Group	Antihistamine
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	Pelton-C Suspension by M/s Vision Pharmaceuticals (Pvt.) Ltd., (Reg#047730)
GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 98G-1PA-Q3QB Initial reply submitted on 20.12.2024 i. Instead of RRA reference firm has submitted me-too of Pelton C suspension.
	Decision: Deferred for Policy decision regarding products with me-too reference but does not have RRA reference, and verification of submission of reply from R&I.	
26.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Covik 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate.....400mg
	Diary No. Date of R& I & fee	Dy.No.14294 dated 22/06/2020Rs. 20,000/- dated 22-06-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	--
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Previous remarks of the Evaluator.	Gen tab GMP certificate
	Previous Decision 291 st meeting	Deferred for following: ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID EVM-7DD-JYNH Initial reply submitted on 25.11.2024 i. Me-too: Plaquin-H Tablet 400mg Macter, Reg No. 067329 ii. RRA: USFDA Approved. (Accord Health HYDROXYCHLOROQUINE SULFATE 400mg)
	Decision: Approved.	
27.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan

Brand Name +Dosage Form + Strength	Arolac tablet 20mg
Composition	Each film coated tablet contains: Ketorolac Tromethamine.....20mg
Diary No. Date of R& I & fee	Dy. No.11887; 15-08-2017; Rs.20,000/- (15-08-2017)
Pharmacological Group	NSAID
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	--
GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
Previous remarks of the Evaluator.	☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
Previous Decision 291 st meeting	Deferred for following: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID GU5-2L5-96VP Initial reply submitted on 25.11.2024 i. Me-too: Kelac 20mg Tablet M/s Rotex ii. RRA not submitted. Reference of South Korea is given.
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
28.	
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Detrudine SR 4mg Capsule
Composition	Each Modified Release Capsule Contains: Tolterodine Tartrate 4mg corresponding to Tolterodine...2.74mg"
Diary No. Date of R& I & fee	Dy. No 28465 dated 20-08-2018 Rs.20,000/- 20-08-2018
Pharmacological Group	Urinary antispasmodics
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status	Detrusitol SR 4mg, Prolonged-Release Capsules of M/s Parke-Davis & Company Limited, Karachi (Reg.# 053805)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Previous remarks of the Evaluator.	Clarification of the applied formulation shall be submitted with reference to Innovator's product, regarding how formulation is made modified release.
	Previous Decision 292 nd meeting	Deferred for clarification of the applied formulation with reference to Innovator's product, regarding how the formulation is made modified release.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID HJT-WJ4-9ZDH Initial reply submitted on 26.12.2024 Firm has submitted that they will use SR pellets. Source of pellets is not provided.
	Decision: Approved. Letter shall be issued after source fixation of pellets alongwith applicable fee, if any.	
29.	Deleted due to duplication with case at serial No. 28	
30.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Spasfree 5mg/5ml Syrup
	Composition	Each 5ml Contains: Hyoscine Butylbromide.....5mg
	Diary No. Date of R& I & fee	Dy.No 15191 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Spacure Syrup of m/s Safe Pharmaceuticals (Reg.# 070564)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.
	Previous Decision 323 rd meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID MBQ-2Q4-3N75 Initial reply submitted on 25.11.2024 Firm has not submitted RRA reference, instead reference of Singapore is submitted.

	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
31.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zeenamet 1mg/500mg tablet
	Composition	Each film coated tablet contains: Glimepiride (USP).....1mg Metformin as (HCl).....500mg
	Diary No. Date of R& I & fee	Dy.No.2545; 10-04-2017; Rs.20,000/- (10-04-2017)
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Diabold Plus Tablet M/s Barret Hodgson
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies
	Previous Decision 279 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID NM1-2T6-WYX1 Initial reply submitted on 20.12.2024 Firm has submitted me-too reference instead of RRA reference. Firm has not submitted RRA reference.
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
32.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Mebever 135mg Tablet
	Composition	Each tablet contains: Mebeverine hydrochloride ...135mg
	Diary No. Date of R& I & fee	Diary No:15731, 20/09/2017, Rs: 20,000/-
	Pharmacological Group	Anti-Diabetic Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Colofac Tablets 135 mg by M/s Mylan Products Ltd. (MHRA Approved)
	Me-too status	MEBEVERINE FORTE TRENKER TAB by M/s FAZUL ELLAHIE (Reg#011166)
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes good level of GMP compliance.

	Previous remarks of the Evaluator.	☐ Firm has applied as plain tablet while approved formulation is RRA is sugar coated.
	Previous Decision 283 rd meeting	Deferred for submission of fee for revision of formulation
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID PRZ-3YJ-GTUJ Initial reply submitted on 11.10.2024 Fee of Rs. 37000/- is submitted vide Slip No. 703220118507. Label is revised as under; Each film coated tablet contains; Mebeverine HCl.....135mg (BP Specifications)
	Decision: Approved with following label; Each film coated tablet contains; Mebeverine HCl.....135mg (BP Specifications)	
33.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ursolox 250mg suspension
	Composition	Each 5ml Contains: Ursodeoxycholic Acid.....250mg
	Diary No. Date of R& I & fee	Dy.No 15192 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholelithic
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Ursodol suspension of M/s OBS Pharma (Reg.# 085632)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. ☐ ☐ Reference for drug product specifications shall be submitted.
	Previous Decision 291 st meeting	Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID RJY-LZS-TA4Y Initial reply submitted on 12.09.2024

		Me-too: Urso 250mg/5ml suspension RRA: Ursofalk 250 mg / 5 ml Suspension HPRA Ireland Approved.
	Decision: Approved.	
34.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tyladol CF
	Composition	Each 5ml contains: Paracetamol...80mg Pseudoephedrine hydrochloride...15mg Chlorpheniramine maleate...1mg
	Diary No. Date of R& I & fee	Dy.No. 24093 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Analgesic, antipyretic/sympathomimetic drug/First-Generation Antihistamine
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Reltus C&F of Pharmatech Pakistan (as provided by the firm)
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Previous remarks of the Evaluator.	☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ Mention type
	Previous Decision 291 st meeting	Deferred for the following: ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided evidence is not verifiable. ☐ Mention type of primary packaging material for applied formulation.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID WZ6-LHN-G781 Initial reply submitted on 20.12.2024 Me-too: Epinol-CF Syrup RRA reference is not submitted.

	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
35.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Coxibex tablet 100 mg
	Composition	Each tablet contains: Celecoxib 100mg
	Diary No. Date of R& I & fee	Dy.No.20064; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Seleco tablet of M/s Wilshire Laboratories (Reg. # 028767)
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Previous remarks of the Evaluator.	International availability for the applied dosage form could not be confirmed. ☐ No USP or BP monograph is available for the applied formulation. ☐ Firm has General Tablet Section as mentioned in the submitted GMP report.
	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID T5X-LZ2-EYGA Initial reply submitted on 12.09.2024 RRA Reference: PMDA Japan Approved.
	Decision: Approved.	
36.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Coxibex tablet 200 mg
	Composition	Each tablet contains: Celecoxib 200mg
	Diary No. Date of R& I & fee	Dy.No.20067; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Seleco tablet of M/s Wilshire Laboratories (Reg. # 028767)
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Previous remarks of the Evaluator.	International availability for the applied dosage form could not be confirmed. ☐ No USP or BP monograph is available for the applied formulation. ☐ Firm has General Tablet Section as mentioned in the submitted GMP report.
	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID T5X-LZ2-EYGA Initial reply submitted on 12.09.2024 RRA Reference: PMDA Japan Approved.
	Decision: Approved.	
37.	Deleted due to duplication with case at serial No. 36	
38.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Spasfree Plus Tablet
	Composition	Each Tablet Contains: Hyoscine Butylbromide...5mg
	Diary No. Date of R& I & fee	Dy. No 15193 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	--
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Previous remarks of the Evaluator.	☐ ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

	☐ ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.																								
Previous Decision 323 rd meeting	Deferred for following: ☐ ☐ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ☐ ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.																								
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 95Y-53T-RG77 Initial reply submitted on 26.10.2022 Firm has stated in their initial reply that 5mg is a typographic mistake in minutes, they had applied for 10mg strength. The firm had again submitted their request with copy of initial submission on 02.03.2023 indicating that firm had applied for 10mg strength. 10mg Hyoscine Butylbromide film coated tablets are MHRA approved. Me-too is also available. Firm needs to submit fee for revision of label (uncoated to film coated)																								
Decision: Approved with following label; Each Film Coated Tablet Contains: Hyoscine Butylbromide...10mg Letter shall be issued after submission of preregistration variation fee.																									
39.	<table> <tr> <td>Name and address of manufacturer / Applicant</td><td>M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan</td></tr> <tr> <td>Brand Name +Dosage Form + Strength</td><td>Dremivate 12.5mg/4ml Syrup</td></tr> <tr> <td>Composition</td><td>Each 4ml Contains: Dimenhydrinate 12.5mg</td></tr> <tr> <td>Diary No. Date of R& I & fee</td><td>Dy. No 24868 dated 18-07-2018 Rs.20,000/- 16-07-2018</td></tr> <tr> <td>Pharmacological Group</td><td>Antihistamine</td></tr> <tr> <td>Type of Form</td><td>Form-5</td></tr> <tr> <td>Finished product Specifications</td><td>MS</td></tr> <tr> <td>Pack size & Demanded Price</td><td>As per SRO</td></tr> <tr> <td>Approval status of product in Reference Regulatory Authorities</td><td>--</td></tr> <tr> <td>Me-too status</td><td>Dymin Syrup by M/s Stanley Pharmaceuticals (Pvt) Ltd., (Reg#001718)</td></tr> <tr> <td>GMP status</td><td>Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products..</td></tr> <tr> <td>Previous remarks of the Evaluator.</td><td>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by</td></tr> </table>	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Brand Name +Dosage Form + Strength	Dremivate 12.5mg/4ml Syrup	Composition	Each 4ml Contains: Dimenhydrinate 12.5mg	Diary No. Date of R& I & fee	Dy. No 24868 dated 18-07-2018 Rs.20,000/- 16-07-2018	Pharmacological Group	Antihistamine	Type of Form	Form-5	Finished product Specifications	MS	Pack size & Demanded Price	As per SRO	Approval status of product in Reference Regulatory Authorities	--	Me-too status	Dymin Syrup by M/s Stanley Pharmaceuticals (Pvt) Ltd., (Reg#001718)	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products..	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan																								
Brand Name +Dosage Form + Strength	Dremivate 12.5mg/4ml Syrup																								
Composition	Each 4ml Contains: Dimenhydrinate 12.5mg																								
Diary No. Date of R& I & fee	Dy. No 24868 dated 18-07-2018 Rs.20,000/- 16-07-2018																								
Pharmacological Group	Antihistamine																								
Type of Form	Form-5																								
Finished product Specifications	MS																								
Pack size & Demanded Price	As per SRO																								
Approval status of product in Reference Regulatory Authorities	--																								
Me-too status	Dymin Syrup by M/s Stanley Pharmaceuticals (Pvt) Ltd., (Reg#001718)																								
GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products..																								
Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by																								

		the Registration Board in its 275th meeting.
	Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID TD6-4WV-5NNE Initial reply submitted on 20.12.2024 RRA reference not submitted. Firm has submitted me-too reference instead. (Gravinate)
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
40.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cefrinex 125mg/5ml Dry Suspension
	Composition	Each 5ml suspension contains: Cephadrine.....125mg
	Diary No. Date of R& I & fee	Dy.No.18908; 24-10-2017; Rs.20,000/- (23-10-2017)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VELOSEF '125' of Apothecon (USFDA) "Discontinued
	Me-too status	Velosef of M/s GSK
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed.
	Previous Decision 284 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID U27-HX7-5A7Q Initial reply submitted on 12.09.2024 RRA reference not submitted. Product discontinued in USFDA. (reason of discontinuation not mentioned) Firm has submitted me-too reference instead. (Velosef)
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
41.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Aloc-D tablet
	Composition	Each film coated tablet contains: Fexofenadine hydrochloride...60mg Pseudoephedrine hydrochloride(as extended release)...120mg

Diary No. Date of R& I & fee	Dy.No. 24091 dated 11-07-2018 Rs.20,000/- 10-07-2018
Pharmacological Group	Second-Generation Antihistamine/Sympathomimetic Drug
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Approved in TGA(bilayer tablet)(EXPORT ONLY) However, applicant has provided sehat .com photocopy as evidence.
Me-too status	Fexofin –D Tablets of Bio-Labs (Pvt) Ltd.
GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
Previous remarks of the Evaluator.	☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable & submit master formulation & manufacturing method in line with reference product. ☐ Evidence of purchase of required manufacturing equipment i.e tablet bilayer machine.
Previous Decision 284 th meeting	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as from provided evidence extended release of Pseudoephedrine hydrochloride is not verifiable & submit master formulation & manufacturing method in line with reference product. • Evidence of purchase of required manufacturing equipment.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID W9M-2L2-99PM Initial reply submitted on 13.11.2024 • Firm has submitted copy of renewal inspection report wherein Bi-layered tablet compression machine is mentioned. • Master formulation of bilayered tablet is submitted. • RRA reference: ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION USFDA Approved.
Decision: Approved.	
42. Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Stomacol-C Tablet
Composition	Each Tablet Contains: Domperidone as Maleate...5mg Cinnarizine...10mg

Diary No. Date of R& I & fee	Dy. No.24871 dated 18-07-2018 Rs.20,000/- 16-07-2018
Pharmacological Group	Antihistamine
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	Pelton-C Tablets by M/s Global Pharma Pharmaceuticals (Pvt.) Ltd., (Reg#032891)
GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID WYM-SN7-Z49A Initial reply submitted on 20.12.2024 Instead of RRA reference firm has submitted me-too of Vomistop-C Tablet Reg no. 056715 M/s Danas
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
43. Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Tyladol CF tablet
Composition	Each tablet contains: Paracetamol...600mg Pseudoephedrine hydrochloride...60mg Chlorpheniramine maleate...4mg
Diary No. Date of R& I & fee	Dy. No 24092 dated 11-07-2018 Rs.20,000/- 10-07-2018
Pharmacological Group	Analgesic, antipyretic/ sympathomimetic drug/ First-Generation Antihistamine
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	--
Me-too status	Registration Number 024908 Local/Imported Local Brand Name Reltus C&F Tablets Composition / Generic Paracetamol BP.....600mg Pseudoephedrine Hcl

	BP.60mg Chlorpheniramine Maleate BP.4mg Manufacturer Name Pharmatec Pakistan (Pvt) Ltd, Manufacturer Address D-86/A, S.I.T.E, Karachi-75700
GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
Previous Decision 291 st meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID SLM-V6P-M41H Initial reply submitted on 20.12.2024 Instead of RRA reference firm has submitted me-too of Reltus C&F Tablet
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
44.	Name and address of manufacturer / Applicant
	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength
	Meco- Q Capsule 500mcg
	Composition
	Each capsule contains: Mecobalamin.....500mcg
	Diary No. Date of R& I & fee
	Dy.No.29492; 03-09-2018; Rs.20,000 (03-09-2018)
	Pharmacological Group
	Anti- anaemic/ Vitamin B-12
	Type of Form
	Form-5
	Finished product Specifications
	MS
	Pack size & Demanded Price
	As per SRO
	Approval status of product in Reference Regulatory Authorities
	Could not be confirmed in the applied strength as 250mcg is available in PMDA, Japan
	Me-too status
	Mecobalamin 500mcg capsules of M/s U.M. Enterprise (Reg. # 022643).
	GMP status
	Last GMP inspection was conducted on 10/04/18 and the report concludes an acceptable level of GMP compliance..
	Previous remarks of the Evaluator.
	• International availability for the applied formulation could not be confirmed in the applied strength. • No official monograph is available in USP, BP, IP or JP for the applied formulation.
	Previous Decision 293 RD meeting
	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Response
	Firm has submitted that the applied formulation is available

	in in Japan and registered in PMDA in the same strength and dosage form. Details are as under; • Brand Name: Height Cobalamin M capsule 500mcg. • Approval No. 21800 AMX 10113. • Trade Mark name: Hitocobamin M capsule. • Active ingredient: (in 1 capsule) Japan pharmacopoeia Mecobalamin 500mcg.
Remarks of the Evaluator XIII	Availability of the above said product in PMDA, Japan could not be confirmed.
Decision of 317 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
Evaluation;	Firm has submitted response on eapp CMS vide tracking ID XMZ-A7W-TAT1 Initial reply submitted on 25.11.2024 Firm has not submitted RRA reference, instead have submitted Meconeuro capsule 500mcg approved in Singapore.
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
45.	
Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Acerin tablet 250/250/65mg
Composition	Each film- coated tablet contains: Acetaminophen.....250mg Aspirin.....250mg Caffeine 65mg
Diary No. Date of R& I & fee	Dy.No.9659 dated 01-03-2019; Rs.20,000/- Dated 25-02-2019
Pharmacological Group	NSAIDs
Type of Form	Form-5
Finished product Specifications	MS
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	USFDA Approved
Me-too status	Could not be confirmed in the applied strength
GMP status	Last GMP inspection was conducted on 20-05-2020 and the report concludes good level of GMP compliance.
Previous remarks of the Evaluator PEC- XIII (a)	• The official monograph for the applied formulation is available in USP. • Me- too could not be confirmed in the applied strength. • General tablet section is available in the firm as mentioned in the submitted DML.
Previous Decision 297 th meeting	Deferred for evidence of applied formulation/drug already approved by DRAP (generic /me-too status) alongwith registration number, brand name and name of firm.
Response	Firm has submitted that the applied formulation is available in in Japan and registered in PMDA in the same strength

		and dosage form. Details are as under; • Brand Name: Height Cobalamin M capsule 500mcg. • Approval No. 21800 AMX 10113. • Trade Mark name: Hitocobamin M capsule. • Active ingredient: (in 1 capsule) Japan pharmacopoeia Mecobalamin 500mcg.
	Remarks of the Evaluator XIII	Availability of the above said product in PMDA, Japan could not be confirmed.
	Decision of 317 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation;	Firm has submitted response on eapp CMS vide tracking ID Y1X-57W-EU6L Initial reply submitted on 20.12.2024 Firm has following me-too status; Excedrin extra strength GSK Consumer Healthcare Ltd. Migache caplet M/s Alpine approved in 145 th meeting. (in DRA online drug index Excedrin data couldn't be found)
	Decision: The board rejected the case on the basis that there is no verifiable me-too of the applied product and should have been applied on Form 5D instead of Form 5.	
46.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zeenamet-SR 1mg/500mg tablet
	Composition	Each bi-layered tablet contains: Glimepiride (USP).....1mg Metformin as (HCl).....500mg(as sustained release)
	Diary No. Date of R& I & fee	Dy.No.2543; 10-04-2017; Rs.20,000/- (10-04-2017)
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Gpride-M SR Tablet M/s Sami pharamaceuticals
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies
	Previous Decision 279 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 9RR-A1W-RBP8 Initial reply submitted on 25.11.2024 Firm has not submitted RRA reference. Instead have submitted reference of South Korea.
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	

47.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zeenamet-SR 2mg/500mg tablet
	Composition	Each bi-layered tablet contains: Glimepiride (USP).....2mg Metformin as (HCl).....500mg(as sustained release)
	Diary No. Date of R& I & fee	Dy.No.2542; 10-04-2017; Rs.20,000/- (10-04-2017)
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	Gpride-M SR Tablet M/s Sami pharamaceuticals
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies
	Previous Decision 279 th meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID G9V-HH7-7BBS Initial reply submitted on 25.11.2024 Firm has not submitted RRA reference. Instead have submitted reference of South Korea.
Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.		
48.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Qutec 50 Tablet
	Composition	Each Tablet Contains: Diclofenac sodium.....50mg Misoprostol.....200mcg
	Diary No. Date of R& I & fee	Dy. No 24875 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	NSAID, Prostaglandin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Misocot 50 Tablet by M/s Nabiqasim, Karachi (R#074965)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Previous remarks of the Evaluator.	☐ The submitted master formulation does not include

		ingredients for enteric coating. ☐ It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. ☐ Manufacturing method has not been submitted. ☐ In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
	Previous Decision 291 st meeting	Deferred for following: ☐ The submitted master formulation does not include ingredients for enteric coating. ☐ It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. ☐ Manufacturing method has not been submitted. ☐ In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID QYN-U88-65WR Initial reply submitted on 20.12.2024 Fee of Rs. 9000/- vide slip No. 37690646 Firm has submitted detailed manufacturing method. As per submitted manufacturing method product is Diclofenac enteric coated core and misoprostol is added as active coating (immediate release). Label claim needs to be revise as under; Each film coated modified release tablet contains; Diclofenac sodium.....50mg (Enteric coated core) Misoprostol.....200mcg
	Decision: Approved with following label subject to the submission of pre-registration variation fee; Each film coated modified release tablet contains; Diclofenac sodium.....50mg (Enteric coated core) Misoprostol.....200mcg	
49.	Deleted due to Duplication with Case 5 of I&V Section.	
50.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Glitfen DS Suspension 200mg/5ml
	Composition	Each 5ml contains:- Ibuprofen 200mg
	Diary No. Date of R& I & fee	Dy. No. 16979; 04-10-2017; Rs.20,000/- (02-10-2017)
	Pharmacological Group	NSAID (Propionic acid derivatives) ATC Code: M01AE01
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Ibuprofen by AUROBINDO PHARMA LTD USFDA Approved.
	Me-too status	Registration Number: 076620 Brand Name: Kata-DS Suspension Manufacturer Name: Cibex Pharmaceuticals
	GMP status	GMP certificate granted on the basis of inspection conducted on 19-09-2017.
	Previous remarks of the Evaluator.	
	Previous Decision 285 th meeting	Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query.
	Decision: Approved subject to the submission of latest GMP inspection report.	
51.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sucral-G 1g/5ml Suspension
	Composition	Each 5ml contains: Sucralfate 1g
	Diary No. Date of R& I & fee	Dy. No. 16978; 04-10-2017; Rs.20,000/- (02-10-2017)
	Pharmacological Group	Cytoprotective agent (Drugs for Peptic Ulcer and Gastro-Oesophageal Reflux Disease -GORD) ATC Code: A02BX02
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Antepsin 1g/5ml Oral Suspension MHRA Approved
	Me-too status	Registration Number: 081988 Brand Name: Sucralate Oral Liquid suspension Manufacturer Name: Regal Pharmaceuticals
	GMP status	GMP certificate granted on the basis of inspection conducted on 19-09-2017.
	Previous remarks of the Evaluator.	
	Previous Decision 285 th meeting	Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query.
	Decision: Approved subject to the submission of latest GMP inspection report.	
52.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.

Brand Name +Dosage Form + Strength	Bronkil Syrup 2mg/5ml
Composition	Each 5ml contains Salbutamol ...2mg
Diary No. Date of R& I & fee	Dy. No. 16976; 04-10-2017; Rs.20,000/- (02-10-2017)
Pharmacological Group	Selective beta-2-adrenoreceptor agonists ATC Code: R03CC02
Type of Form	Form-5
Finished product Specifications	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Internationally it is approved as Salbutamol as sulphate.
Me-too status	Registration Number: 081499 Brand Name: Wintol 2mg/5ml Syrup Composition / Generic: Salbutamol as sulphate ... 2mg Manufacturer Name: Lisko Kar
GMP status	GMP certificate granted on the basis of inspection conducted on 19-09-2017.
Previous remarks of the Evaluator.	Internationally and locally it is approved as Salbutamol as sulphate.
Previous Decision 285 th meeting	Deferred for the following reasons: ☐ ☐ Submission of latest GMP inspection report which should have been conducted within the period of last one year. ☐ ☐ Submission of revised formulation as the applied formulation is approved in referenceregulatory authorities as salbutamol (as sulphate) 2mg/5ml which is different from applied formulation i.e. salbutamol 2mg/5ml syrup.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query. Fee for revision of label is also required.
Decision: Approved subject to the submission of latest GMP inspection report. Letter shall be issued after submission of fee for preregistration variation.	
53.	Name and address of manufacturer / Applicant
	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength
	K-Zole Tablets 200mg
	Composition
	Each film coated tablet contains: Ketoconazole....200mg
	Diary No. Date of R& I & fee
	Dy. No. 16973; 04-10-2017; Rs.20,000/- (02-10-2017)
	Pharmacological Group
	Antimycotics For Systemic Use (Imidazole derivatives) ATC Code: J02AB02
	Type of Form
	Form-5
	Finished product Specifications
	USP
	Pack size & Demanded Price
	As per SRO
	Approval status of product in Reference Regulatory Authorities
	Could not be confirmed..
	Me-too status
	Registration Number: 039742 Brand Name: Tezole Tablets

	Manufacturer Name: Brookes
GMP status	GMP certificate granted on the basis of inspection conducted on 19-09-2017.
Previous remarks of the Evaluator.	Evidence of availability as film coated tablets couldn't be confirmed
Previous Decision 285 th meeting	Deferred for the following reasons: ☐ ☐ Submission of latest GMP inspection report which should have been conducted within the period of last one year. ☐ ☐ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query. Fee for revision of label is also required. Firm has requested to revise label to uncoated tablet, RRA reference MHRA is available.
Decision: Approved with following label; Each tablet contains: Ketoconazole....200mg Letter shall be issued after submission of fee for preregistration variation and latest GMP inspection report.	
54.	Name and address of manufacturer / Applicant
	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength
	Broxylin-DM Syrup
	Composition
	Each 5ml contains Dextromethorphan hydrobromide.....12.5mg Diphenhydramine hydrochloride.....12.5mg
	Diary No. Date of R& I & fee
	Dy No. 1609: 27-10-2015 PKR 20,000/-: 22-10-2015
	Pharmacological Group
	Anti tussive
	Type of Form
	Form-5
	Finished product Specifications
	Pack size & Demanded Price
	As per SRO
	Approval status of product in Reference Regulatory Authorities
	Could not be confirmed..
	Me-too status
	Torax DM by Siza
	GMP status
	Last inspection report dated 29-11-2016 do not have any conclusion and remarks regarding GMP status
	Previous remarks of the Evaluator.
	Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Previous Decision 273 rd meeting
	Deferred for following submissions ☐ Update by QA & LT Division regarding the GMP status of the firm ☐ Evidence of approval in reference regulatory authorities

Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query. Fee for revision of label is also required. Firm has requested to revise label as under so that it complies with RRA approved product. Each 5ml contains Dextromethorphan hydrobromide.....6.5mg Diphenhydramine hydrochloride.....10mg
Decision: Approved with following label; Each 5ml contains Dextromethorphan hydrobromide.....6.5mg Diphenhydramine hydrochloride.....10mg Letter shall be issued after submission of fee for preregistration variation and latest GMP inspection report.	
55.	Name and address of manufacturer / Applicant M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength Govid Gel
	Composition Each gram contains Povidone-iodine.....5% w/w
	Diary No. Date of R& I & fee Dy No. 1806: 3-11-2015 PKR 20,000/-: 2-11-2015
	Pharmacological Group Disinfectant and antiseptic
	Type of Form Form-5
	Finished product Specifications Firm has claimed in house specifications
	Pack size & Demanded Price As per SRO
	Approval status of product in Reference Regulatory Authorities Could not be confirmed..
	Me-too status Pyodine gel by Brooks
	GMP status Last inspection report dated 29-11-2016 do not have any conclusion and remarks regarding GMP status
	Previous remarks of the Evaluator. Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Previous Decision 273rd meeting Deferred for following submissions ☐ Update by QA & LT Division regarding the GMP status of the firm ☐ Evidence of approval in reference regulatory authorities
	Evaluation of PEC-IX Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query. Firm has stated that according to FDA povidone

		iodine 5% to 10% is eligible for over the drug, as their product has strength of 5% so its considered OTC by FDA and No RRA is required for its approval. <i>Firm already have registration of Govid solution</i>
	Decision: Deferred for policy decision regarding products with me-too reference but does not have RRA reference.	
56.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Raze 6mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone...6mg
	Diary No. Date of R& I & fee	Dy. No. 2091; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specifications	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperidone 6mg Film-coated Tablets; MHRA approved
	Me-too status	Could not be confirmed
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.
	Previous remarks of the Evaluator.	Provide proof of me-too product (name and registration No.) with same strength and formulation approved by DRAP, otherwise, submit stability data of three batches conducted in zone IV-A.
	Previous Decision 295 th meeting	Deferred for updated GMP status of the firm from QA&LT division.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID ER3-8EB-PZAR Initial reply submitted on 27.12.2024 Firm has claimed that they had submitted inspection report. Not submitted in query. 6mg Tablet Me-too is not verifiable.
	Decision: The board rejected the case on the basis that there is no verifiable me-too of the applied product and should have been applied on Form 5D instead of Form 5	

Deferred cases of Form 5F

57.	Deleted due to Duplication with case on S. No. 312 of additional agenda.	
58.	Deleted due to Duplication with case on S.No. 313 of additional agenda.	
59.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur.

Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 6542 dated 08-03-2023.
Details of fee submitted	Rs.30,000/- vide slip No. 7017924605 dated 04-012023.
The proposed proprietary name / brand name	Askprol Women Tablets.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol 500mg. Hyoscine Butylbromide 10mg.
Pharmacotherapeutic Group of (API)	NSAIDs/Antispasmodic.
Reference to Finished product specifications	In-house Specifications.
The status in reference regulatory authorities	Buscopan Plus Tablets approved by Germany.
For generic drugs (me-too status)	Buscopan Plus Tablets, Martin Dow, Reg. No. 008358.
Proposed Pack size	10 x 10's.
Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.	
2.	1.5.9	Provide evidence of approval of applied formulation i.e. uncoated tablets in reference regulatory authorities as decided by the Registration Board in its 275 th meeting.	
3.	1.6.5	Valid copy of GMP certificate for both the drug substances issued by concerned/relevant authority shall be submitted.	
4.	3.2.S.4.1	Specifications of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of both the drug substances i.e. paracetamol & Hyoscine performed by the drug product manufacturer shall be submitted.	

7.	3.2.S.4.4	COA of both the drug substances i.e. paracetamol & Hyoscine with same batch number from both the drug substance and drug product manufacturer.
8.	3.2.P.5.1	This section has mentioned In-house specifications, however, each separate test has mentioned BP specifications. Clarification shall be submitted.
9.	3.2.P.5.2	Analytical procedures of the drug product shall be submitted.
10.	3.2.P.8.3	Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. Raw data sheets for calculation of assay and dissolution shall be submitted for both real time and accelerated at each interval. Chromatograms for each time with values of resolution, theoretical plates & tailing factor shall be submitted. Submitted chromatograms has revealed retention time for both the substances as of 1.01 and 1.426 while the actual value on the scale is of 0.2 and 0.6. clarification shall be submitted. Justification shall be submitted for two extra peaks other than the peaks of interest in chromatograms. Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. - Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. - Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.

Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC IX:

Firm has submitted their response on eapp CMS vide tracking ID No. VJB-HHW-G6WD

Fee of Rs. 7500 vide slip No. 5932247285 is submitted.

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.	Tablet section approval letter dated 07.07.2025 is submitted
2.	1.5.9	Provide evidence of approval of applied formulation i.e. uncoated tablets in reference regulatory authorities as decided by the Registration Board in its 275 th meeting.	The firm has stated that their product is film coated.
3.	1.6.5	Valid copy of GMP certificate for both the drug substances issued by concerned/relevant authority shall be submitted.	Paracetamol purchased locally from M/s Citi Pharma. GMP certificate submitted. Hyoscine Butylbromide: GMP certificate issued by FDA Haryana India is submitted.

4.	3.2.S.4.1	Specifications of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of both the drug substances i.e. paracetamol & Hyoscine performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.4	COA of both the drug substances i.e. paracetamol & Hyoscine with same batch number from both the drug substance and drug product manufacturer.	Submitted.
8.	3.2.P.5.1	This section has mentioned In-house specifications, however, each separate test has mentioned BP specifications. Clarification shall be submitted.	The submitted specifications indicate that firm is following in-house specifications. Firm has stated that BP was mistakenly mentioned.
9.	3.2.P.5.2	Analytical procedures of the drug product shall be submitted.	Submitted. Its an in-house method.
10.	3.2.P.8.3	Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. Raw data sheets for calculation of assay and dissolution shall be submitted for both real time and accelerated at each interval. Chromatograms for each time with values of resolution, theoretical plates & tailing factor shall be submitted. Submitted chromatograms has revealed retention time for both the substances as of 1.01 and 1.426 while the actual value on the scale is of 0.2 and 0.6. clarification shall be submitted. Justification shall be submitted for two extra peaks other than the peaks of interest in chromatograms. Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Stability data submitted. 3 batches. 1000 tabs each. Raw data sheets and calculations are submitted. Chromatograms are submitted. Clarification and justification of last 2 points not submitted.

		- Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. - Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

Decision: Approved.

Letter shall be issued after submission of fee for preregistration variation and record of data logger.

60.	Name, address of Applicant / Marketing Authorization Holder	M/s High-Q Pharmaceuticals. (DML # 000597) Plot No. 224 Sector 23 Korangi Industrial Area Karachi
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals. (DML # 000597) Plot No. 224 Sector 23 Korangi Industrial Area Karachi
	Status of the applicant	IX Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11976 Dated: 16-05-2023
	Details of fee submitted	PKR 30,000/-: 17-04-2023 (Slip # 1648515765)
	The proposed proprietary name / brand name	Tablet BARITIB 2 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib..... 2 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	Eli Lilly's product
	Proposed Pack size	10's, 14's, 20's, 28's, 30's, 56's & 60's.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation
3.2.S.3	- Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) - Enantiomeric separation. - Final crystallization. - Micronisation of the active substance.

3.2.S.4	- Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product? As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. - X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). - Malvern master sizer for determination of particle size. - Chromatographic column, Chiralpak ID for determination of R-isomer. - Chromatograms of related substance & residual solvents.
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.
3.2.P.8	Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.

Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm has submitted response in eapp CMS vide tracking ID VYG-T76-TBRS

Section	Observation	Response
3.2.S.3	- Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) - Enantiomeric separation. - Final crystallization. - Micronisation of the active substance.	<u>Enantiomeric separation:</u> Baricitinib is achiral (a molecule that is superimposable on its mirror image). It exists as single specific form of molecule, and because of this property the manufacturer of drug substance has not provided the information about the enantiomeric separation in the DMF. <u>Final Crystallization:</u> With Reference to the flow chart given in the DMF, the manufacturer has used Solvent-aided Crystallization process by using butanol in the final stage of Crystallization (step 3). Butanol is used, particularly as an antisolvent to promote crystallization and improve product purity. <u>Micronization of the active substance:</u> Baricitinib crystalline form A, as mentioned in the DMF, refers to a specific crystalline structure of the Baricitinib which is known for its high purity, stability, and good solubility, making it suitable for pharmaceutical formulations. It is also associated with good bioavailability and a prolonged shelf life. Reference to flow chart given in the DMF, the micronization of Baricitinib, to improve solubility in water, improve dissolution rate and enhance bioavailability, is achieved by Solvent

		Evaporation Technique. For this purpose, the drug substance, in the final stage, is dissolved in Butanol to form a solution, and this solvent is then evaporated at 90°C for 6 hours, leaving behind a fine powder.	
3.2.S.4	Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product?	This is a typo error (Loss on drying printed instead of water content) as water content test is part of the certificates of analysis which are provided under "Batch Analysis" section of the DMF. The method of analysis for water content is also given in the DMF, not for loss on drying	
	As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. v. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). vi. Malvern master sizer for determination of particle size. vii. Chromatographic column, Chiralpak ID for determination of R-isomer. viii. Chromatograms of related substance & residual solvents.	<u>X-Ray Powder Diffraction (XPRD) & Malvern Master Sizer</u> Please note that these QC instruments are not mentioned in the inspection Report. The certificate of analysis of High-Q contains only those tests which were performed in-house, however in order to align with the supplier specification we have revisited the specification and testing methods, <u>Chromatographic column, Chiralpak ID for determination of R-isomer</u> The test for R-isomer is not included in the supplier COA and/or analytical methods, therefore we have not acquired the same, instead we have another Chiral column "Chirobiotic® T used for separation of isomers. <u>Chromatograms of related substance & residual solvent</u> These tests have been included in the revised specification and testing methods and shall be performed on each incoming lot of API.	
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Invoice of Medvitaz Solutions Karachi is submitted. 28 tablets of Olumiant 2mg Tablet are mentioned and 28 tablets of 4mg strength.	
3.2.P.8	Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.	Revised COAs of all three batches at each stability interval containing the tests for the uniformity of dosage unit are submitted.	
Decision: Deferred for submission of evidence that response was submitted within 6 months of time period after publication of minutes of 339th meeting of the Registration Board.			
61.	Name, address of Applicant / Marketing Authorization Holder	M/s High-Q Pharmaceuticals. (DML # 000597) Plot No. 224 Sector 23 Korangi Industrial Area Karachi	

Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals. (DML # 000597) Plot No. 224 Sector 23 Korangi Industrial Area Karachi
Status of the applicant	IX Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15114 Dated: 15-06-2023
Details of fee submitted	PKR 30,000/-: 17-04-2023 (Slip # 6106407007)
The proposed proprietary name / brand name	Tablet BARITIB 4 mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib 4 mg
Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
Reference to Finished product specifications	Innovator Specification
The status in reference regulatory authorities	Olumiant® USFDA approved formulation
For generic drugs (me-too status)	Baritib 4 mg tablet by Jenner Pharma
Proposed Pack size	10's, 14's, 20's, 28's, 30's, 56's & 60's.
Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation
3.2.S.3	- Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) i. Enantiomeric separation. ii. Final crystallization. iii. Micronisation of the active substance.
3.2.S.4	- Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product? As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. v. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). vi. Malvern master sizer for determination of particle size. vii. Chromatographic column, Chiralpak ID for determination of R-isomer. viii. Chromatograms of related substance & residual solvents.
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.
3.2.P.8	Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.

Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Decision of 339th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm has submitted response in eapp CMS vide tracking ID GBT-U53-A6PQ

Section	Observation	Response
3.2.S.3	- Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) i. Enantiomeric separation. ii. Final crystallization. iii. Micronisation of the active substance.	<u>Enantiomeric separation:</u> Baricitinib is achiral (a molecule that is superimposable on its mirror image). It exists as single specific form of molecule, and because of this property the manufacturer of drug substance has not provided the information about the enantiomeric separation in the DMF. <u>Final Crystallization:</u> With Reference to the flow chart given in the DMF, the manufacturer has used Solvent-aided Crystallization process by using butanol in the final stage of Crystallization (step 3). Butanol is used, particularly as an antisolvent to promote crystallization and improve product purity. <u>Micronization of the active substance:</u> Baricitinib crystalline form A, as mentioned in the DMF, refers to a specific crystalline structure of the Baricitinib which is known for its high purity, stability, and good solubility, making it suitable for pharmaceutical formulations. It is also associated with good bioavailability and a prolonged shelf life. Reference to flow chart given in the DMF, the micronization of Baricitinib, to improve solubility in water, improve dissolution rate and enhance bioavailability, is achieved by Solvent Evaporation Technique. For this purpose, the drug substance, in the final stage, is dissolved in Butanol to form a solution, and this solvent is then evaporated at 90°C for 6 hours, leaving behind a fine powder.
3.2.S.4	Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product?	This is a typo error (Loss on drying printed instead of water content) as water content test is part of the certificates of analysis which are provided under "Batch Analysis" section of the DMF. The method of analysis for water content is also given in the DMF, not for loss on drying
	As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the	<u>X-Ray Powder Diffraction (XPRD) & Malvern Master Sizer</u> Please note that these QC instruments are not mentioned in the inspection Report. The certificate of analysis of High-Q contains only those tests

	required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. ix. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). x. Malvern master sizer for determination of particle size. xi. Chromatographic column, Chiralpak ID for determination of R-isomer. xii. Chromatograms of related substance & residual solvents.	which were performed in-house, however in order to align with the supplier specification we have revisited the specification and testing methods, <u>Chromatographic column, Chiralpak ID for determination of R-Isomer</u> The test for R-isomer is not included in the supplier COA and/or analytical methods, therefore we have not acquired the same, instead we have another Chiral column "Chirobiotic® T used for separation of isomers. <u>Chromatograms of related substance & residual solvent</u> These tests have been included in the revised specification and testing methods and shall be performed on each incoming lot of API.	
3.2.P.2	• Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Invoice of Medvitaz Solutions Karachi is submitted. 28 tablets of Olumiant 2mg Tablet are mentioned and 28 tablets of 4mg strength.	
3.2.P.8	• Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.	Revised COAs of all three batches at each stability interval containing the tests for the uniformity of dosage unit are submitted.	
Decision: Deferred for submission of evidence that response was submitted within 6 months of time period after publication of minutes of 339th meeting of the Registration Board.			

Agenda of Evaluator PEC-XI (Dr. Farhad Ullah)

Deferred registration application of Human drugs

S/N	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial Fee including differential fee Demanded Price / Pack size	Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest	Remarks by Evaluator

				inspection report (with date) by the Evaluator	
62.	Remington Pharmaceuticals Industries (Pvt) Ltd.	Valpin 10/160 Tablet Each Film coated tablet contains:- Amlodipine (as besylate).....10mg Valsartan.....160mg (Calcium channel blocker & angiotensin-II receptor antagonist)	Form 5 28-01-2011 Rs.8000/- 30-07-2013 Rs.12,000/- 14's, 28's/ Leader Prices	Extor 10/160 Searle USFDA	Deferred for: • Commitment as per 251 st meeting. • Latest inspection report.
	Previous Decision (M-254 th -RB meeting);	Deferred for: • Commitment as per 251 st meeting. • Latest inspection report.			
	Firm's Response	Firm has submitted response vide general request form tracking ID#S72-XZW-NX74. Firm has submitted commitment as per the 251 st meeting of the Registration Board along with the latest panel GMP inspection report dated 30-01-2025, declaring a satisfactory level of GMP compliance. Firm has submitted evidence of reply submission in DRAP R&I dated 07-06-2023			
Decision; Approved.					
63.	Name and address of manufacturer / Applicant		"M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan BY M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi"		
	Brand Name +Dosage Form + Strength		Astezol Injection 40mg		
	Composition		"Each vial contains: Omeprazole Sodium eq to Omeprazole ...40mg"		
	Diary No. Date of R& I & fee		Dy.No 42014 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018		
	Pharmacological Group		<u>Proton pump inhibitors</u>		
	Type of Form		Form-5		
	Finished product Specification		Inhouse		
	Pack size & Demanded Price		As per SRO.		
	Approval status of product in Reference Regulatory Authorities.		MHRA Approved.		
	Me-too status		045617 Risek 40mg Injection Importer Name Julphar Pakistan (Pvt) Ltd.,		
	GMP status		04-03-2019 Conclusion: All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above		

		observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator (V)	- Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. - Provide manufacturing outline of applied formulation. - Submission of agreement between applicant and manufacturer.
	Previous Decision (M-295th-RB): Deferred for the following : - Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility of manufacturer. - Submit manufacturing outline of applied formulation. - Submit contract manufacturing agreement between applicant & manufacturer. - Capacity assessment report of M/s Safe Karachi Firm's response; Firm has submitted response vide general request form tracking ID#VHY-8MW-VVQB. Firm has submitted evidence of reply submission in DRAP R&I dated 18-12-2024 Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Dry powder injectable (Lyophilized) Firm has also submitted capacity assessment report dated 19-06-2023 Decision; Approved. Registration Board further decided that Registration letter shall be issued after submission of "Manufacturing outline of applied formulation and contract manufacturing agreement between applicant & manufacturer".	
64.	Name and address of manufacturer / Applicant	"M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan BY M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi"
	Brand Name +Dosage Form + Strength	Aste-Eso Injection 40mg
	Composition	"Each vial contains: Esomeprazole Sodium eq to Esomeprazole ...40mg"
	Diary No. Date of R& I & fee	Dy.No 42015 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	<u>Proton pump inhibitors</u>
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As Per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	045386 Somezol Injection Bosch
	GMP status	04-03-2019 Conclusion:

		All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator (V)	• Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide manufacturing outline of applied formulation. • Submission of USP monograph of omeprazole injection. • Submission of agreement between applicant and manufacturer.
	Previous Decision (M-295 th -RB): Deferred for the following : • Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility of manufacturer. • Submit manufacturing outline of applied formulation. • Submit contract manufacturing agreement between applicant & manufacturer. • Capacity assessment report of M/s Safe Karachi	
	Firm's response; Firm has submitted evidence of reply submission in DRAP R&I dated 18-12-2024 Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Dry powder injectable (Lyophilized) Firm has also submitted capacity assessment report dated 19-06-2023	
	Decision; Approved. Registration Board further decided that Registration letter shall be issued after submission of "Manufacturing outline of applied formulation and contract manufacturing agreement between applicant & manufacturer".	
65.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Rexira 1mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole.....1mg"
	Diary No. Date of R& I & fee	Dy.No 38721 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017

		GMP was Satisfactory.	
	Remarks of the Evaluator (VIII)	- Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet. - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Previous Decision (M-295 th -RB)	Deferred for following: - Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method. - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
STABILITY STUDY DATA			
Drug	Rexira 1mg Tablets		
Manufacturer of API	M/s MSN Lifesciences India		
API Lot No.	BG0061018		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TRX-046	TRX-047	TRX-048
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01-2022	10-01-2022	11-01-2022
No. of Batches	03		
Date of Submission	Dy. No. 39310 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	

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

Remarks of Evaluator:

Sr. No.	Observation
1.	Submit differential fee as the applied product is a new drug molecule
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall

	be submitted.
8.	Protocols followed for conduction of stability study shall be submitted.
9.	Method used for analysis of Finished Product shall be submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.
11.	Complete batch manufacturing record of three stability batches shall be submitted.
12.	Record of comparative dissolution data shall be submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Previous Decision (M-344th meeting of RB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response; Firm has submitted response vide general request form tacking ID# ELU-1NU-X52A

Sr. No.	Deferment Reason	Firm's Response
1.	Submit differential fee as the applied product is a new drug molecule	Firm has submitted fee Rs. 17000/- on deposit slip#174578186363. However, fee for new molecule is Rs. 75000/-.
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer is submitted. However, Both submitted COAs of API from API manufacturer and finished product manufacturer bear the same batch number, while the manufacturing and expiry dates differ (API manufacturer: Mfg. Sep-2024 / Exp. Aug-2029; finished product manufacturer: Mfg. Sep-2021 / Exp. Aug-2024). Please clarify this discrepancy and submit corrected CoAs,
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted.
5.	Stability study data of API from API manufacturer shall be submitted.	Stability study data of API at temperature 25°C±2°C, relative humidity 60±5%RH upto 60 months is submitted. Stability study data of API at both accelerated and real time conditions as per as per zone IV-A shall be submitted
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of Licence to manufacture drugs for purposes of examination, test or analysis of API manufacturer issued by Drugs Control Administration Telangana State India valid upto 25-03-2023. Firm has also submitted copy of cGMP certificate of API manufacturer issued by

		Drugs Control Administration Telangana State India valid upto 05-01-2026.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of form 6 dated 17-12-2021 specifying 0.010kg Brexpiprazole attested by AD (I&E) DRAP field office. Firm has also submitted copy of invoice, packing list and airway bill.
8.	Protocols followed for conduction of stability study shall be submitted.	Submitted
9.	Method used for analysis of Finished Product shall be submitted.	Submitted
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Having the same formulation with Innovator (Brand Leader) Drug-excipient compatibility study is not applicable.
11.	Complete batch manufacturing record of three stability batches shall be submitted.	Complete batch manufacturing record of three stability batches having batch size of 1350 tablets is submitted.
12.	Record of comparative dissolution data shall be submitted.	Results of dissolution test is submitted instead of comparative dissolution profile. Complete record of Comparative dissolution profile in three BCS media shall be submitted
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	Stability study data at initial time point is submitted only Stability study data at 3 rd month time point and 6 th month time point shall be submitted
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted

Your reply has been evaluated and still found deficient for the following;

Deficiencies	Firm's response
The fee for new drug molecule is Rs. 75,000/- while you have submitted only Rs. 37,000/- in total. Submit differential fee as the applied product is a new drug molecule	No response submitted
Both submitted COAs of API from API manufacturer and finished product manufacturer bear the same batch number, while the manufacturing and expiry dates differ (API manufacturer: Mfg. Sep-2024 / Exp. Aug-2029; finished product manufacturer: Mfg. Sep-2021 / Exp. Aug-2024). Please clarify this discrepancy and submit corrected CoAs,	Firm has submitted another COA from both API and finished product manufacturer with a different batch number, manufacturing and expiry dated. Batch No. BG0061018, Mfg date; 18-October-2021, Expiry date; September-2025
Stability study data of API at both accelerated and real time conditions as per as per zone IV-A shall be submitted	Not submitted
Complete record of Comparative dissolution profile in three BCS media shall be submitted	Summary report of comparative dissolution profile is submitted
Stability study data at initial time point is submitted only. Stability study data at 3 rd month time point and 6 th month time point shall be submitted	Only stability summary sheets for accelerated stability study upto 6 th months and for long term data upto 36 th months is submitted. However, no chromatograms, raw datasheets and COAs are

	submitted. Furthermore chromatograms of three batches of both strengths Rexira 1mg Tablets and Rexira 2mg Tablets submitted at initial time point has same peak retention time, peak area, peak height, date acquired and date processed.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted

Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

66.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Rexira 2mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole.....2mg"
	Diary No. Date of R& I & fee	Dy.No 38722 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or

		evidence of approval of applied drug product as film coated tablet. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Previous Decision (M-295 th -RB)	Deferred for following: - Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method. - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

STABILITY STUDY DATA

Drug	Rexira 2mg Tablets		
Manufacturer of API	M/s MSN Lifesciences India		
API Lot No.	BG0061018		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TRX-049	TRX-050	TRX-051
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01-2022	10-01-2022	11-01-2022
No. of Batches	03		
Date of Submission	Dy. No. 39311 dated 29-12-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

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

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

Remarks of Evaluator:

Sr. No.	Observation
1.	Submit differential fee as the applied product is a new drug molecule
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
8.	Protocols followed for conduction of stability study shall be submitted.
9.	Method used for analysis of Finished Product shall be submitted.
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.

11.	Complete batch manufacturing record of three stability batches shall be submitted.
12.	Record of comparative dissolution data shall be submitted.
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Previous Decision (M-344th meeting RB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response; Firm has submitted response vide general request form tacking ID# 3MN-8SZ-VDU8

Sr. No.	Deferment Reason	Firm's Response
1.	Submit differential fee as the applied product is a new drug molecule	Firm has submitted fee Rs. 17000/- on deposit slip#97528780. However, fee for new molecule is Rs. 75000/-.
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
3.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer shall be submitted	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer is submitted. However, Both submitted COAs of API from API manufacturer and finished product manufacturer bear the same batch number, while the manufacturing and expiry dates differ (API manufacturer: Mfg. Sep-2024 / Exp. Aug-2029; finished product manufacturer: Mfg. Sep-2021 / Exp. Aug-2024). Please clarify this discrepancy and submit corrected CoAs,
4.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted.
5.	Stability study data of API from both API manufacturer shall be submitted.	Stability study data of API at temperature 25°C±2°C, relative humidity 60±5%RH upto 60 months is submitted. Stability study data of API at both accelerated and real time conditions as per as per zone IV-A shall be submitted
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of Licence to manufacture drugs for purposes of examination, test or analysis of API manufacturer issued by Drugs Control Administration Telangana State India valid upto 25-03-2023. Firm has also submitted copy of cGMP certificate of API manufacturer issued by Drugs Control Administration Telangana State India valid upto 05-01-2026.
7.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of form 6 dated 17-12-2021 specifying 0.010kg Brexpiprazole attested by AD (I&E) DRAP field office. Firm has also submitted copy of invoice, packing list and airway bill.

8.	Protocols followed for conduction of stability study shall be submitted.	Submitted
9.	Method used for analysis of Finished Product shall be submitted.	Submitted
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Having the same formulation with Innovator (Brand Leader) Drug-excipient compatibility study is not applicable.
11.	Complete batch manufacturing record of three stability batches shall be submitted.	Complete batch manufacturing record of three stability batches having batch size of 1350 tablets is submitted.
12.	Record of comparative dissolution data shall be submitted.	Results of dissolution test is submitted instead of comparative dissolution profile. Complete record of Comparative dissolution profile in three BCS media shall be submitted
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	Stability study data at initial time point is submitted only Stability study data at 3 rd month time point and 6 th month time point shall be submitted
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted

Your reply has been evaluated and still found deficient for the following;

Deficiencies	Firm's response
The fee for new drug molecule is Rs. 75,000/- while you have submitted only Rs. 37,000/- in total. Submit differential fee as the applied product is a new drug molecule	No response submitted
Both submitted COAs of API from API manufacturer and finished product manufacturer bear the same batch number, while the manufacturing and expiry dates differ (API manufacturer: Mfg. Sep-2024 / Exp. Aug-2029; finished product manufacturer: Mfg. Sep-2021 / Exp. Aug-2024). Please clarify this discrepancy and submit corrected CoAs,	Firm has submitted another COA from both API and finished product manufacturer with a different batch number, manufacturing and expiry dated. Batch No. BG0061018, Mfg date; 18-October-2021, Expiry date; September-2025
Stability study data of API at both accelerated and real time conditions as per as per zone IV-A shall be submitted	Not submitted
Complete record of Comparative dissolution profile in three BCS media shall be submitted	Summary report of comparative dissolution profile is submitted
Stability study data at initial time point is submitted only. Stability study data at 3 rd month time point and 6 th month time point shall be submitted	Only stability summary sheets for accelerated stability study upto 6 th months and for long term data upto 36 th months is submitted. However, no chromatograms, raw datasheets and COAs are submitted. Furthermore chromatograms of three batches of both strengths Rexira 1mg Tablets and Rexira 2mg Tablets submitted at initial time point has same peak retention time, peak area, peak height, date acquired and date processed.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted

Decision; R Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

67.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32620: 05-01-2023
	Details of fee submitted	Slip No:80436731 PKR 30,000/-
	The proposed proprietary name / brand name	Find Tablet 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride.....60mg.
	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
	For generic drugs (me-too status)	Product Name: Fexocare 60mg Tablet Registration No: 062860
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.

2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol , report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.
13.	3.2.P.5.4	a) The dissolution specifications are not as per USP. b) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	a) Submit the BMRs of stability batches F-01, F-02, F-03. (Find 60mg).

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response;

S. No	Sections	Deferment Reason	Firm's Response
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Copy of DML and application submitted for renewal of DML is submitted
2.	1.3.5	Provide GMP inspection report/ GMP	The GMP inspection of our facility

		certificate of the manufacturing unit issued within the last three years.	has been conducted, and the report is currently pending. You are kindly requested to approve the product, with issuance of the approval letter subject to submission of the GMP Inspection Report.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.	Firm has submitted Nomenclature, Structure & General Properties of drug substance
4.	3.2.S.4.3	Submit method verification report with supporting data.	Submitted
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.	New Stability Data Sheets, Provided by Drug Substance Manufacturer has been submitted
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP, whereas section 3.2.S.4.1 references USP.	It was Typographic Error, the specification is USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol, report and supporting documents. c) Provide dissolution specifications as per applied test.	• Xadine 60mg tablets by Searle Company Ltd is used for Pharmaceutical Equivalence study. Report is attached. • CDP protocol, report is submitted • Dissolution was performed against Test 3 in USP with the limit of NLT 75% (Q) in 45mins. SAP of Finished Product attached.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.	Firm has submitted master formulation of applied product.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.	Process validation protocol is submitted
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.	Firm has submitted details in this section
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.	Dissolution was performed against Test 3 in USP with the limit of NLT 75%(Q) in 45mins. SAP OF Finished Product Attached. Firm has submitted fee Rs. 9400/- on deposit slip#80055126508 for revision of specifications
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.	submitted
13.	3.2.P.5.4	a) The dissolution specifications are not as per USP. b) The dissolution results of each unit should be provided separately.	• Revised dissolution specifications are attached in Annexure 6. • Submitted
14.	3.2.P.6	Submit COA of primary reference standard.	COA of working standard is submitted

15	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.	FEXOFENADINE HCL TABLET is available as 1x10's TABLET further packed in Bleachboard Box along with leaflet
16	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Firm has submitted cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 03-03-2022. • Firm has submitted copy of loan intimation, form 6 cleared by AD (I&E) DRAP, invoice. • Audit trail is submitted
17	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.	• Total 1200 tabs with a pack size of 1x10s tabs/pack. batch size of tablets in stability summary datasheets attached. • The dissolution results of each unit should be provided separately. • Firm submitted formula is provided in the SAP. • No clarification is submitted
18	3.2.R.1	Submit the BMRs of stability batches F-01, F-02, F-03. (Find 60mg).	Submitted

Decision; Deferred for submission of following;

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
- **Compliance Record of HPLC software 21CFR**
- **Copy of clearance certificate or goods declaration for procurement of API**
- **Clarification for not performing the system suitability test for assay before each time point which is mandatory as per monograph.**

68.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 607: 06-01-2023
	Details of fee submitted	Slip No: 91211664508 PKR 30,000/-
	The proposed proprietary name / brand name	Find Tablet 120mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride.....120mg.

	Pharmacotherapeutic Group of (API)	Antihistamine R06AX26
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
	For generic drugs (me-too status)	Product Name: Fexocare 120mg Tablet Registration No: 062861
	Proposed Pack size	As per SRO
Evaluation by PEC-V:		
The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.		
S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol , report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.
13.	3.2.P.5.4	a) The dissolution specifications are not as per USP. b) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	a) Submit the BMRs of stability batches F-04, F-05, F-06.

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response;

S. No	Sections	Deferment Reason	Firm's Response
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Copy of DML and application submitted for renewal of DML is submitted
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	The GMP inspection of our facility has been conducted, and the report is currently pending. You are kindly requested to approve the product, with issuance of the approval letter subject to submission of the GMP Inspection Report.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.	Firm has submitted Nomenclature, Structure & General Properties of drug substance
4.	3.2.S.4.3	Submit method verification report with supporting data.	Submitted
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.	New Stability Data Sheets, Provided by Drug Substance Manufacturer has been submitted
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP, whereas section 3.2.S.4.1 references USP.	It was Typographic Error, the specification is USP.
7.	3.2.P.2.2.1	d) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. e) Submit CDP protocol, report and supporting documents. f) Provide dissolution specifications as per applied test.	• Xadine 120mg tablets by Searle Company Ltd is used for Pharmaceutical Equivalence study. Report is attached. • CDP protocol, report is submitted • Dissolution was performed against Test 3 in USP with the limit of NLT 75% (Q) in 45mins. SAP of Finished Product attached.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.	Firm has submitted master formulation of applied product.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.	Process validation protocol is submitted
10.	3.2.P.4	The control of excipients is not as per DRAP	Firm has submitted details in this

		CTD guidance document.	section
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.	Dissolution was performed against Test 3 in USP with the limit of NLT 75%(Q) in 45mins. SAP OF Finished Product Attached. Firm has submitted fee Rs. 9400/- on deposit slip# 908522419 for revision of specifications
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.	submitted
13.	3.2.P.5.4	c) The dissolution specifications are not as per USP. d) The dissolution results of each unit should be provided separately.	- Revised dissolution specifications are attached in Annexure 6. - Submitted
14.	3.2.P.6	Submit COA of primary reference standard.	COA of working standard is submitted
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.	FEXOFENADINE HCL TABLET is available as 1x10's TABLET further packed in Bleachboard Box along with leaflet
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	- Firm has submitted cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 03-03-2022. - Firm has submitted copy of loan intimation, form 6 cleared by AD (I&E) DRAP, invoice. - Audit trial is submitted
17.	3.2.P.8.3	e) Submit batch size of tablets in stability summary datasheets. f) The dissolution results of each unit should be provided separately. g) Provide the formula on the basis of which dissolution has been calculated. h) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.	- Total 1200 tabs with a pack size of 1x10s tabs/pack. batch size of tablets in stability summary datasheets attached. - The dissolution results of each unit should is provided separately. - Firm submitted formula is provided in the SAP. - No clarification is submitted
18.	3.2.R.1	Submit the BMRs of stability batches F-04, F-05, F-06.	Submitted

Deferred for submission of following;

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Compliance Record of HPLC software 21CFR
- Copy of clearance certificate or goods declaration for procurement of API
- Clarification for not performing the system suitability test for assay before each time point which is mandatory as per monograph.

69.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.

Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot 23, 24, S 1, RCCI, Industrial Estate, Rawat.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 483: 05-01-2023
Details of fee submitted	Slip No:79999139063 PKR 30,000/-
The proposed proprietary name / brand name	Find Tablet 180mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride.....180mg.
Pharmacotherapeutic Group of (API)	Antihistamine;R06AX26
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA Approved. ALLEGRA Tablets
For generic drugs (me-too status)	Product Name: Fexocare 180mg Tablet Registration No: 062862
Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.
4.	3.2.S.4.3	Submit method verification report with supporting data.
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP ,whereas section 3.2.S.4.1 references USP.
7.	3.2.P.2.2.1	a) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed. b) Submit CDP protocol, report and supporting documents. c) Provide dissolution specifications as per applied test.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.

13.	3.2.P.5.4	c) The dissolution specifications are not as per USP. d) The dissolution results of each unit should be provided separately.
14.	3.2.P.6	Submit COA of primary reference standard.
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Submit batch size of tablets in stability summary datasheets. b) The dissolution results of each unit should be provided separately. c) Provide the formula on the basis of which dissolution has been calculated. d) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.
18.	3.2.R.1	b) Submit the BMRs of stability batches F-07, F-08, F-09.

Previous Decision (M-336th-RB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response;

S. No	Sections	Deferment Reason	Firm's Response
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Copy of DML and application submitted for renewal of DML is submitted
2.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	The GMP inspection of our facility has been conducted, and the report is currently pending. You are kindly requested to approve the product, with issuance of the approval letter subject to submission of the GMP Inspection Report.
3.	3.2.S.1	The chemical name and CAS number of drug substance is different then as provided in USP.	Firm has submitted Nomenclature, Structure & General Properties of drug substance
4.	3.2.S.4.3	Submit method verification report with supporting data.	Submitted
5.	3.2.S.7.3	The stability summary data sheets mentions (Ph. Eur), whereas specifications are of USP. Clarification is required. Moreover, the specifications of water content are different then USP i.e. NMT 2 %.	New Stability Data Sheets, Provided by Drug Substance Manufacturer has been submitted
6.	3.2.P.2.1	The composition of the drug product mentions pharmacopeia reference as BP, whereas section 3.2.S.4.1 references USP.	It was Typographic Error, the specification is USP.
7.	3.2.P.2.2.1	g) The CDP report is of desloratadine. Provide the details of the product against which pharmaceutical equivalence has been performed.	• Fexet 180mg tablets by Getz Pharma is used for Pharmaceutical Equivalence study. Report is attached.

		h) Submit CDP protocol, report and supporting documents. i) Provide dissolution specifications as per applied test.	• CDP protocol, report is submitted • Dissolution was performed against Test 3 in USP with the limit of NLT 75% (Q) in 45mins. SAP of Finished Product attached.
8.	3.2.P.3.2	Provide batch formula for proposed commercial batch, as the provided batch size is 0.402kg. The batch formula mentions reference of drug substance as BP, whereas section 3.2.S.4.1 references USP.	Firm has submitted master formulation of applied product.
9.	3.2.P.3.5	Provide process validation protocol of commercial batches.	Process validation protocol is submitted
10.	3.2.P.4	The control of excipients is not as per DRAP CTD guidance document.	Firm has submitted details in this section
11.	3.2.P.5.1	Submit specifications as per USP. Provide which test of dissolution has been used.	Dissolution was performed against Test 3 in USP with the limit of NLT 75%(Q) in 45mins. SAP OF Finished Product Attached. Firm has submitted fee Rs. 9400/- on deposit slip# 7268768539 for revision of specifications
12.	3.2.P.5.2	Submit analytical procedures used for testing the drug product.	submitted
13.	3.2.P.5.4	e) The dissolution specifications are not as per USP. f) The dissolution results of each unit should be provided separately.	• Revised dissolution specifications are attached in Annexure 6. • Submitted
14.	3.2.P.6	Submit COA of primary reference standard.	COA of working standard is submitted
15.	3.2.P.7	A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.	FEXOFENADINE HCL TABLET is available as 1x10's TABLET further packed in Bleachboard Box along with leaflet
16.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Firm has submitted cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 03-03-2022. • Firm has submitted copy of loan intimation, form 6 cleared by AD (I&E) DRAP, invoice. • Audit trial is submitted
17.	3.2.P.8.3	i) Submit batch size of tablets in stability summary datasheets. j) The dissolution results of each unit should be provided separately. k) Provide the formula on the basis of which dissolution has been calculated.	• Total 1200 tabs with a pack size of 1x10s tabs/pack. batch size of tablets in stability summary datasheets attached. • The dissolution results of each unit should is provided separately.

		1) The system suitability for assay has not been performed before each time point which is mandatory as per monograph.	- Firm submitted formula is provided in the SAP. - No clarification is submitted
18.	3.2.R.1	Submit the BMRs of stability batches F-07, F-08, F-09.	Submitted

Decision: Deferred for submission of following;

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Compliance Record of HPLC software 21CFR
- Copy of clearance certificate or goods declaration for procurement of API
- Clarification for not performing the system suitability test for assay before each time point which is mandatory as per monograph.

70.	Name, address of Applicant / Marketing Authorization Holder	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi - 7500, Pakistan
	Name, address of Manufacturing site.	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi - 7500, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28456 Dated 15/ 10/ 2021
	Details of fee submitted	PKR 30,000/-: Dated 04/10/2021 (Deposit Slip#489820062060)
	The proposed proprietary name / brand name	Ondansetron Tablet 4mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron.....4mg (as Ondansetron Hydrochloride Dihydrate BP)
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Antiemetics and antinauseants, Serotonin (5-HT3) antagonists.
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 4mg film coated tablet MHRA approved
	For generic drugs (me-too status)	Ongene 4mg Tablet by M/s High-Q Pharmaceuticals (Reg#091206)

GMP status of the Finished product manufacturer	The firm was inspected on 22-03-2022 & 05-04-2022 by the panel for renewal of DML, regularization of section as per layout plan and additional sections and decision of panel is: Keeping in view the good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at the site and overall good maintenance of plan and the required documentation and SOPs, the panel recommended the grand of DML of the firm as well as regularization of sections as per layout plan and approval of additional sections
Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ Stability of all three batches at accelerated conditions (AOND-17002, AOND-17003, AOND-17004) conducted for 06 months Real time stability study of two batches AOND-17002, AOND-17003, conducted for 36 months while real time stability study of one batch AOND-17004 conducted for 24 months
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Zofran 8mg Tablet by GlaxoSmithKline Research Triangle Park, NC 27709 Marketed by: Novartis Pharmaceuticals UK Limited performing quality tests (Identification, Assay,

		Dissolution, disintegration). CDP of ondansetron 8mg tablets has been performed against the zofran 8mg tablets in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.		
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity and robustness.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India		
API Lot No.		AOND-20013		
Description of Pack (Container closure system)		ALU-ALU Blister pack packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		MA096C	MA097C	MA098C
Batch Size		4200 Tablets	4220 Tablets	4490 Tablets
Manufacturing Date		03/2021	03/2021	03/2021
Date of Initiation		25/03/2021	25/03/2021	25/03/2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the basis of which Registration Board in its 277 th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet. Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DCD/SPL.CL-1/CR-1510/2020-21 dated 06-02-2021 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto one year from the date of issue. The firm has submitted copy of DML #DCD/MFG/Applicant Id-240 dated 26/06/2020 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63,		

		KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto 13/02/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # OND1200 dated 10-11-2020 for import on 300gm of Ondansetron HCl Dihydrate Batch #AOND-20014, AOND-20012 and AOND-20013 in the name of M/s Atco Laboratories Ltd Karachi form M/s Agraha Chemical India. <i>However, the invoice is not attested by AD (I&E) DRAP field office</i>
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator ^{XI}:

Section	Observations	Response																
1.6.5	Submit valid GMP certificate of drug substance manufacturer																	
3.2.S.4	- Copies of the analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required. - Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.																	
3.2.S.5	Firm has submitted COA of primary reference standard which follows usp specifications and secondary reference standard which has followed Ph. Eu specifications while applied product manufacturer follows bp specifications																	
3.2.P.2	- Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product. <table border="1"><tr><td>Applied product</td><td>Zofran 4mg tab</td></tr><tr><td>Lactose anhydrous</td><td>Lactose</td></tr><tr><td>Sodium starch glycolate</td><td>Microcrystalline Cellulose</td></tr><tr><td>Crospovidone</td><td>Pregelatinized maize starch</td></tr><tr><td>Magnesium stearate</td><td>Magnesium Stearate,</td></tr><tr><td>Opadry white</td><td>Methyl hydroxypropyl cellulose</td></tr><tr><td>Purified water</td><td>Titanium dioxide (E171)</td></tr><tr><td></td><td>Iron oxide (E172)</td></tr></table> - Justification is required as the pharmaceutical equivalence and CDP of higher strength has been submitted	Applied product	Zofran 4mg tab	Lactose anhydrous	Lactose	Sodium starch glycolate	Microcrystalline Cellulose	Crospovidone	Pregelatinized maize starch	Magnesium stearate	Magnesium Stearate,	Opadry white	Methyl hydroxypropyl cellulose	Purified water	Titanium dioxide (E171)		Iron oxide (E172)	
Applied product	Zofran 4mg tab																	
Lactose anhydrous	Lactose																	
Sodium starch glycolate	Microcrystalline Cellulose																	
Crospovidone	Pregelatinized maize starch																	
Magnesium stearate	Magnesium Stearate,																	
Opadry white	Methyl hydroxypropyl cellulose																	
Purified water	Titanium dioxide (E171)																	
	Iron oxide (E172)																	

	- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by USP monograph (dissolution, identification, assay, uniformity of dosage unit). - Provide details of innovator product used during pharmaceutical equivalence study (batch #, mfg, exp)	
3.2.P.5.1	Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco.	
3.2.P.6	Firm has submitted COA of secondary reference standard which has followed Ph. Eu specifications while the applied product follows USP specifications	
3.2.P.8	Submit documents for the procurement of API with approval from DRAP.	

Previous Decision (M-322-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

Section	Observations	Response								
1.6.5	Submit valid GMP certificate of drug substance manufacturer	The firm has submitted valid copy of GMP certificate #DCD/SPL-1/CR-13/2023-24 dated 10-04-2023 of M/s Anugraha Chemicals, D-47, TO D-50 C-62 AND C-63, KSSIDC, Industrial Estate, Doddaballapur, India valid upto one year from the date of issue.								
3.2.S.4	- Copies of the analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required. - Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	- Firm has submitted copy of the analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer - Firm has submitted analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.								
3.2.S.5	Firm has submitted COA of primary reference standard which follows usp specifications and secondary reference standard which has followed Ph. Eu specifications while applied product manufacturer follows bp specifications	M/s. Anugraha Chemicals is manufacturing and supplying Ondansetron Hydrochloride Dihydrate worldwide and complies with both USP specifications and Ph. Eur. specifications depending on the requirements of their customers. They have also provided COA of reference standard which follows Ph. Eur. Specifications.								
3.2.P.2	Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product. <table><tr><td>Applied product</td><td>Zofran 4mg tab</td></tr><tr><td>Lactose anhydrous</td><td>Lactose</td></tr><tr><td>Sodium starch glycolate</td><td>Microcrystalline Cellulose</td></tr><tr><td>Crospovidone</td><td>Pregelatinized maize starch</td></tr></table>	Applied product	Zofran 4mg tab	Lactose anhydrous	Lactose	Sodium starch glycolate	Microcrystalline Cellulose	Crospovidone	Pregelatinized maize starch	- Firm has submitted protocol for drug excipient compatibility study and the report of drug excipient compatibility study. The results show that insignificant variation occurs during compatibility studies. Hence it is concluded that drug is compatible with excipients - Pharmaceutical Equivalence report of Ondansetron Tablets 4mg and comparative dissolution profile studies (CDP) report for our product Ondansetron Tablets 4mg is being attached.
Applied product	Zofran 4mg tab									
Lactose anhydrous	Lactose									
Sodium starch glycolate	Microcrystalline Cellulose									
Crospovidone	Pregelatinized maize starch									

	<table><tr><td>Magnesium stearate</td><td>Magnesium Stearate,</td></tr><tr><td>Opadry white</td><td>Methyl hydroxypropyl cellulose</td></tr><tr><td>Purified water</td><td>Titanium dioxide (E171)</td></tr><tr><td></td><td>Iron oxide (E172)</td></tr></table> - Justification is required as the pharmaceutical equivalence and CDP of higher strength has been submitted - Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by USP monograph (dissolution, identification, assay, uniformity of dosage unit). - Provide details of innovator product used during pharmaceutical equivalence study (batch #, mfg, exp)	Magnesium stearate	Magnesium Stearate,	Opadry white	Methyl hydroxypropyl cellulose	Purified water	Titanium dioxide (E171)		Iron oxide (E172)	- Critical tests recommended by USP monograph e.g. Physical Description, Identification, Disintegration, Assay, Dissolution and Impurities was included in the pharmaceutical equivalence study of Ondansetron Tablets 4mg. Furthermore, Uniformity of dosage units (content uniformity) is an in-process control test and should meet the requirements of Acceptance value at the time of release which is well controlled during release of drug product. The firm has submitted pharmaceutical equivalence report - Firm has provided details of innovator product. Zofran 4mg tablets, Batch Number B83122A, Manufactured by M/s Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany for Novartis Pharma AG, Basle, Switzerland Mfg date; 01-2022, Exp date; 12-2024.
Magnesium stearate	Magnesium Stearate,									
Opadry white	Methyl hydroxypropyl cellulose									
Purified water	Titanium dioxide (E171)									
	Iron oxide (E172)									
3.2.P.5.1	Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco.	The firm submitted that initially at the time of development, we have started the material and product development according to British pharmacopeia monograph. During the development of product, we found that the drug release of both test and reference sample is greater than 85% within 15 minutes in comparison studies while the time limit mentioned in BP was 45 minutes. We switched to more stringent specification for our products and complies with USP specifications which states that “NLT 80% (Q) of the labeled amount of ondansetron is dissolved in 15 minutes”.								
3.2.P.6	Firm has submitted COA of secondary reference standard which has followed Ph. Eu specifications while the applied product follows USP specifications	The firm submitted that initially, at the time of development, we have started the material and product development according to British pharmacopeia monograph which is sync with Ph. Eur. Monograph. Afterwards, we switched to more stringent specification for our products and complies with USP specifications.								
3.2.P.8	Submit documents for the procurement of API with approval from DRAP. The firm submitted that for product development purpose, initially ATCO has arranged Ondansetron drug substance form M/s Anugrha Chemicals, India via our UAE based indenter Pan Golf Sourcing and Trading International on 10-11-2020. This sample was imported by our indenter in Sharja, UAE and then supplied us complementary through courier service. Due to direct courier of material on ATCO premises from Sharja, material was not hold at port for clearance and we forgot to attest the invoice with DRAP ADC.									

	We have used this material for product development and further put the 03 development batches for stability studies up to 6 months on accelerated and real time conditions as per requirement of Zone IV-B. Same stability data as well as material arrangement documents with non-attested invoice were initially submitted with dossier in DRAP. After pre-screening, dossiers were accepted by DRAP and log for further evaluation. At the time of dossier compilation before the submission in DRAP, we have already gauged that non-attested ADC invoice issue can be identified during dossier evaluation. Therefore, we have immediately arranged another lot of Ondansetron drug substance from the same manufacturer i.e. M/s Anugrha Chemicals, India with attested ADC invoice. We have manufactured another 03 development batches with this material and also conducted the stability studies up to 6 months on accelerated and real time conditions as per Zone (IV-B) requirement. At the time of dossier evaluation, Evaluator has advised us to submit the attested ADC invoice and we have submitted the ADC attested invoice of second supply mentioned Ondansetron Batch#AOND-21007. But the BMR and Stability report which was produced with first supply of Ondansetron Batch# AOND-20013 were not replaced in dossier. This is the reason for difference in Batch No. of API between the material invoice and product development documents. Now all tracking record for import of first material (API) dated 10-11-2020 which was imported by our UAE based indenter Pan Golf Sourcing and Trading International form M/s Anugrha Chemicals, India has been arranged from indenter and attached along with CoA and un-attested sale invoice for your kind perusal. Above clarification related to submitted API invoice via letter number 197/Reg/11-2022 dated 3rd November, 2022 (copy with supporting documents enclosed) which was accepted by the Drug Registration Board in its 322nd meeting and we have been granted the drug registration certificate of Ondansetron Tablet 8mg and Ondansetron Syrup 4mg/5ml with brand name Ubkino (copy of meeting minutes and drug registration certificate, enclosed). We would like to state that kindly consider the same justification/explanation regarding procurement of API for Ondansetron Tablet 4mg. Keeping in view the above facts, the firm has requested to consider that we have tried our level best to meet all quality requirements for the development and stability studies of ondansetron tablet. And executed more development work to meet the compliance requirement. We are expecting your favorable response regarding the approval of subject products by ignoring our reluctance regarding the ADC attestation of material invoice and consider the development record and stability studies produced with ondansetron first supply. We assure you that we will be more vigilant in future to meet the compliance as per requirement.
	Previous Decision (M-329th-RB): Deferred for submission of transportation details of API from supplier including courier details
	Firm's Response; This letter addresses the deferral of our Ondansetron 4mg Tablet product, specifically regarding the reasons cited in the 329th and 322nd meetings of the Drug Registration Board (DRB). Our application was initially deferred in the 322nd DRB meeting for "submission of documents for the procurement of API with approval from DRAP." Subsequently, in the 329th meeting, the reason for deferral was "submission of transportation details of API from supplier including courier details." We wish to provide a comprehensive justification and clarify the discrepancies. Background and Clarification:

- **Initial API Procurement (Product Development):**

For initial product development, we procured Ondansetron drug substance (Batch # AOND-20013) from M/s Anugrha Chemicals, India, via our UAE-based indenter, Pan Golf Sourcing and Trading International, on November 10, 2020. This sample was imported by our indenter in Sharjah, UAE, and then supplied to ATCO via courier service. Due to direct courier delivery to our premises, the material was not held at the port for clearance, and consequently, the invoice was not attested by the DRAP Assistant Director Customs (ADC).

- This material was used to manufacture three development batches, which were then placed on stability studies (accelerated and real-time conditions) for up to six months, as per Zone IV-B requirements for both tablet and syrup formulations. The stability data and material arrangement documents, including the non-attested invoice, were part of the initial dossier submitted to DRAP. The dossier was accepted after pre-screening.

Subsequent API Procurement (Addressing Attestation Concern): Recognizing the potential issue with the non-attested invoice, we immediately arranged for a second lot of Ondansetron drug substance (Batch # AOND-21007) from the same manufacturer, M/s Anugrha Chemicals, India, ensuring this time that the invoice was duly attested by the ADC.

- We manufactured an additional three development batches using this second API lot and conducted stability studies for up to six months under accelerated and real-time conditions, adhering to Zone IV-B requirements for both formulations.
- **Discrepancy in Batch Numbers:** During the dossier evaluation, the evaluator requested an attested ADC invoice. We submitted the attested invoice for the second supply (Batch # AOND21007). However, the Batch Manufacturing Records (BMRs) and Stability Reports within the dossier, which were generated using the first API supply (Batch # AOND-20013), were inadvertently not replaced. This led to the observed difference in API batch numbers between the material invoice and the product development documents.
- **Transportation Details:** We have then attached all available tracking records for the import of the first API material (dated November 10, 2020), including the Certificate of Analysis (CoA) and the un-attested sales invoice, from our UAE-based indenter.

Current Situation and Proposed Solution:

Despite our previous detailed justification, the DRB-322 meeting advised us to submit transportation details, which we believe were already provided to the best of our ability given the circumstances of the initial sample procurement.

To definitively address the concerns and ensure full compliance, we have initiated the procurement of a fresh lot of Ondansetron API with attested ADC invoice. We are recently developed new product batches using this material and placed them on stability studies up to six months for both real time and accelerated studies. We intend to submit the comprehensive data generated from these new batches, ensuring complete alignment between the API procurement documents, BMRs, and stability reports. Firm has submitted complete data of new batches (NO460C, NO461C, NO462C.)

We are confident that our diligent efforts demonstrate our commitment to meeting all quality requirements for the development and stability studies of Ondansetron tablets.

We kindly request your favorable consideration for the approval of our product based on the revised stability data. Please include our product in the agenda of upcoming drug registration board meeting for the grant of approval of registration.

Decision. Approved. The Registration Board further decided that the registration letter shall be issued after submission of Half fee of registration as per S.R.O. 1399(I)/2025 dated 01-08-2025 for submission of afresh stability data of drug product.

71.	Name, address of Applicant / Marketing Authorization Holder	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer

		Importer Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9675 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 30-08-2022
	The proposed proprietary name / brand name	Vocinza 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan...10mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
72.	Name, address of Applicant / Marketing Authorization Holder	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9676 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 30-08-2022
	The proposed proprietary name / brand name	Vocinza 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan...20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
Evaluation by PECII:		
Sr.#	Section#	Observation
1	1.5.2	Submitted claim shall be elaborated for the dosage form as “film coated”, as per innovator drug product along with submission of relevant fee.
2	1.5.6	Relevant information shall be submitted for the reference of drug product specifications.
3	1.6.5	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.
4	3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.
5	3.2.S.4.4	COA relevant batch of drug substance, used for manufacturing of drug product stability batches, shall be submitted.
6	3.2.P.1	Justification shall be submitted for not including fumaric acid in the composition of applied product, as used by the innovator drug product.
7	3.2.P.2.2.1	Justification shall be submitted for not including sampling time point of “15

		minutes” in the performance of CDP studies, as recommended by the relevant guidelines.
8	3.2.P.5	- Reference shall be submitted for the adopted dissolution parameters. - Justification shall be submitted that how the “specificity” of the applied method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.
9	3.2.P.8.3	Following shall be submitted: - Compliance Record of HPLC software 21CFR & audit trail reports on product testing. - Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.

Previous Decision (M-339th-RB): Registration Board deferred the applications of Vocinza 10mg Tablet & Vocinza 20mg Tablet for submission of reply of above cited shortcomings.

Firm's Response;

Sr.#	Section#	Observation	Firm's Response
1	1.5.2	Submitted claim shall be elaborated for the dosage form as “film coated”, as per innovator drug product along with submission of relevant fee.	We would like to clarify that our product is Film coated based on information already submitted in relevant sections of CTD. Therefore, we are revising our label claim as per innovator product that is film coated tablet.
2	1.5.6	Relevant information shall be submitted for the reference of drug product specifications.	SRA Status: PMDA approved Company Name: Takeda Pharmaceutical Company Limited Brand Name: Takecab Tablets 20mg, 10mg
3	1.6.5	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	Firm has submitted copy of Guangdong GMP evaluation report issued by Guangdong Pharmaceutical Center for Economic Development valid till 04-05-2026
4	3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.	Drug substance specifications, analytical procedure and analytical method verification studies from drug product manufacturer is submitted. We have performed the fumaric acid test, revised specification and COA attached
5	3.2.S.4.4	COA relevant batch of drug substance, used for manufacturing of drug product stability batches, shall be submitted.	COA relevant batch of drug substance, used for manufacturing of drug product stability batches, is submitted.
6	3.2.P.1	Justification shall be submitted for not including fumaric acid in the composition of applied product, as used by the innovator drug product.	1) The above mentioned products itself contains fumaric acid in form of fumarate (Vonoprazan Fumarate). Fumaric acid has already been included in the synthesis of API. (2) In formulation effervescent tablets, it is used as lubricant but our products contains Magnesium stearate as lubricant replacing the need of fumaric

			acid externally. (3) WHO has stated the establishment of Fumaric Acid or its salt was unnecessary since it is normal constituent of body tissue and also as food additives in 3600ppm. (4) The said product first appeared in Japan (2014) that comparison of CDP at all stages using (TAKECAB tablet) as a reference product and no reasonable differences in product performance was noticed. (5) As per FDA guidelines, generic product may differ in shape, size, packaging and excipients. (6) The product in question is qualitatively almost same to (TAKECAB tablet of Japan)
7	3.2.P.2.2.1	Justification shall be submitted for not including sampling time point of “15 minutes” in the performance of CDP studies, as recommended by the relevant guidelines.	The above product falls under BCS class III. CDP of both products (reference and test) found to be $\geq 85\%$ even at sampling points of 10 minutes. So, as per observed trend we can assume the release, which will found to be $\geq 85\%$ in the sampling point of 15 minutes. Even FDA did not provide sampling for multiple points study. The graph of all 3 pH attached which shows release of $\geq 85\%$ at sampling point of 15 minutes
8	3.2.P.5	- Reference shall be submitted for the adopted dissolution parameters. - Justification shall be submitted that how the “specificity” of the applied method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.	a) Dissolution information is not available in any reference regulatory authority or in published literature nor in the drug product pharmacopoeia at the time of development. Any (i) 6.8 pH Phosphate buffer is used as dissolution medium as the drug substance is found to be highly soluble in all physiological pH ranges i.e. pH 1.2, 4.5 and 6.8 (BCS III). Usually SRA (Stringent Regulatory Authority), FDA or EMA provide dissolution medium, apparatus and both single and multiple time point in dissolution study via literature reference. (ii) USP type II apparatus and 900mL is used as per USP chapter 1092. 50 rpm as lowest rpm for paddle apparatus. (iii) As the product is soluble in all three physiological pH, we have selected 6.8 pH, apparatus (II) paddle, 50 rpm and time point 30 minutes. We

			hereby, commit to change the dissolution parameter to achieve Q within 15 minutes at the time of commercialization of product. (b) We had performed method validation according to ICH guidelines which did not specify peak purity test in specificity parameter but to fully resolve this query we provided the chromatogram with peak purity results which shows that there is only one component present (Chromatogram is attached)
9	3.2.P.8.3	Following shall be submitted: • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.	• Audit trial report is submitted • Raw datasheet and chromatograms of dissolution test of only one batch at 3rd month time point real time conditions is submitted

Decision; Deferred for submission of following;

- **Justification for not including fumaric acid in the composition of applied product, as used by the innovator drug product.**
- **Performance of dissolution test as per the specifications of innovator's product**
- **Compliance Record of HPLC software 21CFR**
- **Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.**

73.	Name and address of manufacturer/ Applicant	M/s Crown Pharmaceuticals, Plot No. 286 kahuta Industrial Triangle Kahuta Road Islamabad. (DML No. 000456) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	Everon 0.25mg Tablets
	Composition	Each Tablet Contains; Everolimus.....0.25mg
	Diary No. Date of R & I & fee	Dy.No. 14712 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0550983, dated 07.03.2019 endorsed on 07.03.2019
	Pharmacological Group	Selective immunosuppressants ATC Code: L04AA18
	Form-5	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	60's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Certican® 0.25 mg tablets & 0.75mg Tablets MHRA Approved.
	Me-too status	Certican 0.25mg Tablets Reg. No. 044829 (imported) M/s Novartis Pharma Karachi.
	GMP status	Last inspection conducted on 03.08.2016.
	Remarks of the Evaluator	i. Latest GMP inspection report/ certificate required.

		ii. Reference of finished product specification is not mentioned. iii. The same active has ATC code L01EG02 as protein kinase inhibitor (anti-cancer). Section approval for such products is required.
	Previous Decision (M-324 th -RB dated 24 th to 26 th January 2023)	Deferred for submission of evidence of approval of required manufacturing facility i.e., Tablet (Oncology) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5F, within six months.
	Firm's Response Firm has submitted response vide general request form tracking ID#2XX-4L7-AGD5 as; On behalf of Crown Pharmaceuticals, we respectfully request the grant of registration for Everolimus 0.25 mg and 0.75 mg tablets to be manufactured in the General Tablet Section, based on DRB precedent, therapeutic indication, dosage strength, and international regulatory classification. It is submitted that the Drug Registration Board (DRB) in its 293rd meeting held from 6–8 January 2020 has already approved Everolimus 0.25 mg and 0.75 mg, recognizing these strengths under the immunosuppressant class. This establishes a clear local regulatory precedent that low-dose Everolimus is not categorized as an anti-cancer product. Internationally, Everolimus is a dose- and indication-dependent molecule. As per US FDA–approved labeling, Everolimus 0.25 mg and 0.75 mg tablets (Zortress®) are indicated exclusively for prophylaxis of organ rejection in transplant patients and are classified as immunosuppressants. In contrast, higher strengths (2.5 mg, 5 mg, 10 mg and above) marketed as Afinitor® are approved for oncology indications and are regulated as antineoplastic (anti-cancer) agents (details provided in Annexure-I). Similarly, EMA SmPCs maintain two distinct regulatory pathways: Certican® (0.25mg & 0.75mg) – Immunosuppressant Afinitor® (≥2.5 mg) – Antineoplastic agent This global regulatory practice confirms that only higher-strength Everolimus intended for oncology requires manufacturing in a dedicated anti-cancer tablet section, whereas lower immunosuppressant strengths do not present the same cytotoxic occupational exposure risk and are manufactured in standard oral solid dosage GMP areas. Furthermore, international practice supports different brand names for low-dose immunosuppressant Everolimus and high-dose oncological Everolimus, solely to distinguish therapeutic classes, prevent medication errors, and ensure pharmacovigilance clarity, despite the molecule being identical. In view of: DRB approval in the 293rd meeting, FDA and EMA strength-based therapeutic classification, and International GMP and occupational safety principles, we humbly request DRAP to kindly grant registration of Everolimus 0.25 mg & 0.75 mg tablets under the General Tablet Section for Crown Pharmaceuticals. We assure full compliance with DRAP GMP, quality, and pharmacovigilance requirements. Firm has also not submitted DRAP R&I received on or before 31-12-2024 Decision: Rejected, as the firm failed to submit the reply within six months, as per the decision of the Registration Board	
74.	Name and address of manufacturer/ Applicant	M/s Crown Pharmaceuticals, Plot No. 286 kahuta Industrial Triangle Kahuta Road Islamabad. (DML No. 000456) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	Everon 0.75mg Tablets
	Composition	Each Tablet Contains; Everolimus.....0.75mg

Diary No. Date of R & I & fee	Dy.No. 14713 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0550984, dated 07.03.2019 endorsed on 07.03.2019
Pharmacological Group	Selective immunosuppressants ATC Code: L04AA18
Form-5	Form-5
Finished product Specification	Not mentioned
Pack size & Demanded Price	60's. As per SRO.
Approval status of product in Reference Regulatory Authorities	Certican® 0.25 mg tablets & 0.75mg Tablets MHRA Approved.
Me-too status	Certican 0.75mg Tablets Reg. No. 044830 (imported) M/s Novartis Pharma Karachi.
GMP status	Last inspection conducted on 03.08.2016.
Remarks of the Evaluator	i. Latest GMP inspection report/ certificate required. ii. Reference of finished product specification is not mentioned. iii. The same active has ATC code L01EG02 as protein kinase inhibitor (anti-cancer). Section approval for such products is required.
Previous Decision (M-324 th -RB dated 24 th to 26 th January 2023)	Deferred for submission of evidence of approval of required manufacturing facility i.e., Tablet (Oncology) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5F, within six months.
Firm's Response Firm has submitted response vide general request form tracking ID#2XX-4L7-AGD5 as; On behalf of Crown Pharmaceuticals, we respectfully request the grant of registration for Everolimus 0.25 mg and 0.75 mg tablets to be manufactured in the General Tablet Section, based on DRB precedent, therapeutic indication, dosage strength, and international regulatory classification. It is submitted that the Drug Registration Board (DRB) in its 293rd meeting held from 6–8 January 2020 has already approved Everolimus 0.25 mg and 0.75 mg, recognizing these strengths under the immunosuppressant class. This establishes a clear local regulatory precedent that low-dose Everolimus is not categorized as an anti-cancer product. Internationally, Everolimus is a dose- and indication-dependent molecule. As per US FDA–approved labeling, Everolimus 0.25 mg and 0.75 mg tablets (Zortress®) are indicated exclusively for prophylaxis of organ rejection in transplant patients and are classified as immunosuppressants. In contrast, higher strengths (2.5 mg, 5 mg, 10 mg and above) marketed as Afinitor® are approved for oncology indications and are regulated as antineoplastic (anti-cancer) agents (details provided in Annexure-I). Similarly, EMA SmPCs maintain two distinct regulatory pathways: Certican® (0.25mg & 0.75mg) – Immunosuppressant Afinitor® (≥2.5 mg) – Antineoplastic agent This global regulatory practice confirms that only higher-strength Everolimus intended for oncology requires manufacturing in a dedicated anti-cancer tablet section, whereas lower immunosuppressant strengths do not present the same cytotoxic occupational exposure risk and are manufactured in standard oral solid dosage GMP areas. Furthermore, international practice supports different brand names for low-dose immunosuppressant Everolimus and high-dose oncological Everolimus, solely to distinguish therapeutic classes, prevent medication errors, and ensure pharmacovigilance clarity, despite the molecule being identical.	

	In view of: DRB approval in the 293rd meeting, FDA and EMA strength-based therapeutic classification, and International GMP and occupational safety principles, we humbly request DRAP to kindly grant registration of Everolimus 0.25 mg & 0.75 mg tablets under the General Tablet Section for Crown Pharmaceuticals. We assure full compliance with DRAP GMP, quality, and pharmacovigilance requirements. Firm has also not submitted DRAP R&I received on or before 31-12-2024 Decision: Rejected, as the firm failed to submit the reply within six months, as per the decision of the Registration Board	
75.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 10mg
	Decision: Duplicate case deleted, as the same has already been discussed in main agenda serial number 17	
76.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 2.5mg
	Decision: Duplicate case deleted, as the same has already been discussed in main agenda serial number 18	

Farooq Aslam

Deferred cases of Form 5F:

77.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27473 dated 23-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	Ersita 15/100 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglyutamic Acid... 15mg Sitagliptin as Phosphate Monohydrate... 100mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Trevia R2 of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Decision of 343rd meeting:

Deferred for submission of reply to above cited shortcomings.

The firm has submitted the reply through G.R. No. V8W-HXG-J9TY.

Sr.#	Observations	Firm's reply
1.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	The firm has submitted Form 6 dated 03-10-2022 for Ertugliflozin (0.1Kg) along unattested invoice No. HHSC-220906-1 dated 22-09-2022. For sitagliptin, the firm has submitted Form 5 dated 15-08-2018 along with unattested invoice No. HN191128-F dated 28-11-2019.
2.	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted. Batches: ES-04, ES-05, ES-06 (Batch size: 1200 tablets)
3.	Analytical record i.e., Chromatograms, raw data sheets & COAs for the drug product stability studies shall be submitted.	Submitted.

Decision: Deferred for submission of documents confirming procurement of Sitagliptin.

78.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27576 dated 24-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	Ersita 5/100 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyrogutamic Acid...5mg Sitagliptin as Phosphate Monohydrate...100mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Trevia R2 of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Decision of 343rd meeting:

Deferred for submission of reply to above cited shortcomings.

The firm has submitted the reply through G.R. No. V8W-HXG-J9TY.

Sr.#	Observations	Firm's reply
1.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	The firm has submitted Form 6 dated 03-10-2022 for Ertugliflozin (0.1Kg) along unattested invoice No. HHSC-220906-1 dated 22-09-2022. For sitagliptin, the firm has submitted Form 5 dated 15-08-2018 along with unattested invoice No. HN191128-F dated 28-11-2019.
2.	Complete batch manufacturing record of drug product stability batches shall be submitted	Submitted. Batches: ES-01, ES-02, ES03 (Batch size: 1200 tablets)
3.	Analytical record i.e., Chromatograms, raw data sheets & COAs for the drug product stability studies shall be submitted.	Submitted.

Decision: Deferred for submission of documents confirming procurement of Sitagliptin.

79.	Name, address of Applicant / Marketing Authorization Holder	M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar.
	Name, address of Manufacturing site.	M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar. (DML No. 000216)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22059: 07.09.2023
	Details of fee submitted	PKR 30,000/- : 303729367277
	The proposed proprietary name / brand name	I-CARE 10mg/ml Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains; Tropicamide.....10mg
	Pharmacotherapeutic Group of (API)	Anticholinergics ATC Code: S01FA06
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MINIMS TROPICAMIDE 1%W/V MHRA Approved.
	For generic drugs (me-too status)	Mydromide Ophthalmic solution M/s Remington
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Decision of 343rd meeting:

The case was deferred for submission of Reply of above mentioned deficiencies. The firm has submitted the reply through G.R. ID No. R1M-281-53M2

Sr. No.	Section	Observation	Reply
1.	-	GMP certificate of drug substance manufacturer is required.	GMP certificate No. 6126196 valid till 25-03-2026 is submitted. Correct address as per DML and GMP Certificate:

			M/s Polyfine Chempharma, 51-Hayatabad Industrial Estate, Peshawar
2.	-	GMP Certificate of drug product manufacturer is required.	GMP certificate issued on the basis of inspection conducted on 26-05-2023.
3.	3.2.S.4	Analytical method verification studies data for drug substance performed by drug product manufacturer is required. (along with chromatograms)	AMV studies are submitted without chromatograms.
4.	3.2.P.1	Please justify use of Benzalkonium Chloride in light of innovator product formulation. Further also justify 2% NaCl in formulation, how is it making it isotonic as claimed in 3.2.P.1	1. Innovator Reference (Mydriacyl eye drops®): The innovator product, Mydriacyl ® 1%, developed by ALCON LABORATORIES INC and approved by the U.S. FDA, contains Benzalkonium Chloride 0.01% w/v as a preservative. 2. Regulatory and Scientific Justification: Benzalkonium Chloride is a USP-recognized antimicrobial preservative that is effective and commonly used in ophthalmic preparations to prevent microbial contamination in multi-dose containers. Its inclusion in our formulation at the same concentration (0.01%) ensures alignment with the innovator in both qualitative and quantitative composition of excipients. 3. Preservative Effectiveness Testing (PET): The formulation has been evaluated for antimicrobial effectiveness per USP, and the results confirm compliance with acceptance criteria. With reference to your query regarding the sodium chloride concentration mentioned in Section 3.2.P.1 of the submitted CTD, we would like to clarify that the stated concentration of 2% w/v NaCl was a typographical error. The correct concentration used in the formulation is 0.9% w/v, which is intended to render the ophthalmic solution isotonic with lacrimal fluid.
5.	3.2.P.8	Copies of BMR of trial batches are required.	Submitted.
6.	3.2.P.8	Please submit water loss studies data performed with stability studies. (as container is of plastic)	Submitted
The board was informed that deficiencies have been communicated to the firm and reply is awaited			
Decision: Approved. The firm shall submit chromatograms for submitted AMV studies and applicable fee for correction of title and address of the firm as per submitted DML.			

80.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8636 Dated 04-04-2022
	Details of fee submitted	PKR 30,000/- Dated 25-01-2022
	The proposed proprietary name / brand name	ALDROX 250mg/5ml Dry powder for Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefadroxil as monohydrate... ..250mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, First-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by UK MHRA
	For generic drugs (me-too status)	Duricef 250mg /5mL Oral Suspension of Glaxo Smith Kline Pakistan Limited. (Reg # 010057)
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Limited., Address: Kot nabi Buksh wala, 34-Km, Ferozpur Road, Lahore.

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Cefadroxil as Monohydrate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 30°C±2°C/ 65% ± 5% RH for 36 months Accelerated: 40°C±2°C/75% ± 5% RH for 6 months Batches: (00221/001, 00221/002, 00221/003)
Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product of Helicef 250mg/5ml dry suspension (Batch #) by Pharma Pakistan Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Loxadril 500mg capsule in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited., Address: Kot nabi Bukshwala, 34-Km, Ferozpur Road, Lahore.
API Lot No.	00243 / 160 / 2021

Description of Pack (Container closure system)	60 ml HDPE Amber coloured bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	14-06-2021	14-06-2021	14-06-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Pharmagen limited, Lahore issued by Additional Director, Drug Regulatory Authority of Pakistan, Lahore. It is valid till 07-01-2022.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that our current HPLC system is not 21 CFR compliant, please accept our submitted dossier, we will try to upgrade our system as soon as possible.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks OF Evaluator:			
Sr.#	Section	Observation	Response of firm
1.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer	Copies of the Drug substance specifications and analytical procedures used for routine testing of the drug substance /Active Pharmaceutical

		are required.	Ingredient by both Drug substance & Drug Product manufacturer have been submitted.
2.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer have been submitted.
3.	3.2.S.4.4	•The submitted COA of drug substance manufacturer is of Cefadroxil as monohydrate while identification shows Cefixime reference standard. Moreover, text editing in the COA is evident which is creating doubt. •The limits of water contents of drug substance are different from USP monograph. •The tests of optical rotation, crystallinity are not performed by drug substance manufacturer as recommended by Pharmacopoeia.	•As per firm Mistakenly the COA of Cefixime compacted was submitted. However, in provided COA limits/tests are not in accordance with USP monograph
4.	3.2.S.4.5	This section mentions that cefixime is a pharmacopoeial product. Clarification is required.	As per firm Due to a typographic mistake cefixime is written instead of cefadroxil.
5.	3.2.S.5	Provide COAs of reference standards used in the analysis of drug substance including source and lot number.	Firm has provided working standard COA of Batch no.: 002200/06/2021.
6.	3.2.P.1	•Submit master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cefadroxil monohydrate. •List all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications).	•Firm has Submitted master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cefadroxil monohydrate.
7.	3.2.P.2.2.1	•Justify why pharmaceutical equivalence studies have not been performed against innovator product (Duricef). •Justify the addition of tests of optical rotation, weight variation, loss on drying, clarity and sterility in pharmaceutical equivalence studies since these tests are not recommended by pharmacopoeia. •The limit of pH mentioned is not as per recommendation of pharmacopoeia.	•Due to un availability of innovator pack. •Firm has stated that mistakenly these tests were included in this section. Firm has submitted revised specifications.

8.	3.2.P.3	A batch formula for proposed commercial batch size shall be provided that includes a	Submitted

		list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	
9.	3.2.P.5.1	The submitted specification does not include test for dissolution, uniformity of dosage units, deliverable volume, water determination as recommended by USP. Moreover, justify the addition of tests of pH, loss on drying, weight variation, BET and sterility test in the specifications of Cefadroxil suspension.	The firm has revised the specifications as per Pharmacopoeia. However, fee for such revision has not been submitted.
10.	3.2.P.5.2	Submit analytical procedures of Cefadroxil suspension stating actual concentrations of sample and standard instead of submitting USP monograph.	Submitted.
11.	3.2.P.5.3	- Provide standard and sample preparation methods used in analytical method verification studies. - Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 100% and 120% solutions.	Submitted
12.	3.2.P.6	Provide COA of reference standard used in the analysis of drug product including source and lot number.	Firm has submitted Cefdroxil micronized working standard . lot no. 002200/06/2021.

13.	3.2.P.8	• The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by pharmacopoeia. • The limit used for the test of pH in stability studies of cefadroxil suspension is not as per USP monograph. • Clarification regarding Batch size is required since you have mentioned as 1000 dry suspensions which is not correct. • Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. • Submit copy of invoice for evidence of purchase of drug substance used in the development of analysis of each batch of drug product. • Provide copy of Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is	• Not submitted. • Firm has provided commercial invoice specifying the purchase of cefadroxil (micronized and compacted, 25 kg each), dated 29-04-2021 • BMR has been submitted.

		provided in Module 3 section 3.2.P.8.3. • The submitted copy of GMP certificate of drug substance manufacturer is not valid. Provide updated copy of GMP certificate. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted copy of GMP certificate of M/s Pharmagen limited, Lahore issued by Additional Director, Drug Regulatory Authority of Pakistan, Lahore. It is valid till 07-01-2022 No provided.

Decision of 322nd meeting:

Deferred the case for following submissions:

- COA from drug substance and drug product manufacturer in accordance with pharmacopoeia.
- Submit the valid copy of GMP Certificate of Drug substance manufacturer.
- Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets involving the performance of all pharmacopoeial tests.
- Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Reply by the firm:

The firm has submitted the reply through G.R. No. 5EE-GUA-1EQM.

1.. COA of Cefadroxil Micronized is submitted.

2. GMP certificate of drug substance manufacturer issued on the basis of inspection conducted on 18-11-2022.

3. 06 months real time and 06 month accelerated stability studies have been submitted along with chromatograms and raw data sheets.

4. The firm has not submitted any fee.

Decision: Approved. The firm shall submit applicable fee for revision of specifications.

81.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglw Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglw Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5859 Dated 03-03-2022
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022
	The proposed proprietary name / brand name	PENSEF 250mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephadrine as monohydrate... 250mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, First-generation cephalosporins.
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x12's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefracare 250mg capsule USFDA Approved.
	For generic drugs (me-too status)	Velosef 250 mg Capsule of M/s GSK
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.

Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Cephadrine as Monohydrate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G &

	related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 5°C ± 3°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% RH for 6 months Batches: (32051704109, 32051704110, 32051704111)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the brand leader that is Velosef 250 mg Capsule (Batch # 646D5G) by Glaxosmithkline Pakistan Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Velosef 250 mg Capsule by Glaxosmithkline Pakistan Limited in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API		M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.	
API Lot No.		00203-08/110/2021	
Description of Pack (Container closure system)		Blister pack of 2x6's, Printed Unit Carton, Product Insert	
Stability Condition	Storage	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	004	005	006
Batch Size	10000 Capsules	10000 Capsules	10000 Capsules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation		14-06-2021	14-06-2021
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice (2021042801) specifying purchase of Cephadrine compacted (100kg, Batch # 32052010034) attested by Assistant Director (I &E), Peshawar dated 18-05-2021.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator:			

Sr.#	Section	Observation	Response of firm
1.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/ Active pharmaceutical ingredient by both drug substance & drug product manufacturer is required.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/ Active pharmaceutical ingredient by both drug substance & drug product manufacturer have been submitted
2.	3.2.S.4.3	Analytical method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Analytical method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug product manufacturer have been submitted
3.	3.2.S.4.4	The Submitted COA of Drug substance and drug product manufacturer does not include contents of cephalixin as recommended by USP (NMT 5.0%) The submitted COA from drug product manufacturer is not readable. Provide readable copy of COA.	Firm has stated that in the testing of Raw material the peak of Cephalixin is also present in the chromatogram, so the results of cephalixin can be calculated from Chromatogram. COA of batch no. 32052010034 has been submitted.

4.	3.2.S.5	Provide COA of reference standards for both cephradine and cephalixin which is actually used in the analysis of drug substance including source and lot number.	Firm has provided in house working standard COA of Cephradine compacted of batch no. 32052010034
5.	3.2.S.7	The details of batches of stability study data of drug substance in module 3 are different from the batches provided in module 2.	Firm has submitted following batches(32051704109, 32051704112, 32051704111)
6.	3.2.P.1	Submit master formulation including theoretical fill weight per bottle along with details of equivalency factor for cephradine. List all components of the dosage form , and their amount on a per unit basis (including overages, if any), the function of the components , and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications).	Submitted
7.	3.2.P.2.2.1	Justify how same results are obtained for Pharmaceutical equivalence and CDP studies for both Cephradine 250mg and 500mg Capsule.	CDP of both strengths are different. In dossier while compiling same CDP was attached for both strengths.

8.	3.2.P.2.2.4	Justify why the tests of reconstitution time, clarity and colour after reconstitution are included in this section. Moreover , flow chart of manufacturing also showed the process for dry powder for suspension.	Both reconstitution test and test for clarity of solution are for ceftriaxone injection, while drafting these test appeared in these section.
9.	3.2.P.3	A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	submitted
10.	3.2.P.5.1	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. The assay limits mentioned in specifications are 90%-102% which are different from USP specifications (90%-125%)	Firm has submitted revised specifications. However requisite fee for change in specifications has not been submitted.
11.	3.2.P.5.2	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	Submitted

12.	3.2.P.5.3	Provide standard and sample preparation method used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 1005 and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies while applied formulation is cephradine Capsules. The peak area of standard solution concentration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concentration in stability studies is 585429. Clarify the difference in Peak areas.	Submitted The mistake occurred while compiling the empazin tablet dossier and pansef sapsule dossier. The actual area is near about 585429 approx. The are differences because of different in injection volume. The method was verified with actual injection volume.

13.	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided in house working standard COA of Cephadrine compacted of batch no. 32052010034
14.	3.2.P.8	- The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by Pharmacopoeia. - Justify the addition of test of pH in stability studies of Cefadroxil capsule which is not present in USP monograph applied product. - Provide raw data sheets to justify the calculation of results for assay testing at each time point during the the stability testing of each batch.	The dissolution test was performed at each interval of accelerated and real time stability study. USP dissolution parameter were adopted and all the results were found within the specified limit. Firm has not provided revised stability data sheets. pH test was performed as an internal test. The pH test was performed by same method as that of cephradine raw material. Raw data sheets submitted but chromatograms have not been submitted.

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

Decision of 322nd meeting:
 Deferred the case for following submissions:

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

Reply by the firm:
 The firm has submitted the reply through G.R. No. D2Q-JY5-NNRP.

1.. The correct batch number and other details are:
 Batches: 001, 002, 003 (the batch numbers mentioned above are of Pensef 500mg capsules)
 Batch size: 10,000 capsules
 Date of manufacturing: 28-05-2021
 Stability data is submitted including 06 months real time and 06 months accelerated.

2. GMP certificate of drug substance manufacturer issued on the basis of inspection conducted on 18-11-2022.

3. The firm has not submitted any fee.

Decision: Approved. The firm shall submit applicable fee for revision of specifications.

82.	Name, address of Authorization Holder	Applicant	/ Marketing	M/s Alpenglw Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan	
	Name, address of Manufacturing site.			M/s Alpenglw Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan	
	Status of the applicant			☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application			☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product			☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission			Dy. No.5858	Dated 03-03-2022
	Details of fee submitted			PKR 30,000/-:	Dated 25/01/2022
	The proposed proprietary name / brand name			PENSEF 250mg/5ml Dry powder for Suspension	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit			Each 5ml contains: Cephadrine as monohydrate.....250mg	
	Pharmaceutical form of applied drug			Dry powder for suspension	
	Pharmacotherapeutic Group of (API)			Antibacterials for systemic use, First-generation cephalosporins.	
	Reference to Finished product specifications			USP	
	Proposed Pack size			1x12's	
	Proposed unit price			As per SRO	

	The status in reference regulatory authorities	ANSPOR 250mg/5ML Powder for Suspension USFDA Approved.

For generic drugs (me-too status)	Velosef 250MG/5ML Suspension
GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Cephadrine as Monohydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (32052010037, 32052010038, 32052010039)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	N/A.

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.	

API Lot No.	32052010034		
Description of Pack (Container closure system)	60ml HDPE Bottle with embossed board unit carton UV coated.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	1000 Bottle	1000 Bottle	1000 Bottle
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	28-05-2021	28-05-2021	28-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. #	Section	Observation	Response of firm
1.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are required.	Firm has submitted USP specifications and Monograph
2.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision)	Firm has submitted Method Verification studies report encompassing system suitability,

		performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Accuracy and recovery, Repeatability, intermediate precision and specificity.
3.	3.2.S.4.4	- The submitted COAs from both drug substance and drug product manufacturer shows that the material used is of compacted nature. Justify the type of drug substance used in cephradine suspension since the same is used in Capsule dosage form. - Provide readable copy of COA performed by M/s Alpenglow Pharmaceuticals.	Firm has submitted that Mistakenly the COA of compacted was submitted. The material used in dry suspension is of micronized nature. Firm has submitted COA
4.	3.2.S.5	Provide COA of reference standard which is actually used in the analysis of drug substance alongwith source and lot no.	Firm has submitted COA of in-house working standard for Cephradine (micronized) no. 0023/110/2021,
5.	3.2.P.1	Submit master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cephradine monohydrate.	Master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cephradine monohydrate submitted.
6.	3.2.P.2.2.1	- Details of applicant and reference product used in pharmaceutical equivalence are required. - Submit data of compatibility studies of the drug product with recommended diluent in section 3.2.P.2.6. - Justify the performance of pharmaceutical equivalence studies with Velosef 250mg / 5ml IV Dry powder injection while applied formulation is dry powder for suspension. Justify why drug release studies / comparative dissolution studies were not performed to justify your formulation development process.	- Firm has submitted Pharmaceutical equivalence studies against VELOSEF 250 mg mg/5ml powder for suspension - Firm has submitted that compatibility studies involving the reconstitution of Cephradine 250 mg/5ml dry suspension using purified water was performed. - The Pharmaceutical equivalence studies were performed with velosef dry powder for suspension. This is typographic mistake that velosef injection is mentioned. - As the cephradine suspension is formulated as per USP specifications, and USP does not define the test for dissolution of product nor FDA suggests, so the dissolution is not considered in specification of finished product. However, in the process of

			pharmaceutical development comparative dissolution was performed in three different medium under in-house set parameters.
7.	3.2.P.5.1	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. • The assay limits mentioned in specifications are 90% -102% which are different from USP specifications (90%-125%).	• Firm has provided Revised specifications of finished product. <i>However, fee for specification revision has not been provided.</i> • This is a typographic mistake. Actual limit is 90.0% -125.0%
8.	3.2.P.5.2	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	• Submitted
9.	3.2.P.5.3	• Provide standard and sample preparation methods used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy test including the details of concentration of 80%, 100% and 120% solutions.	• submitted
10.	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	• Firm has provided COA of in house working standard of batch no. 0023/110/2021.
11.	3.2.P.8	• The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by pharmacopoeia. • Justify the addition of test of pH in stability studies of cephadrine capsule which is not present in USP monograph of applied product. • Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. • Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of drug product. Submit compliance Record of HPLC software 21CFR & audit trail reports on	• The firm has submitted only raw data sheets at different testing time points. However, other information has not been provided.

		product testing.	

Decision of 322nd meeting:

Deferred the case for following submissions:

- Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.
- Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of drug product.
- Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Reply by the firm:

The firm has submitted the reply through G.R. No. VTJ-GAZ-Q4GY.

1.. The firm has submitted stability summary sheets mentioning the required tests along with raw data sheets and chromatograms. 06 months real time and 06 months accelerated stability data is submitted.

2. Invoice from M/s Pharmagen is submitted.

3. GMP certificate of drug substance manufacturer issued on the basis of inspection conducted on 18-11-2022.

4. The firm has not submitted any fee.

Decision: Approved. The firm shall submit applicable fee for revision of specifications.

83.	Name, address of Applicant / Marketing Authorization Holder	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22787 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 85121070440 dated 05-09-2023.
	The proposed proprietary name / brand name	Candeza 8mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Candesartan Cilexetil..... 8mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Blockers (Arbs), Plain ATC Code: C09CA06.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Candesartan Cilexetil 8 mg Tablets, MHRA Approved.
	For generic drugs (me-too status)	Miscand 8mg Tablet, Mission Pharma, Reg. No. 081603.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm

1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	DML No. 000610 issued w.e.f. 13-04-2022.
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	Tablet General is approved.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	1*14's
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	DML No. 20000311 valid till 05-11-2029. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9YWRiZmE5YzhkMGY2NTViYjQ0ZmFkMGUyYzZlOTgyNTEmaXRlbUlkPWZmODM4MDgxOGI2NGIyNDlwMThiN2ZhMjllYjgwYWRj
5.	2.3	- Copies of executed BMR's shall be submitted along with one copy of blank production document. - Table for literature references with correct information regarding both drug substance and drug product with applicable fee shall be submitted.	Submitted Batches: CS-01, CS-02, CS-03 (Batch size: 1200 tablets) Submitted. The firm has not submitted any fee.
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted
7.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.4	Assay limit in COA are different from that in the specification provided by the drug substance manufacturer. Clarification shall be submitted.	<i>The Limits of COA are according to European Pharmacopeia, and the DMF data was of 2007 when Candesartan was not added in European Pharmacopeia. Updated Data Specification and Stability Data sheets have been attached along with. Updated COA as per compendia is submitted.</i>
9.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted.	Working standard b.No. STD12-020R.
10.	3.2.S.7	Assay limit in stability data sheets i.e. 98% - 102% and loss on drying limits both are changed from that provided in specifications (98.7% - 101%). Clarification shall be submitted.	<i>The Limits of COA are according to European Pharmacopeia, and the DMF data was of 2007 when Candesartan was not added in European Pharmacopeia. Updated Data Specification and Stability Data</i>

			<i>sheets have been attached along with.</i> The firm has submitted 06 months accelerated and 36 months real time stability data of new batches wherein the limits are 99-101%.
11.	3.2.P.2.2.1	Complete CDP studies with each time point dissolution of both reference and test product with analytical record shall be submitted.	CDP report is submitted against the comparator's product i.. Advant 8mg tablet by M/s Getz Pharma.
12.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph.	<i>The UDU test was performed but mistakenly not mentioned in test specification report.</i>
13.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted.	Submitted.
14.	3.2.P.5.3	Method verification studies submitted are for drug substance. Clarification shall be submitted.	AMV study report is submitted.
15.	3.2.P.8	- Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. - Complete six month stability studies shall be submitted. - Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.8mg/ml while raw data sheets has 0.05mg/ml. - USP monograph has mentioned 10µl injection volume while submitted chromatograms has 20µl. clarification shall be submitted. - USP monograph has mentioned Run time of NLT 2.7 times the retention time of candesartan Cilexetil while submitted chromatograms have shown retention time of 7.4 minutes and run time of 9 minutes. Clarification shall be submitted. - Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.	(i) Six month Stability summary sheets are attached including API lot no. used in stability study. (ii) <i>The concentration of Candesartan Cilexetil used in for the analysis of drug product was 0.8mg/ml as mentioned in SAP while in the raw data sheets is 0.05mg/ml is typographic mistake.</i> (iii) In 10µl peak response was not enough to comply the system suitability therefor injection volume changed to 20µl (iv) There is no peak emerging after the main peak, also no interference from the placebo or blank is observed. (v) Raw data sheets of assay and dissolution as per calculation formula is attached. (vi) The whole stability study performed at wavelength for Assay and dissolution (282, 254) as mentioned in SAP, on Empower-2 software which does not have the option of wavelength during printing of chromatogram.

		- Chromatograms also does not reveal any wavelength. Clarification shall be submitted. - Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	v) The firm has not submitted record of HPLC software 21FR. However, report of configuration for electronic record of the HPLC software used i.e Empower 2. vi) Record of digital data logger is submitted

Decision: Deferred for the following points:

- Submission of Chromatograms for submitted AMV studies for drug substance performed by drug product manufacturer.
- Scientific justification for not selecting the injection volume as recommended by USP with supporting data.
- Scientific justification for not selecting the run time as recommended by USP with supporting data.
- Submission of audit trail report of HPLC software for stability studies.

84.	Name, address of Applicant / Marketing Authorization Holder	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22786 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 26175772757 dated 05-09-2023.
	The proposed proprietary name / brand name	Candeza 16mg Tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Candesartan Cilexetil..... 16mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Blockers (Arbs), Plain ATC Code: C09CA06.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Candesartan Cilexetil 16 mg Tablets, MHRA Approved.
	For generic drugs (me-too status)	Miscand 16mg Tablet, Mission Pharma, Reg. No. 081602.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Decision of 343rd meeting:

The Board deferred the case for submission of the reply mentioned below.

The firm has submitted the reply through G.R. No. QUB-72J-1E92.

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	DML No. 000610 issued w.e.f. 13-04-2022.

2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	Tablet General is approved.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	1*14's
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	DML No. 20000311 valid till 05-11-2029. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9YWRiZmE5YzhkMGY2NTViYjQ0ZmFkMGUyYzZlOTgyNTEmaXRlbUlKZWZmODQ4MDgxOGI2NGIyNDEwMTIhN2ZhMjllYjgwYWRj
5.	2.3	- Copies of executed BMR's shall be submitted along with one copy of blank production document. - Table for literature references with correct information regarding both drug substance and drug product with applicable fee shall be submitted.	Submitted Batches: CS-04, CS-05, CS-06 (Batch size: 1200 tablets) Submitted. The firm has not submitted any fee.
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted
7.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.4	Assay limit in COA are different from that in the specification provided by the drug substance manufacturer. Clarification shall be submitted.	<i>The Limits of COA are according to European Pharmacopeia, and the DMF data was of 2007 when Candesartan was not added in European Pharmacopeia. Updated Data Specification and Stability Data sheets have been attached along with. Updated COA as per compendia is submitted.</i>
9.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted.	Working standard b.No. STD12-020R.
10.	3.2.S.7	Assay limit in stability data sheets i.e. 98% - 102% and loss on drying limits both are changed from that provided in specifications (98.7% - 101%). Clarification shall be submitted.	<i>The Limits of COA are according to European Pharmacopeia, and the DMF data was of 2007 when Candesartan was not added in European Pharmacopeia. Updated Data Specification and Stability Data sheets have been attached along with. The firm has submitted 06 months accelerated and 36 months real time stability data of new batches wherein the limits are 99-101%.</i>
11.	3.2.P.2.2.1	Complete CDP studies with each time point dissolution of both reference and test product with analytical record	CDP report is submitted against the comparator's product i.e. Advant 8mg tablet by M/s Getz Pharma.

		shall be submitted.	
12.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph.	<i>The UDU test was performed but mistakenly not mentioned in test specification report.</i>
13.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted.	Submitted.
14.	3.2.P.5.3	Method verification studies submitted are for drug substance. Clarification shall be submitted.	AMV study report is submitted.
15.	3.2.P.8	- Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. - Complete six month stability studies shall be submitted. - Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.8mg/ml while raw data sheets has 0.05mg/ml. - USP monograph has mentioned 10µl injection volume while submitted chromatograms has 20µl. clarification shall be submitted. - USP monograph has mentioned Run time of NLT 2.7 times the retention time of candesartan Cilexetil while submitted chromatograms have shown retention time of 7.4 minutes and run time of 9 minutes. Clarification shall be submitted. - Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. - Chromatograms also does not reveal any wavelength. Clarification shall be submitted. - Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	(i) Six month Stability summary sheets are attached including API lot no. used in stability study. (ii) <i>The concentration of Candesartan Cilexetil used in for the analysis of drug product was 0.8mg/ml as mentioned in SAP while in the raw data sheets is 0.05mg/ml is typographic mistake.</i> (iii) In 10µl peak response was not enough to comply the system suitability therefor injection volume changed to 20µl (iv) There is no peak emerging after the main peak, also no interference from the placebo or blank is observed. (v) Raw data sheets of assay and dissolution as per calculation formula is attached. (vi) The whole stability study performed at wavelength for Assay and dissolution (282, 254) as mentioned in SAP, on Empower-2 software which does not have the option of wavelength during printing of chromatogram. v) The firm has not submitted record of HPLC software 21FR. However, report of configuration for electronic record of the HPLC software used i.e Empower 2. vi) Record of digital data logger is submitted
Decision: Deferred for the following points: - Submission of Chromatograms for submitted AMV studies for drug substance performed by drug product manufacturer. - Scientific justification for not selecting the injection volume as recommended by USP with supporting data.			

• Scientific justification for not selecting the run time as recommended by USP with supporting data. • Submission of audit trail report of HPLC software for stability studies.		
85.	Name, address of Applicant / Marketing Authorization Holder	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Name, address of Manufacturing site.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13638: 01-06-2023
	Details of fee submitted	PKR 30,000/- : 24-02-2023
	The proposed proprietary name / brand name	Pedlote 0.5% Ophthalmic Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Loteprednol Etabonate...5mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Lotepred forte by Sante
	Proposed Pack size	As per SRO
Evaluation by PEC ³ :		
Decision of 339 th meeting:		
Registration Board deferred the case for submission of reply to the above cited shortcomings.		
The firm has submitted the reply through General Request ID No. BR7-BHA-8QAS.		
Sr. No	Shortcomings	Response by the firm
1.	Name of the firm mentioned in section 1.3.1 and 1.3.2. is M/s Polyfine Chempharma, while the name of the firm as per DML is M/s Polyfine Chempharma (Pvt) Ltd. Moreover, as per submitted fee challan the name of the firm is also M/s Polyfine Chempharma. Revision of the title of the firm is required along with submission of requisite fee.	The firm has submitted DML No. 000216 w.e.f. 14-03-2021 with title "Polyfine Chempharma" and address "51-Hayatabad Industrial Estate, Peshawa" The firm has not submitted any fee for correction of title of the firm.
	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
2.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	AMV report is submitted.
3.	Submit COA of reference / working standard actually used in analysis of	Submitted

	drug substance.	
4.	Submit microbiological attributes of the drug product in section 3.2.P.2.5 including preservative effectiveness studies.	Submitted
5.	Justify why test for assay of preservative i.e. benzalkonium chloride is not included in drug product specification.	The firm has submitted following reply: 1.. It is added in the formulation solely as a preservative to maintain microbial quality. 2. It is strictly controlled at the raw material stage in accordance with the relevant pharmacopoeial standards. 3. The quantity of BAK added is strictly monitored and controlled during the manufacturing process using validated methods. This ensures that the final product consistently contains the intended amount of preservative within acceptable limits. 4. Stability studies conducted on the final product confirm that the preservative remains stable and within acceptable concentration limits throughout the shelf life. Hence, its routine testing in the final drug product is not warranted. 5. Preservative effectiveness is evaluated and verified through Preservative Efficacy Testing (PET) as per USP /BP guidelines. The results meet the acceptance criteria for antimicrobial effectiveness. 6. Many pharmacopoeial monographs and regulatory submissions do not require routine assay of preservatives in the final product if the preservative is controlled during manufacturing and effectiveness is demonstrated through PET.
6.	Submit valid GMP certificate of API manufacturer	GMP certificate No. 6126615 valid till 18-04-2026.
7.	Submit documents for procurement of API including DRAP clearance certificate.	AD attested invoice No. FLX/EX/21-22/018 dated 30-06-2021 Dy. No. 1560 dated 16-07-2021 is submitted.

Decision: Approved. The firm shall submit applicable fee for correction of the title and address of the firm as per submitted DML.

86.	Name, address of Applicant / Marketing Authorization Holder	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Name, address of Manufacturing site.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13639: 01-06-2023
	Details of fee submitted	PKR 30,000/- : 24-02-2023
	The proposed proprietary name / brand name	OPANAC FORTE 3mg/ml Ophthalmic Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Nepafenac...3mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory

	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Acukat Ophthalmic Suspension 0.3% by Genix
	Proposed Pack size	As per SRO
Evaluation by PEC ³ :		
Decision of 339 th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The reply is submitted through General Request ID No. NG8-2XW-8S7Q.		
Sr. No	Shortcomings	Response by the firm
1.	Name of the firm mentioned in section 1.3.1 and 1.3.2. is M/s Polyfine Chempharma, while the name of the firm as per DML is M/s Polyfine Chempharma (Pvt) Ltd. Moreover, as per submitted fee challan the name of the firm is also M/s Polyfine Chempharma. Revision of the title of the firm is required along with submission of requisite fee.	The firm has submitted DML No. 000216 w.e.f. 14-03-2021 with title "Polyfine Chempharma" and address "51-Hayatabad Industrial Estate, Peshawar" The firm has not submitted any fee for correction of title of the firm.
	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
2.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted.
3.	Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted. Batch number: NE/003/08/21
4.	Submit microbiological attributes of the drug product in section 3.2.P.2.5 including preservative effectiveness studies.	Submitted.
5.	Justify why test for assay of preservative i.e. benzalkonium chloride is not included in drug product specification.	The firm has submitted following reply: 1.. It is added in the formulation solely as a preservative to maintain microbial quality. 2. It is strictly controlled at the raw material stage in accordance with the relevant pharmacopeial standards. 3. The quantity of BAK added is strictly monitored and controlled during the manufacturing process using validated methods. This ensures that the final product consistently contains the intended amount of preservative within acceptable limits. 4. Stability studies conducted on the final product confirm that the preservative remains stable and within acceptable concentration limits throughout the

		shelf life. Hence, its routine testing in the final drug product is not warranted. 5. Preservative effectiveness is evaluated and verified through Preservative Efficacy Testing (PET) as per USP /BP guidelines. The results meet the acceptance criteria for antimicrobial effectiveness. 6. Many pharmacopoeial monographs and regulatory submissions do not require routine assay of preservatives in the final product if the preservative is controlled during manufacturing and effectiveness is demonstrated through PET.
6.	Submit valid GMP certificate of API manufacturer	GMP certificate No. 6126041 dated 18-03-2028.
7.	Submit documents for procurement of API including DRAP clearance certificate.	GD NO. PPAF-286-2021 dated 11-10-2021 Cash payment receipt for Pakistan customs, No. CPPAF-000047-15102021 dated 15-10-2021. Copy of unattested invoice dated 28-07-2021.
Decision: Approved. The firm shall submit applicable fee for correction of the title and address of the firm as per submitted DML		

Deferred cases of form 5:

87.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No. 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Lignocaine Injection I/V & I/M
	Composition	Each 2ml ampoule contains: Lignocaine HCl..... 20mg
	Diary No. Date of R & I & fee	Dy.No.39082; 28-11-2018; Rs.20,000 (27-11-2018)
	Pharmacological Group	Local Anesthetic.
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 25's, 50's, 100's & as per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lidocaine 1% Injection of M/s Zafa Pharma (Reg. # 030216)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing.

	Previous Remarks of the Evaluator PEC-XIII	- Manufacturing facility needs to be verified. - Firm was asked through letter on 04-12-2019 about the section which was replied as: <i>M/s Horizon Healthcare (Pvt.) Ltd, Plot No. 35- A, Small Industrial Estate, Taxilla.</i> While the applied address is: <i>M/s Horizon Healthcare (Pvt.) Ltd Plot No. 33, Sunder Industrial Estate, Lahore.</i> - M/s Horizon Healthcare (Pvt.) Ltd, Plot No. 35- A, Small Industrial Estate, Taxilla has Liquid Injection Ampoule (General) Section.
	Decision of 293 rd meeting of Registration Board:	Deferred for the following reasons: - Confirmation of manufacturing facility for the applied formulation.
		- Confirmation of actual address of the applicant. - Confirmation of route of administration IM or IV.
	Submission of the firm:	- Firm has submitted that the applicant for applied formulation is M/s Horizon Healthcare (Pvt.) Ltd, Plot No. 35- A, Small Industrial Estate, Taxilla and also provided section approval letter wherein they have Liquid Injection ampoule (General section). - They further clarified the route which is IM with solvent.
	Remarks of the Evaluator PEC-XIII	
	Decision of 307th meeting: Deferred for review regarding applied manufacturing site in Form 5 and relevant documents. Reply by the firm: The firm has submitted the reply through G.R. No. S48-RV1-8SDU. The correct address is "M/s Horizon Healthcare (Pvt.) Ltd, Plot No. 35- A, Small Industrial Estate, Taxilla". Moreover, the firm has submitted R&I receiving (covering letter) confirming the that the application is submitted by M/s Horizon HealthCare (pvt) Ltd., Plot No. 35-A, small industrial estate Taxila. Furthermore, the firm has submitted R&I receiving dated 13-06-2024 for submission of the reply. The firm shall submit applicable fee for correction of address of manufacturing site.	
	Decision: Deferred for verification of receiving of reply from R&I. The firm shall submit applicable fee for correction of address of the applicant.	
88.	Name and address of manufacturer / Applicant	M/s. Kohinoor Industries, Plot # 159-160/B Small Industrial Estate, Sahiwal
	Brand Name +Dosage Form + Strength	Betno S Lotion
	Composition	Each ml contains: Betamethasone dipropionate.....0.05% Salicylic acid.....3%
	Diary No. Date of R& I & fee	Dy. No. 1410; 27-03-2017; Rs.20,000/- (27-03-2017)
	Pharmacological Group	Antibacterial / Corticosteroid

	Type of Form	Form 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	60 ml , 25ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Provate S Lotion of M/s Saffron
	GMP status	Last GMP inspection was conducted on 07-09- 2017 and the report concludes satisfactory level of GMP compliance. Resumption of production of respective areas was decided.
	Remarks of the Evaluator	The applied drug couldn't be searched in the reference regulatory authorities.
	Decision of 279 th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275 th meeting and correction of pharmacological group. Reply: The firm has submitted the reply through G.R. NO. QLT-Y1U-SQ7L. The provided reference is Scalp Solution. The deadline for submission of reply of deferred cases of form 5 was 31 st December 2024. The firm has not submitted any R&I receiving as an evidence that the reply was received till 31 st December, 2024.	
	Decision: Deferred for submission of R&I receiving for confirmation of submission of reply before 31st December, 2024.	
89.	Name and address of manufacturer / Applicant	M/s Wnsfield Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form+Strength	Trestron 5mg Capsule
	Composition	Each Capsule contains:- Tropisetron as HCl 5mg
	Diary No. Date of R& I & fee	Dyn# 1117, 11-1-2017, Rs, 20,000/-
	Pharmacological Group	5HT3-antagonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Tropit 5mg Capsule (Reg#066337) by Global Pharma.
	GMP status	DML Renewal Inspection Date: 18th January, 2018
	Remarks of Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board missing.
	Decision in 279 th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275 th	

	meeting Reply: The reference submitted by the firm could not be verified. Moreover the firm has not submitted R&I receiving for submission of the reply. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting				
90.	Name and address of manufacture / Applicant		M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar		
	Brand Name + Dosage Form and Strength		Libri 5/2.5mg Capsules		
	Composition		Each Capsule Contains: Chlordiazepoxide Hydrochloride...5mg Clidinium Bromide...2.5mg		
	Dairy No. date of R &I fee		Form-5 Dy.No 39663 (03-12-2018) Rs.20,000/- 03-12-2018		
	Pharmacological Group		Anxiolytics and anticholinergic/spasmolytic combinations		
	Type of form		Form 5		
	Finished product specifications		USP		
	Pack size and Demand Price		10's; 20's; 30's; As per SRO		
	Approval status of product in Reference Regulatory Authorities		Librax Capsules (USFDA Approved)		
	Me-too-status		Could not be verified		
	GMP Status		The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of GMP compliance .		
	Remark of the Evaluator ^{XI}		Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet		
			- Evidence of psychotropic section. - Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be verified.		
	Decision of 296 th meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Confirmation of required manufacturing facility for applied formulation. Response: The firm has submitted the reply through G.R. No. UD8-7Z3-HSBY. The firm has not submitted the required documents. The firm has attached fee challan No. 7786283158 dated 29-09-2025 which is not required. Moreover, the deadline for submission of reply for form 5 was 31 st Dec, 2024. Decision: Rejected as the firm failed to provide the required documents as per the previous decision of Registration Board.				
91.	M/s Kohinoor Industries Sahiwal, Plot # 159-160/B Small Industrial Estate, Sahiwal. Sachet (General)	Komizol Sachet 20 Each sachet contains:- Omeprazole...20 mg Sodium bicarbonate	Form-5 29-07-2015 diary No 4693. Rs20,000 As per SRO/ Box of	Zegerid Powder For oral suspension, USA, by M/s Santarus Risek Insta by M/s Getz Panel vide Inspection vide dated 08-09-	Deferred as the Formulation is under Review Reply: The firm has submitted the reply through G.R. No. 2QZ-BWU-ZNJ7. The firm has submitted that in Meeting No. 275 th , Hirani's

	approved in 241 st meeting of CLB	1680mg PPI & Antacid Manufacturer's Specifications	sachet 10	2014, new section recommended.	Pharmaceutical's Karachi product, which had the same formulation, was approved. The firm has submitted the R&I receiving through G.R ID No. GUB-79Q-JSMJ. The firm has submitted the reply on 23-12-2024.
Decision: Approved with innovator's specifications. The firm shall submit applicable fee for change of specifications.					
92.	M/s Kohinoor Industries Sahiwal, Plot # 159-160/B Small Industrial Estate, Sahiwal. Sachet (General) approved in 241 st meeting of CLB.	Komizol Sachet Each sachet contains:- Omeprazole...40 mg Sodium bicarbonate 1680mg PPI & Antacid Manufacturer's Specifications	Form-5 29-07-2015 diary No 4692. Rs20,000 As per SRO/ Box of 10 sachet	Zegerid Powder For oral suspension, USA, by M/s Santarus Risek Insta by M/s Getz Panel vide Inspection vide dated 08-09-2014, new section recommended.	Deferred as the Formulation is under Review Reply: The firm has submitted the reply through G.R. No. 2QZ-BWU-ZNJ7. The firm has submitted that In Meeting No. 275 th , Hirani's Pharmaceutical's Karachi product, which had the same formulation, was approved. The firm has submitted the R&I receiving through G.R ID No. GUB-79Q-JSMJ. The firm has submitted the reply on 23-12-2024.
Decision: Approved with innovator's specifications. The firm shall submit applicable fee for change of specifications.					
93.	M/s Epharm Laboratories, Karachi	PAGABIN Capsules 300mg	Form-5 Dy. No. 12000/- dated 21-07-15 700/ pack of 2x7's Manufacturer	LYRICA Capsules (25, 50, 75, 100, 150, 200, 225 and 300mg) US FDA GABICA Capsules (50, 75, 100, 150 and 300mg) Getz	Deferred in 254 th meeting for: - Evidence of submission of initial fee. - Latest GMP inspection report. - Undertaking approved in 251st meeting of registration board. Reply by the firm: The firm has submitted the reply through G.R. No. 7AJ-1YE-GYYN. 1. Yellow slip No. 0053246 dated 05-07-2014 (Rs. 12,000/-) verified by ABL on 27-11-2024. 2. Last inspection report

					dated 09-05-2024. 3. Commitment as per 251st meeting of Registration Board. 4. Moreover, the firm has submitted R&I receiving for the reply dated 09-12-2024.
Decision: Approved with BP specifications. The firm shall submit the applicable fee for change of specifications.					

Deferred cases of form 5 with stability:

94.	Name and address of manufacturer / Applicant		M/s Navegal Laboratories- 41/1-A2, Phase-1, Industrial Estate, Hattar	
	Brand Name +Dosage Form + Strength		Gliem 25mg Tablets	
	Composition		Each Film Coated Tablet Contains: Empagliflozin...25mg	
	Diary No. Date of R& I & fee		Form-5 Dy.No 38602 dated 23-11-2018 Rs.20,000/- dated 23-11-2018	
	Pharmacological Group		Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors)	
	Type of Form		Form 5-D.	
	Finished product Specifications		Manufacturer's Specification	
	Pack size & Demanded Price		Pack size and MRP as per SRO.	
	Approval status of product in Reference Regulator Authorities		Jardiance tablets (USFDA Approved)	
	Me-too status		Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089)	
	GMP status		Not Submitted	
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug		Gliem 25mg Tablets		
Manufacturer of API		Not submitted		
API Lot No.		Not submitted		
Description of Pack (Container closure system)		1x10's, PVC foil.		
Stability Storage Condition		Real time: 30°C ± 2 °C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.		Trial 01	Trial 02	Trial 03
Batch Size		2000 Tablets	2000 Tablets	2000 Tablets

Manufacturing Date	08-2020	08-2020	08-2020
No. of Batches	03		
Date of Submission	29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Not submitted.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.	
7.	Protocols followed for conduction of stability study	Submitted.	
8.	Method used for analysis of FPP	Not submitted.	
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.	
10.	Complete batch manufacturing record of three stability batches.	Not submitted.	
11.	Record of comparative dissolution data (where applicable)	Not submitted.	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches, along with chromatograms.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.	
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.	
Remarks of Evaluator:			
Sr. No.	Observation	Reply by the firm	

1.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
3.	Stability study data of API from both API manufacturer shall be submitted.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
6.	Method used for analysis of Finished Product shall be submitted.	
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
8.	Complete batch manufacturing record of three stability batches shall be submitted..	
9.	Record of comparative dissolution data shall be submitted.	

Decision of 344th meeting:

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

The firm has submitted the reply through General Request ID SNA-6PJ-L5PN.

Sr. No.	Observation	Reply by the firm
1.	Certificate of Analysis of API from respective drug substance manufacturer shall be submitted.	Submitted. Manufacturer: M/s Zhejian Huahai Pharmaceutical Co., Ltd., China.
2.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted.
3.	Stability study data of API from both API manufacturer shall be submitted.	06 months accelerated and 36 months real time stability data for 03 batches is submitted. However, the data is not as per Zone IV-A. The firm was asked against to submit the stability data but the firm has attached the same data.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	GMP certificate is expired. The firm was asked to submit the certificates but in reply the firm has not attached the required documents.
5.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	Form 6 No. 001313/2021-DRAP/4865 dated 21-12-2021 for 75g of material along with GD.
6.	Method used for analysis of Finished Product shall be submitted.	Submitted.
7.	Drug-excipients compatibility studies (where applicable) shall be submitted.	Only report is submitted. No chromatograms no raw data sheets are submitted.
8.	Complete batch manufacturing record of three stability batches shall be submitted..	Submitted.
9.	Record of comparative dissolution data shall be submitted.	CDP report is submitted against the reference product i.e. Jardiance 25mg tablet in only 0.1NHCl dissolution media. Initially the firm has submitted the report against Synjardy which is having a different composition. No clarification is submitted by the firm.

Decision: Deferred for the following points: • Submission of stability study data for drug substance according to the conditions of Zone IV-A. • Submission of chromatograms for Stability studies of drug product and CDP data along with raw data sheets. • Clarification regarding initially submitted CDP studies against the product Synjardy which has the different composition from the applied product. • Submission of chromatograms for drug-excipient compatibility studies along with raw data sheets.	

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

STABILITY STUDY DATA

Drug	Gliem-M 5/500mg Tablet.		
Manufacturer of API	Empagliflozin: M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. Metformin HCl (MEF/11030557): Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-007	TGM-008	TGM-009

Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39312 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.	
7.	Protocols followed for conduction of stability study	Not submitted.	
8.	Method used for analysis of FPP	Not submitted.	
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.	
10.	Complete batch manufacturing record of three stability batches.	Not submitted.	
11.	Record of comparative dissolution data (where applicable)	Not submitted.	
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.	
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.	

14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.																																																			
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Remarks of Evaluator:																																																					
Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The reply has been received via General Request ID No. XUX-TUU-AB63.																																																					
Reason for deferment		Response																																																			
Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.		The firm has used following source for Metformin: Manufacturer: M/s Arti Drugs Limited, India Batch: MEF/11030557																																																			
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Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.		COAs for Empagliflozin and Metformin are submitted.																																																			

Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted	
Stability study data of API from both API manufacturer shall be submitted.	Metformin: 48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of Zone IV-B. Empagliflozin: Data is not according to Zone IV-A. The firm as asked to provide the stability data and the was sent back, in reply the firmhas attached the same data again.	
Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Empagliflozin: Form 6 dated 21-12-2021 for 75gram of material is submitted along with copy of airway bill and DHL receipt. DML valid till 12-01-2025 Metformin HCl: Clearance certificate dated 09-06-2021 for 150kg material is submitted. GMP certificate valid till 15-10-2021.	
Protocols followed for conduction of stability study shall be submitted.	Submitted.	
Method used for analysis of Finished Product shall be submitted.	Submitted	
Drug-excipients compatibility studies (where applicable) shall be submitted.	<i>“Drug excipient compatibility study not applicable because we have same formulation to that of innovator’s.”</i>	
Complete batch manufacturing record of three stability batches shall be submitted..	Submitted	
Record of comparative dissolution data shall be submitted.	PE and CDP studies have been performed against the innovator’s product i.e. Synjardy tablet 5/50mg tablet by M/s Boehringer Ingelheim, USA.	
Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	The firm has submitted same chromatograms for all the strengths.	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Not submitted. The was asked to clarify again, but the firm has not responded to this query.	
Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	As per Innovator’s product literature available on the official website of USFDA, the dissolution sampling time point is 20mintes while the firm has selected 30 minutes as sampling time. The was asked to clarify again, but the firm has not responded to this query.	
As per submitted BMRs, the applied product is film coated tablet.		
Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.		
Sr. No.	General Request Tracking	Brand Name

	ID	
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

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

STABILITY STUDY DATA

Drug	Gliem-M 5/1000mg Tablet.
Manufacturer of API	Empagliflozin: M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. Metformin HCl: Aarti Drugs Limited, India.
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.

Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-010	TGM-011	TGM-012
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39313 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.	
4.	Stability study data of API from API manufacturer	Not submitted.	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.	
7.	Protocols followed for conduction of stability study	Not submitted.	
8.	Method used for analysis of FPP	Not submitted.	
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.	

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
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9.	Method used for analysis of Finished Product shall be submitted.	
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11.	Complete batch manufacturing record of three stability batches shall be submitted..	
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13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings. The reply has been received via General Request ID No. H6E-HZP-1NGQ.	
Reason for deferment	Response
Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	The firm has used following source for Metformin: Manufacturer: M/s Arti Drugs Limited, India Batch: MEF/11030557
Reference of previous approval of applications with stability study data of the firm shall be submitted.	
Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	COAs for Empagliflozin and Metformin are submitted.
Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted
Stability study data of API from both API manufacturer shall be submitted.	Metformin: 48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of Zone IV-B. Empagliflozin: Data is not according to Zone IV-A. The firm was asked to submit the data but the firm has attached the same data again.
Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Empagliflozin: Form 6 dated 21-12-2021 for 75gram of material is submitted along with copy of airway bill and DHL receipt. DML valid till 12-01-2025 Metformin HCl: Clearance certificate dated 09-06-2021 for 150kg material is submitted. GMP certificate valid till 15-10-2021.
Protocols followed for conduction of stability study shall be submitted.	Submitted.
Method used for analysis of Finished Product shall be submitted.	Submitted
Drug-excipients compatibility studies (where applicable) shall be submitted.	<i>"Drug excipient compatibility study no applicable because we have same formulation to that of innovator's."</i>
Complete batch manufacturing record of three stability batches shall be submitted..	Submitted
Record of comparative dissolution data shall be submitted.	PE and CDP studies have been performed against the innovator's product i.e. Synjardy tablet 5/1000mg tablet by M/s Boehringer Ingelheim, USA.
Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA	The firm has submitted same chromatograms

shall be submitted.		for all the strengths.																																	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..		Not submitted. The firm was asked to submit the required data but the firm has not responded to this query.																																	
Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.		As per Innovator's product literature available on the official website of USFDA, the dissolution sampling time point is 20minutes while the firm has selected 30 minutes as sampling time. The firm was asked to clarify but the firm has not responded to this query.																																	
As per submitted BMRs, the applied product is film coated.																																			
Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.																																			
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Sr. No.	General Request Tracking ID	Brand Name																																	
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The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.																																			
97.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.																																	
	Brand Name +Dosage Form + Strength	Gliem-M 12.5/500mg Tablet.																																	
	Composition	Each film coated tablet contains: Empagliflozin 12.5mg. Metformin HCl 500mg.																																	
	Diary No. Date of R& I & fee	Form-5 Dy. No 38605 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on20-12-2024 with receiving of 29-12-2022 & 23-11-2018.																																	
	Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.																																	
	Type of Form	Form 5.																																	
	Finished product Specifications	Navegal's Specifications.																																	
	Pack size & Demanded Price	Not available.																																	

	Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.		
	Me-too status	Empozin-M Tablets 12.5 mg+500mg Tablets, M/s Macter International.		
	GMP status	Not submitted.		
	Remarks of the Evaluator			
STABILITY STUDY DATA				
Drug	Gliem-M 12.5/500mg Tablet.			
Manufacturer of API	Empagliflozin: M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. Metformin HCl: Aarti Drugs Limited, India.			
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)			
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.			
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%			
Time Period	Real time: 09 months Accelerated: 06 months			
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)			
Batch No.	TGM-001	TGM-002	TGM-003	
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets	
Manufacturing Date	01-2022	01-2022	01-2022	
Date of Initiation	06-01.2022	10-01.2022	11-01.2022	
No. of Batches	03			
Date of Submission	Dy. No. 39314 dated 29-12-2022.			
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Sr. No.	Documents to Be Provided	Status		
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.		
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.		
4.	Stability study data of API from API manufacturer	Not submitted.		

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

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	
2.	Reference of previous approval of applications with stability study data of the firm shall be submitted.	
3.	Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	
4.	Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	
5.	Stability study data of API from both API manufacturer shall be submitted.	
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	
7.	Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted..	
8.	Protocols followed for conduction of stability study shall be submitted.	

9.	Method used for analysis of Finished Product shall be submitted.	
10.	Drug-excipients compatibility studies (where applicable) shall be submitted.	
11.	Complete batch manufacturing record of three stability batches shall be submitted..	
12.	Record of comparative dissolution data shall be submitted.	
13.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	
14.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	
16.	Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	

Decision of 344th meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings. The reply has been received via General Request ID No. 1N3-Q2P-EHQS.

Reason for deferment	Response
Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	The firm has used following source for Metformin: Manufacturer: M/s Arti Drugs Limited, India Batch: MEF/11030557
Reference of previous approval of applications with stability study data of the firm shall be submitted.	
Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	COAs for Empagliflozin and Metformin are submitted.
Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted
Stability study data of API from both API manufacturer shall be submitted.	Metformin: 48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of Zone IV-B. Empagliflozin: Data is not according to Zone IV-A. The firm has attached the data again upon query.
Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Empagliflozin: Form 6 dated 21-12-2021 for 75gram of material is submitted along with copy of airway bill and DHL receipt. DML valid till 12-01-2025 Metformin HCl: Clearance certificate dated 09-06-2021 for 150kg material is submitted. GMP certificate valid till 15-10-2021.
Protocols followed for conduction of stability study shall be submitted.	Submitted.

Method used for analysis of Finished Product shall be submitted.	Submitted
Drug-excipients compatibility studies (where applicable) shall be submitted.	<i>"Drug excipient compatibility study no applicable because we have same formulation to that of innovator's."</i>
Complete batch manufacturing record of three stability batches shall be submitted..	Submitted
Record of comparative dissolution data shall be submitted.	PE and CDP studies have been performed against the innovator's product i.e. Synjardy tablet 12.5/500mg tablet by M/s Boehringer Ingelheim, USA.
Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	The firm has submitted same chromatograms for all the strengths.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Not submitted. The firm has not responded to the query when asked again to submit.
Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	As per Innovator's product literature available on the official website of USFDA, the dissolution sampling time point is 20minutes while the firm has selected 30 minutes as sampling time. The firm has not submitted clarification when the was sent back again.

As per submitted BMRs, the applied product is film coated.

Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.

Sr. No.	General Request Tracking ID	Brand Name
1	ELU-1NU-X52A	Rexira 1mg Tablets
2	3MN-8SZ-VDU8	Rexira 2mg Tablets
3	H4G-48T-Z3JL	Daplo 5mg Tablets
4	H4G-48T-Z3JL	Daplo 10mg Tablets
5	5W6-51X-LJQP	Empline 10mg/5mg
6	DY5-1Y4-WD7J	Emplina 25mg/5mg
7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet
9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet
10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet
11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet

The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

98.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A-2, Phase -1, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Gliem-M 12.5/1000mg Tablet.
	Composition	Each film coated tablet contains: Empagliflozin 12.5mg. Metformin HCl..... 1000mg.

Diary No. Date of R& I & fee	Form-5 Dy. No 38597 dated 23-11-2018; Rs. 20,000/- dated 23-11-2018. (As per Excel sheet of PEC). Duplicate Dossier of Form 5 submitted on20-12-2024 with receiving of 29-12-2022 & 23-11-2018.		
Pharmacological Group	Combination of Oral blood glucose lowering drugs. ATC Code: A10BD20.		
Type of Form	Form 5.		
Finished product Specifications	Navegal's Specifications.		
Pack size & Demanded Price			
Approval status of product in Reference Regulator Authorities	Synjardy® Tablets, USFDA approved.		
Me-too status	Empozin-M Tablets 12.5 mg+1000mg Tablets, M/s Macter International.		
GMP status	Not submitted.		
Remarks of the Evaluator			
STABILITY STUDY DATA			
Drug	Gliem-M 12.5/1000mg Tablet.		
Manufacturer of API	Empagliflozin: M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Duqiao, Zhejiang, China. Metformin HCl: Aarti Drugs Limited, India.		
API Lot No.	Empagliflozin: (D5284-21-001). Metformin HCl: (MEF/11030557)		
Description of Pack (Container closure system)	10's, 20's & 30's tablets in Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TGM-004	TGM-005	TGM-006
Batch Size	1350 Tablets	1350 Tablets	1350 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	06-01.2022	10-01.2022	11-01.2022
No. of Batches	03		
Date of Submission	Dy. No. 39315 dated 29-12-2022.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	

2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance Empagliflozin (D5284-21-001, Mfg. date 28-06-2021) from drug product manufacturer only. Firm has submitted copy of COA of the drug substance Metformin HCl (MEF/11030557, Mfg. date 03-2021) from drug product manufacturer only.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Not submitted.
4.	Stability study data of API from API manufacturer	Not submitted.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
7.	Protocols followed for conduction of stability study	Not submitted.
8.	Method used for analysis of FPP	Not submitted.
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	Not submitted.
11.	Record of comparative dissolution data (where applicable)	Not submitted.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.
Remarks of Evaluator:		
Sr. No.	Observation	Reply by the firm
	1. Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	

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

Decision of 344th meeting:

Registration Board deferred the case for submission of reply to the above cited shortcomings. The reply has been received via General Request ID No. JPW-R7J-6QVD.

Reason for deferment	Response
Two different sources for Metformin HCl and also different batch No. are mentioned in the submitted application. Clarification shall be submitted.	The firm has used following source for Metformin: Manufacturer: M/s Arti Drugs Limited, India Batch: MEF/11030557
Reference of previous approval of applications with stability study data of the firm shall be submitted.	
Certificate of Analysis of both the drug substances from respective drug substance manufacturer shall be submitted.	COAs for Empagliflozin and Metformin are submitted.
Method used for analysis of drug substance/API from both API Manufacturer and Finished Product Manufacturer shall be submitted.	Submitted
Stability study data of API from both API manufacturer shall be submitted.	Metformin: 48 months real time and 06 months accelerated stability data of 03 batches according to the conditions of Zone IV-B. Empagliflozin: Data is not according to Zone IV-A. The firm has attached the same data again.

Documents for the procurement of both the APIs with approval from DRAP (in case of import) shall be submitted.. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted..	Empagliflozin: Form 6 dated 21-12-2021 for 75gram of material is submitted along with copy of airway bill and DHL receipt. DML valid till 12-01-2025 Metformin HCl: Clearance certificate dated 09-06-2021 for 150kg material is submitted. GMP certificate valid till 15-10-2021.																																	
Protocols followed for conduction of stability study shall be submitted.	Submitted.																																	
Method used for analysis of Finished Product shall be submitted.	Submitted																																	
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Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	The firm has submitted same chromatograms for all the strengths.																																	
Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted..	Not submitted. The firm was communicated but the the reply does not contains the required data.																																	
Justification shall be submitted for using 30 minute time for dissolution test of both the drug substances with respect to that of the innovator product.	As per Innovator’s product literature available on the official website of USFDA, the dissolution sampling time point is 20mintes while the firm has selected 30 minutes as sampling time. No clarification is submitted by the firm even after the shortcomings were communicated.																																	
As per submitted BMRs, the applied product is film coated.																																		
Decision: The Board was apprised that the firm has submitted similar chromatograms in the follow applications.																																		
<table><tr><th>Sr. No.</th><th>General Request Tracking ID</th><th>Brand Name</th></tr><tr><td>1</td><td>ELU-1NU-X52A</td><td>Rexira 1mg Tablets</td></tr><tr><td>2</td><td>3MN-8SZ-VDU8</td><td>Rexira 2mg Tablets</td></tr><tr><td>3</td><td>H4G-48T-Z3JL</td><td>Daplo 5mg Tablets</td></tr><tr><td>4</td><td>H4G-48T-Z3JL</td><td>Daplo 10mg Tablets</td></tr><tr><td>5</td><td>5W6-51X-LJQP</td><td>Empline 10mg/5mg</td></tr><tr><td>6</td><td>DY5-1Y4-WD7J</td><td>Emplina 25mg/5mg</td></tr><tr><td>7</td><td>XUX-TUU-AB63</td><td>Gliem-M 5/500mg Tablet</td></tr><tr><td>9</td><td>H6E-HZP-1NGQ</td><td>Gliem-M 5/1000mg Tablet</td></tr><tr><td>10</td><td>1N3-Q2P-EHQS</td><td>Gliem-M 12.5/500mg Tablet</td></tr><tr><td>11</td><td>JPW-R7J-6QVD</td><td>Gliem-M 12.5/1000mg Tablet</td></tr></table>	Sr. No.	General Request Tracking ID	Brand Name	1	ELU-1NU-X52A	Rexira 1mg Tablets	2	3MN-8SZ-VDU8	Rexira 2mg Tablets	3	H4G-48T-Z3JL	Daplo 5mg Tablets	4	H4G-48T-Z3JL	Daplo 10mg Tablets	5	5W6-51X-LJQP	Empline 10mg/5mg	6	DY5-1Y4-WD7J	Emplina 25mg/5mg	7	XUX-TUU-AB63	Gliem-M 5/500mg Tablet	9	H6E-HZP-1NGQ	Gliem-M 5/1000mg Tablet	10	1N3-Q2P-EHQS	Gliem-M 12.5/500mg Tablet	11	JPW-R7J-6QVD	Gliem-M 12.5/1000mg Tablet	
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The Board observed that the submitted chromatograms have exactly the same height (i.e. 14426 and 832984), considering this fact the Board decided to reject the aforementioned applications alongwith issuance of show cause to the firm for submission of similar data for various products. Furthermore, the Board decided to refer the case to the division of QA&LT for comprehensive GMP inspection of the firm. The Director QA&LT shall constitute the panel for this purpose.

99.	Duplication at Sr. No. 94

Shahrukh Ali

N o.	Name and Address of Manufacturer / Applicant.	1. Brand Name 2. Dosage Form 3. Composition 4. Pharmacological Group.	1. Type Form. 2. Type of Application. 3. Demanded Price/Pack Size. 4. Initial Date & Diary. 5. Date on which fee becomes complete according to type of application / Form.	GMP Inspection report	Decision of previous meeting	Evaluation by PEC	Decision of 277th meeting	Evaluation by PEC
100	M/s Aurik Pharmaceuticals, Plot. No 6 & 7, St. No, S-9, National Industrial zone, Rawat Islamabad	Pridosul Tablets 50mg Each film coated tablet contains:- Levosulpiride... 50mg (Benzamide antipsychotic) Manufacturer	Form-5 16/07/14 Dy No: 1588 20,000/- As per SRO, Pack of 2x10's	15-9-2017: No observations by the panel as per the data provided by QA	Deferred for review by the Review Committee as per Reiteration Board decision in its M-241 meeting (M-245)	☐ Firm has submitted formulation of film coated tablet while reference product is uncoated.	Deferred for the following submission: ☐ Change in formulation to uncoated (plain) tablet as per the reference	Pec Evaluation Firm has submitted R&I receipt dated 31.08.2022 for change in formulation request Firm will

							product in Italy. ☐ Fee for change of formulat ion.	submit evidenc e of fee submiss ion
Tracking ID DRD-VSM-6T3E Decision: Approved. The firm shall submit applicable fee for revision of label claim from “film coated” to “uncoated tablet”.								

101.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Recowel 100mg/10ml
	Composition	Each Vial Contains:- Rocuronium Bromide..... 100mg
	Diary No. Date of R& I & fee	Dy. No. 11708: 30.03.2018 PKR 20,000/- 30.03.2018
	Pharmacological Group	Non-depolarizing neuromuscular blocker
	Type of Form	Form5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 12's
	Approval status of product in Reference Regulatory Authorities.	Esmeron Injection By M/S NV Organon, Approved by MHRA.
	Me-too status	Esmeron Injection 50mg of M/s Organon Pakistan (Pvt) (Reg.#021155)
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision DRB-289: Deferred for confirmation of vial manufacturing facility.	
102.	Deferred for confirmation of vial manufacturing facility	1. 11-96/2021-wellmark-DRAP-P-61 dated 2-05-2025 mentioning liquid injectable section.(GMP). 2. 3.3.2006-lic (Vol-III) renewal of DML dated 6-02-25 mentioning liquid injectable section. 3. Firm failed to provide evidence of submission of the reply in DRAP R&I on or before 31-12-2024.
	Tracking ID BPS-YGX-EHL1 Decision: Rejected, as the firm failed to provide evidence of submission of the reply within the notified time i.e. 31-12-2024.	
102.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Recowel 50mg/5ml Injection
	Composition	Each Vial Contains:- Rocuronium Bromide... .. 50mg
	Diary No. Date of R& I & fee	Dy. No. 11707: 30.03.2018 PKR 20,000/- 30.03.2018
	Pharmacological Group	Non-depolarizing neuromuscular blocker
	Type of Form	Form5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 12's
	Approval status of product in Reference Regulatory Authorities.	Esmeron Injection By M/S NV Organon, Approved by MHRA.
	Me-too status	Esmeron Injection 50mg of M/s Organon Pakistan (Pvt) (Reg.#021155)
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision DRB-289: Deferred for confirmation of vial manufacturing facility.	
	Deferred for confirmation of vial manufacturing facility	1. 11-96/2021-wellmark-DRAP-P-61 dated 2-05-2025 mentioning liquid injectable

		section.(GMP). 2. 3.3.2006-lic (Vol-III) renewal of DML dated 6-02-25 mentioning liquid injectable section. 3. Firm failed to provide evidence of submission of the reply in DRAP R&I on or before 31-12-2024
Tracking ID BPS-YGX-EHL1 Decision: Rejected, as the firm failed to provide evidence of submission of the reply within the notified time i.e. 31-12.2024.		
103.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Calcifed 5mg Injection
	Composition	Each injection contains: Cholecalciferol...5mg
	Diary No. Date of R& I & fee	Dy. No. 40716: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Vitamin D and analogues
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule. VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule. AN inSM approved
	Me-too status	Accu-D Injection. Reg. No. 79755
	GMP status	Applicant: could not be confirmed. Manufacturer: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	- The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. - The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. - Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295 th meeting deferred the case for capacity
		assessment of m/s welmark.
	Evaluation by PEC	The firm submitted the capacity assessment report as presented above.
	Decision 312: Deferred for the following: - Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. - Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. - Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. - Evaluation of the applied formulation with reference to the Pharmacopoeial monographs available for "Cholecalciferol injection".	

	Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years.	Not submitted
	Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years.	11-96/2021-Wellmark-Drap(P)-61 dated 2.05.25
	Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma.	Presented in 339 th meeting of registration board
	Evaluation of the applied formulation with reference to the Pharmacopoeia monographs available for “Cholecalciferol injection”.	Pharmacopoeia monographs available for “Cholecalciferol injection”. 300,000IU. Firm will revise specs to innovator with submission of requisite fee
Decision: Approved with innovator’s specifications. The firm shall submit applicable fee for change of specifications.		

104.	Name and address of manufacturer/ Applicant	M/s Crown Pharmaceuticals, Plot No. 286 kahuta Industrial Triangle Kahuta Road Islamabad. (DML No. 000456) Capsule (General) Section.
	Brand Name + Dosage Form + Strength	Tebi 500mg Capsule
	Composition	Each Capsule Contains; Tranexamic acid....500mg
	Diary No. Date of R & I & fee	Dy.No. 14717 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0550996, dated 07.03.2019 endorsed on 07.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Form-5	Form 5
	Finished product Specification	Not mentioned.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for capsule dosage form.
	Me-too status	Haemic Capsule 500mg Reg. No. 039016 M/s Genix Pharma Karachi.
	GMP status	Last inspection conducted on 03.08.2016.
	Remarks of the Evaluator	i. Latest GMP inspection report/ certificate required. ii. Reference of finished product specification is not mentioned. iii. Evidence of product approval in RRA is required.
	Decision 324: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision 324: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	PMDA JAPAN
	Tracking ID	2H6-VTX-YQW6
Decision: Approved with innovator’s specifications. The firm shall submit applicable fee for change of specifications.		

105.

Name, address of Applicant / Marketing	M/s Semos Pharmaceuticals Pvt Ltd.

Authorization Holder	Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan 1L7-YBL-QQ52
Brand Name + Dosage Form and Strength	Luras 40mg Tablet
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No 7283 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Lurasidone as HCl.....40mg
Pharmacotherapeutic Group of (API)	Anti-psychotic
Reference to Finished product specifications	Manufacturer's specifications
The status in reference regulatory authorities	LATUDA (20mg, 40mg, 60mg, 80mg, 120mg) film coated tablets USFDA Approved
For generic drugs (me-too status)	Luda 40mg tablets of Genome pharmaceuticals (Reg#095155)
GMP Status	The firm was inspected on 04-07-2018 and conclusion of inspection was: Based on above observations their current GMP compliance level is rated as GOOD.
Remark of the Evaluator XI	☐ ☐ The firm revised the formulation from uncoated to film coated tablets and submitted revised master formulation. The firm also revised the label claim without considering the salt factor along with submission of Rs. 5000/- on deposit slip No# 2032873 dated 01.02.2021. the revised label claim is as under: Each Film Coated Tablet Contains: Lurasidone HCl.....40mg ☐ ☐ Submit stability studies data as per the guidelines approved in 293rd meeting of Registration Board.
Decision of 307th meeting of RB:	Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.
Decision of 344th meeting:	Deferred for submission of the following: ☐ ☐ Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board, ☐ ☐ Valid GMP certificate of applicant.
Decision of 347th meeting:	Copy of receiving of initial stability data submitted in DRAP, ☐ Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin ☐ Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36

	months. ☐ Record of comparative dissolution data.
Proposed Pack size	20's;
Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1		Copy of receiving of initial stability data submitted in DRAP,	Copy of receiving of initial stability data submitted in DRAP dated 23.01.23
2	1.6.5	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Valid till 23.10.2021
3	3.2.S.7	Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36months	Firm submitted Real time stability studies data for total three batches for complete assigned shelf life of API i.e. 36months
4	3.2.P.2.2.1	Record of comparative dissolution data.	Submitted

Tracking ID

T5Y-WMY-XTPD

Decision: Approved with innovator's specifications. The firm shall submit applicable fee for change of specifications.

106-A(4)	Name, address of Applicant / Marketing Authorization Holder	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan 1L7-YBL-QQ52
	Brand Name + Dosage Form and Strength	Vortex Tablet 20mg
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Dy. No 12538 dated 05-04-2018 Rs.20,000/- Dated 04-04-2018
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Vortioxetine hydrobromide 25.42 Eq. to Vortioxetine...20mg"
	Pharmacotherapeutic Group of (API)	Psychoanaleptics
	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Brintellix 10mg tablet by M/s Lundbeck
	GMP Status	GMP inspection dated 04-07-2018 concluding good GMP compliance.

	Decision of 290th meeting of RB:	Registration Board reviewed the previous decision and deferred the cases of Vortex 10mg tablet and Vortex 20mg tablet for submission of stability studies as directed by Registration Board in its 278th meeting.	
	Decision of 344 meeting of RB:	Decision: Deferred for submission of the following: ☐ Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board, ☐ Valid GMP certificate of applicant.	
STABILITY STUDY DATA			
Drug	Vortex Tablet 20mg		
Manufacturer of API	Lianyungang Jari Pharmaceutical Co.,Ltd		
API Lot No.	20140403		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton/bottle		
Stability Storage Condition	Real time: 30°C ± 2 °C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RVH T01	RVH T02	RVH T03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04.2022	28-04.2022	28-04.2022
No. of Batches	03		
Date of Submission	23-01-2023.		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	N/A	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	API Manufacturer has submitted Method used for analysis of assay on HPLC however Finished Product Manufacturer has developed assay method on UV	
4.	Stability study data of API from API manufacturer	Submitted	
5.	Approval of API/ DML/GMP certificate of API manufacturer	valid till 11-04-24	

	issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	AD attested invoice dated 24-09-21
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	
10.	Complete batch manufacturing record of three stability batches.	submitted.
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against vrontil tab M/s Genix pharmaceutical in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted. Firm has used UV spectrophotometer
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Remarks of Evaluator: Firm has performed assay testing on UV spectrophotometer however the API manufacturer has performed testing on HPLC. Stability batches are expired now. Decision: Approved with innovator's specifications. The firm shall submit revised method of analysis on HPLC and analytical method validation studies for drug product. Moreover, the firm shall submit applicable fee for revision of specifications.		
106. B	Name, address of Applicant / Marketing Authorization Holder	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan 1L7-YBL-QQ52
	Brand Name + Dosage Form and Strength	Vortex Tablet 10mg
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Dy. No 12537 dated 05-04-2018 Rs.20,000/- Dated 04-04-2018	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Vortioxetine hydrobromide 12.7 Eq. to Vortioxetine...10mg"	
	Pharmacotherapeutic Group of (API)	Psychoanaleptics	
.	Reference to Finished product specifications	Manufacturer's specifications	
	The status in reference regulatory authorities	Approved by MHRA of UK	
	For generic drugs (me-too status)	Brintellix 10mg tablet by M/s Lundbeck	
	GMP Status	GMP inspection dated 04-07-2018 concluding good GMP compliance.	
	Decision of 290th meeting of RB:	Registration Board reviewed the previous decision and deferred the cases of Vortex 10mg tablet and Vortex 20mg tablet for submission of stability studies as directed by Registration Board in its 278th meeting.	
	Decision of 344 meeting of RB:	Decision: Deferred for submission of the following: ☐ Complete Stability study reports and data as per the guidelines approved in 293rd meeting of Registration Board, ☐ Valid GMP certificate of applicant.	
STABILITY STUDY DATA			
Drug	Vortex Tablet 20mg		
Manufacturer of API	Lianyungang Jari Pharmaceutical Co.,Ltd		
API Lot No.	20140403		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton/bottle		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RVH T01	RVH T02	RVH T03
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04.2022	28-04.2022	28-04.2022
No. of Batches	03		
Date of Submission	23-01-2023.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents to Be Provided	Status
15.	Reference of previous approval of applications with stability study data of the firm.	N/A
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
17.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	API Manufacturer has submitted Method used for analysis of assay on HPLC however Finished Product Manufacturer has developed assay method on UV
18.	Stability study data of API from API manufacturer	Submitted
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	valid till 11-04-24
20.	Documents for the procurement of API with approval from DRAP (in case of import).	AD attested invoice dated 24-09-21
21.	Protocols followed for conduction of stability study	Submitted
22.	Method used for analysis of FPP	Submitted
23.	Drug-excipients compatibility studies (where applicable)	
24.	Complete batch manufacturing record of three stability batches.	submitted.
25.	Record of comparative dissolution data (where applicable)	Comparative dissolution was performed against vrontil tab M/s Genix pharmaceutical in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data sheets for three batches. Respective documents like, Raw data sheets, COA, summary data sheets etc. are not submitted by the firm.
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted. Firm has used UV spectrophotometer
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and	Submitted.

	accelerated)	
Remarks of Evaluator: Firm has performed assay testing on UV spectrophotometer however the API manufacturer has performed testing on HPLC. Stability batches are expired now.		
Decision: Approved with innovator's specifications. The firm shall submit revised method of analysis on HPLC and analytical method validation studies for drug product. Moreover, the firm shall submit applicable fee for revision of specifications.		
107.	Name, address of Applicant / Marketing Authorization Holder	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan 1L7-YBL-QQ52
	Brand Name + Dosage Form and Strength	Dexprazole 60mg Capsules
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No 9752 dated 04-03-2019 Rs.20,000 dated 25-02-2019
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) 60mg (Source of pellets Vision Pharma)
	Pharmacotherapeutic Group of (API)	PPI. ATC Code: A02BC06 .
.	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	DEXILANT ® Capsule, USFDA approved.
	For generic drugs (me-too status)	Razodex 60mg capsule by M/s Getz Pharma (Reg#086976).
	GMP Status	GMP Certificate No. 241/2019-DRAP (K), Dated, 20-09-2019.
	Decision of 344 meeting of RB:	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings. 1. Reference of previous approval of applications with stability study data of the firm shall be submitted. 2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. 3. Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. 4. Record of comparative dissolution data shall be submitted. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. 6. Compliance Record of HPLC software 21CFR & audit trail

		reports on product testing shall be submitted. 7. Submit valid GMP certificate of Semos Pharmaceuticals	
STABILITY STUDY DATA			
Drug	Dexprazole 60mg Capsules		
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.		
API Lot No.	DP 775		
Description of Pack (Container closure system)	1x10's, 2x7's, 3x10's, MRP as per SRO		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RDC-01	RDC-01	RDC-01
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	16-09.2021	16-09.2021	16-09.2021
No. of Batches	03		
Date of Submission	Dy No. 9752 dated 04-03-2019		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Finished product manufacturer and API manufacturer provided method of analysis for API.	
4.	Stability study data of API from API manufacturer	Submitted	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019, dated 31-07-19 valid for 3 years	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased	

7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.
10.	Complete batch manufacturing record of three stability batches.	submitted.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Dexprazole 60mg Capsule (Dexlansoprazole) against Razodex 60mg Capsule, Btach No. 052C48, Mfg. Date 06-2020, manufactured by Getz Pharmaceuticals Pvt Ltd. in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted summary data sheets, besides this other data not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted. Firm has used UV spectrophotometer
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted. (instead of digital data firm submitted manual data)

Remarks of Evaluator:

	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	M/s Vision Pharmaceuticals
	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	Firm has submitted data of 3 batches and employed UV for assay
	Record of comparative dissolution data shall be submitted.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	Not submitted performed assay on UV spectrophotometer
	Submit valid GMP certificate of Semos Pharmaceuticals	84/2023-DRAP valid till 20.12.25

Decision: Approved with innovator's specifications. The firm shall submit revised method of analysis on HPLC and analytical method validation studies for drug product. Moreover, the firm shall submit

applicable fee for revision of specifications.		
108.	Name, address of Applicant / Marketing Authorization Holder	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan 1L7-YBL-QQ52
	Brand Name + Dosage Form and Strength	Dexprazole 30mg Capsules
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5 Dy.No 9752 dated 04-03-2019 Rs.20,000 dated 25-02-2019
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) 30mg (Source of pellets Vision Pharma)
	Pharmacotherapeutic Group of (API)	PPI. ATC Code: A02BC06 .
.	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	DEXILANT ® Capsule, USFDA approved.
	For generic drugs (me-too status)	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976).
	GMP Status	GMP Certificate No. 241/2019-DRAP (K), Dated, 20-09-2019.
	Decision of 344 meeting of RB:	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings. 1. Reference of previous approval of applications with stability study data of the firm shall be submitted. 2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. 3. Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted. 4. Record of comparative dissolution data shall be submitted. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. 6. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. 7. Submit valid GMP certificate of Semos Pharmaceuticals
STABILITY STUDY DATA		
Drug	Dexprazole 30mg Capsules	
Manufacturer of API	M/s. Vision Pharmaceuticals Pvt Ltd, Islamabad.	
API Lot No.	DP 775	

Description of Pack (Container closure system)	1x10's, 2x7's, 3x10's, MRP as per SRO		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	RDC-01	RDC-01	RDC-01
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	16-09.2021	16-09.2021	16-09.2021
No. of Batches	03		
Date of Submission	Dy No. 9752 dated 04-03-2019		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr. No.	Documents to Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm.	Not submitted.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Certificate of Analysis of API from API Manufacturer Provided Certificate of Analysis of API from Finished Product manufacturer. Provided	
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Finished product manufacturer and API manufacturer provided method of analysis for API.	
4.	Stability study data of API from API manufacturer	Submitted	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of API manufacturer certificate No. F.3-26/2019, dated 31-07-19 valid for 3 years	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Vision Pharmaceuticals, locally purchased	
7.	Protocols followed for conduction of stability study	Submitted	
8.	Method used for analysis of FPP	Submitted	
9.	Drug-excipients compatibility studies (where applicable)	Not submitted.	
10.	Complete batch manufacturing record of three stability batches.	submitted.	
11.	Record of comparative dissolution	Firm has submitted comparative dissolution of their	

	data (where applicable)	applied formulation i.e. Dexprazole 60mg Capsule (Dexlansoprazole) against Razodex 60mg Capsule, Btach No. 052C48, Mfg. Date 06-2020, manufactured by Getz Pharmaceuticals Pvt Ltd. in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has only submitted summary data sheets, besides this other data not submitted.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not Submitted. Firm has used UV spectrophotometer
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted. (instead of digital data firm submitted manual data)

Remarks of Evaluator:

	Reference of previous approval of applications with stability study data of the firm shall be submitted.	N/A
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted	M/s Vision Pharmaceuticals
	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA shall be submitted.	Firm has submitted data of 3 batches and employed UV for assay
	Record of comparative dissolution data shall be submitted.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	Not submitted performed assay on UV spectrophotometer
	Submit valid GMP certificate of Semos Pharmaceuticals	84/2023-DRAP valid till 20.12.25

Decision: Approved with innovator's specifications. The firm shall submit revised method of analysis on HPLC and analytical method validation studies for drug product. Moreover, the firm shall submit applicable fee for revision of specifications.

109.

Name and address of manufacturer / Applicant	M/s Efroze chemical Industries ,Korangi Industrial Are, Karachi
Brand Name +Dosage Form + Strength	Mefnac DS Suspension
Composition	Each 5ml contains: Mefenamic acid....100mg
Diary No. Date of R& I & fee	Dy. No.15413; 18-9-2017; Rs.20,000/- (18-9-2017)
Pharmacological Group	Analgesic and Antipyretic
Type of Form	Form-5
Finished product Specification	Mfg
Pack size & Demanded Price	60ml, Rs.35/-
Approval status of product in Reference Regulatory Authorities.	CDSCO by India
Me-too status	Deemac Forte Suspension Reg # 039179

GMP status	19-3-2018, panel recommends the grant of renewal of the DML by way of formulation
Remarks of the Evaluator.	Evidence of approval in RRA could not be confirmed
Decision of 284 th meeting of RB:	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting
Remarks of Evaluator:	
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting	Firm has requested to reconsider our application and grant registration for our long-pending product, Mefnac DS Suspension.as per decision of the 179 th meeting of the Authority as the formulation is already registered / available in Pakistan. RRA not confirmed
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which adopted by Registration Board in its 275th meeting.	

110.

Name and address of manufacturer / Applicant	M/s Efroze chemical Industries ,Korangi Industrial Are, Karachi
Brand Name +Dosage Form + Strength	Algaphan Forte Tablet
Composition	Each film coated tablet contains: Paracetamol.....650mg Orphenadrine Citrate.....50mg
Diary No. Date of R& I & fee	Dy. No.52; 24-5-2017; Rs.20,000/- (31-3-2017)
Pharmacological Group	Analgesic and Antipyretic
Type of Form	Form-5
Finished product Specification	Innovators
Pack size & Demanded Price	15's. Rs.75/-
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in this strength
Me-too status	Nubrol Forte tablet of M/s Searle
GMP status	19-3-2018, panel recommends the grant of renewal of the DML by way of formulation
Remarks of the Evaluator.	Fee challan photocopy attached
Decision 283: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting.	
Decision 283: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting.	Firm has requested to reconsider our application and grant registration for our long-pending product, Algaphan Forte Tablet.as per decision of the 179 th meeting of the Authority as the formulation is already registered / available in Pakistan. RRA not confirmed
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which adopted by Registration Board in its 275th meeting.	

Najia Saleem

111.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers

	Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).	
Name and address of manufacturer	M/s Bimeda-MTC Animal Health Inc. 420 Beaverdale Road Cambridge, Ontario Canada N3C 2W4	
Name and address of marketing authorization holder	M/s Bimeda Animal Health Limited 2, 3,& 4 Airton close, Airton Road Tallaght Dublin 24 Ireland.	
Name of exporting country	Ireland	
Type of Form	Form-5A	
Diary No. & Date of R& I	Dy.No 38 Dated 02-01-2023	
Fee including differential fee	Rs : 75,000/- Dated 26-12-2022 (slip No. 0903499699)	
Brand Name +Dosage Form + Strength	Bimectin Horse Oral Paste	
Composition	Each gram contains: Ivermectin... 18.7mg	
Finished Product Specification	Inhouse	
Pharmacological Group	Anthelmintic	
Shelf life	24 months	
Demanded Price	Decontrolled	
Pack size	6.42gm	
International availability	Ireland approved	
Me-too status	N/A	
Detail of certificates attached	➤ Copy of original legalized GMP certificate No. 79477 dated 25-03-2025 issued by Health Canada ➤ Free sale certificate (FSC) is not provided by the firm. ➤ Copy of un-notarized Power of attorney dated 15-11-2022 provided.	
Remarks of the Evaluator ^{xxv}	The firm has submitted 6 months accelerated and 36 months' real time stability studies data as per zone II conditions. Shortcomings: • Original legalized valid FSC/ COPP • original notarized Power of attorney/sole agency certificate. • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions since you have submitted data as per zone II-A conditions.	
Decision of 336th meeting: Deferred for submission of following: • Original legalized valid FSC/ COPP • original notarized Power of attorney/sole agency certificate. • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions		
Updated status: The firm has submitted the following:		
Sr. No.	Observation	Firm's response
1	Original legalized valid	Original legalized COPP issued by HPRA Ireland confirm

	FSC/ COPP	only free sale status of the drug in country of origin.
2	original notarized Power of attorney/sole agency certificate	Original notarized Power of attorney was submitted in dossier application dated 02-01-2023. However, un-notarized POA was submitted as already mentioned in minutes
3	06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions	Copy of unsigned letter from Ms Bimeda Animal Health Limited, Ireland stating that “we cannot carry out accelerated and long-term stability studies according to the ICH guidelines for stability testing zone IV-A of Bimectin horse oral paste manufactured at Bimeda MTC Animal Health inc., Canada due to its high expense and the time frame required to get the data.” Additionally, Ms Ghazi brothers ensure proper storage conditions are maintained throughout the supply chain to preserve product integrity. Moreover, the product is exported to following countries: United states Ireland France South Africa
Decision of M-347th meeting: Deferred for submission of following: • original valid Power of attorney/sole agency certificate notarized from country of origin. • Scientific justification for not performing stability studies of finished product as per zone IV-A conditions.		
Updated status: Technical Justification: Although Bimectin Paste contain ivermectin which remain chemically stable at 30°C, it is important to consider physical stability, which directly affects product performance and user acceptability. The following points justify why the product should not be stored at or above 30°C. 1. Viscosity in relation to temperature The paste formulation contains excipients (e.g., thickeners) that are thermo-sensitive. At elevated temperatures (approaching or exceeding 30°C), these components may soften or liquefy, leading to a reduction in viscosity. This may result in: o Difficulty in accurate dosing from the syringe. o Inconsistent paste extrusion due to flow variability. o Risk of settling or phase separation. 2. Loss of Consistency Bimectin Paste is designed to maintain a semi-solid consistency to ensure proper adhesion to the oral cavity of animals. At higher temperatures, the paste may become too fluid, affecting the retention time. 3. Packaging Integrity Increased softness of the paste at 30°C may increase pressure within the syringe or tube, which can compromise packaging integrity, leading to leakage, dose inaccuracy, or microbial contamination upon exposure. 4. User Acceptability and Handling End-users (veterinarians or animal owners) may experience handling difficulties at higher temperatures due to the paste becoming sticky, runny, or uneven, thereby impacting compliance and proper administration. B) ICH Q1A(R2)-Stability Testing Justification The parent guide provides only a general guideline; therefore, for semisolid dosage forms—where physical attributes are critical to dosage form integrity—the approach of using 25°C is not only relevant but essential for ensuring compliance. Conclusion: In light of regulatory and technical justification as the active ingredient (Ivermectin) remain chemically stable at 30°C, the physical stability of Bimectin Paste especially consistency and viscosity. Therefore, it is recommended that the product be stored below 25°C to maintain its formulation integrity and preserve overall product quality and performance therefore stability at 25°C has been conducted and submitted accordingly. Shortcomings:		

	• original valid Power of attorney/sole agency certificate notarized from country of origin.
	Decision: The Registration Board was apprised that the firm failed to submit original LOA notarized from country of origin and long term stability studies data as per zone-IV/A conditions, even after lapse of 3 years. Hence the Board rejected the instant case.

Saima Hussain

112.	Name, address of Applicant / Marketing Authorization Holder	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24502 dated 06-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 1091083124 dated 29-08-2023.
	The proposed proprietary name / brand name	Suprimun S 180mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Released Tablet Contains: Mycophenolate Sodium, Equivalent to Mycophenolic Acid 180mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Myfortic 180mg Tablet. Novartis Ireland Limited. Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland. HPRA Approved.
	For generic drugs (me-too status)	Myfortic 180mg Tablet. (Registration No. 033172) M/s. Novartis Pharma Pakistan limited.
	Proposed Pack size	Pack size 120's, MRP As per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Specify the polymorphic form of the drug substance used	
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from the API manufacturer.	
5.	Submit details of the reference product against which pharmaceutical	

	equivalence studies and CDP studies are conducted.	
6.	Justify why compatibility studies are not performed while your qualitative composition is different from that of innovator's product.	
7.	Submit details of all excipients used in section 3.2.P.4.	
8.	Submit complete report of verification studies of the analytical method of drug product.	
9.	Submit COA of reference standard used for analysis of drug product.	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
12.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 343rd meeting of Registration Board:

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

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Firm submitted the specification and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer.
2.	Specify the polymorphic form of the drug substance used	Firm informed that the polymorphic form of API is Crystalline M2 Form, the same was mentioned in section 3.2.S.
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Firm submitted the assay verification studies of drug substance performed by drug product manufacturer.
4.	- Submit COA of relevant batch of API from the API manufacturer. - Justify for not performing the sodium content test and X-ray diffraction (XRD) test during the quality analysis of the drug substance by the drug product manufacturer, since these tests are recommended by USP.	Firm submitted the COA of API both from drug substance and drug product manufacturer. However, drug product manufacturer has not performed the sodium content test and X-ray diffraction test during the quality analysis of drug substance and informed that these test were only performed by drug substance manufacturer.
5.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	Firm informed that they performed comparative studies against the Myfortic 180mg Tablet (Novartis Pharma-Germany) (Mycophenolate Sodium) B# LX6013. Further, firm submit the snapshot of carton pack of reference product against which comparative studies has performed.
6.	Justify why compatibility studies are not performed while your qualitative composition is different from that of innovator's product.	Firm refer the section 3.2.P.2.2.1, in which mentioned that the quality is ensured by the literature review and FTIR study that did not show any excipients - excipients or drug - excipients incompatibility.
7.	Submit details of all excipients used in section 3.2.P.4.	Submitted
8.	Submit complete report of verification studies of the analytical method of drug product.	Firm submitted assay verification report of drug product.
9.	Submit COA of reference standard used for	Firm submitted the COA of working

	analysis of drug product.	standard.
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Firm submitted the raw data sheets, chromatograms, GMP certificate of API ,procurement documents of API ,audit trail report and data logger.
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submit the GMP certificate of API manufacturer that was valid till 14/07/2024
12.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the clearance certificate dated 28-04-2022.

Decision: Approved. Firm shall submit commitment that they will perform sodium content test and X-Ray Diffraction test on the drug substance at the time of manufacturing of commercial batches prior to the issuance of Registration letter.

113.	Name, address of Applicant / Marketing Authorization Holder	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25737 dated 24-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 4766216941 dated 11-09-2023.
	The proposed proprietary name / brand name	Suprimun S 360mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Released Tablet Contains: Mycophenolate Sodium, Equivalent to Mycophenolic Acid 360mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Myfortic 360mg Tablet. Novartis Ireland Limited. Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland. HPRA Approved.
	For generic drugs (me-too status)	Myfortic 360mg Tablet. (Registration No. 033173) M/s. Novartis Pharma Pakistan limited.
	Proposed Pack size	Pack size 120's, MRP As per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in	

	section 3.2.S.4.1 and 3.2.S.4.2	
2.	Specify the polymorphic form of the drug substance used	
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from the API manufacturer.	
5.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	
6.	Justify why compatibility studies are not performed while your qualitative composition is different from that of innovator's product.	
7.	Submit details of all excipients used in section 3.2.P.4.	
8.	Submit complete report of verification studies of the analytical method of drug product.	
9.	Submit COA of reference standard used for analysis of drug product.	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
12.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 343rd meeting of Registration Board:

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

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Firm submitted the specification and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer.
2.	Specify the polymorphic form of the drug substance used	Firm informed that the polymorphic form of API is Crystalline M2 Form, the same was mentioned in section 3.2.S.
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Firm submitted the assay verification studies of drug substance performed by drug product manufacturer.
4.	- Submit COA of relevant batch of API from the API manufacturer. - Justify for not performing the sodium content test and X-ray diffraction (XRD) test during the quality analysis of the drug substance by the drug product manufacturer, since these tests are recommended by USP.	Firm submitted the COA of API both from drug substance and drug product manufacturer. However, drug product manufacturer has not performed the sodium content test and X-ray diffraction test during the quality analysis of drug substance and informed that these test were only performed by drug substance manufacturer.
5.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	Firm informed that they performed comparative studies against the Mentioned in Module III section Formulation Development Myfortic 360mg Tablet (Novartis Pharma-Germany) (Mycophenolate Sodium) B# WMU28 Further, firm submit the snapshot of carton pack of reference product against which comparative studies has performed.
6.	Justify why compatibility studies are not performed while your qualitative composition is	Firm refer the section 3.2.P.2.2.1, in which mentioned that the quality is ensured by the

	different from that of innovator's product.	literature review and FTIR study that did not show any excipients - excipients or drug - excipients incompatibility.
7.	Submit details of all excipients used in section 3.2.P.4.	Submitted
8.	Submit complete report of verification studies of the analytical method of drug product.	Firm submitted assay verification report of drug product.
9.	Submit COA of reference standard used for analysis of drug product.	Firm submitted the COA of working standard.
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Firm submitted the raw data sheets, chromatograms, GMP certificate of API ,procurement documents of API ,audit trail report and data logger.
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submit the GMP certificate of API manufacturer that was valid till 14/07/2024
12.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the clearance certificate dated 28-04-2022.

Decision: Approved. Firm shall submit commitment that they will perform sodium content test and X-Ray Diffraction test on the drug substance at the time of manufacturing of commercial batches, prior issuance of Registration letter.

114.	Name, address of Applicant / Marketing Authorization Holder	M/s. Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura
	Name, address of Manufacturing site.	M/s. Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11789 : dated 15-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.98430327031 dated 26-12-2023
	The proposed proprietary name / brand name	Phenytoin Sodium Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml ampoule contains: Phenytoin Sodium....250mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Phenytoin Sodium 50mg/ml)
	For generic drugs (me-too status)	Epigran 250mg/5ml IV/IM of M/s. Atco (Reg.no. 047189)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1	Submit specification of drug substance used for analysis by the drug product

		manufacturer with the clarification that which pharmacopeia has been followed for analysis of drug substance by finished product manufacturer.
2.	3.2.S.4.2	- Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer, since the submitted analytical procedure neither included the test of free phenytoin, water content test and appearance of solution test as recommended in the specification of drug substance by drug substance manufacturer. - Justify for using different assay method for analysis of drug substance by drug product manufacturer from that recommended by drug substance manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.1	Justify the formulation without any pH adjuster, since the innovator/reference product used sodium hydroxide for pH adjustment.
5.	3.2.P.2.2.1	Justify for not including all the quality test as per specification of drug product in the pharmaceutical equivalence study of drug product.
6.	3.2.P.3.3	Description of Manufacturing procedure given in the requisite section reflect that the drug product neither undergone any terminal sterilization process nor the manufacturing has been done under aseptic condition, justify for not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.
7.	3.2.P.5.1	Justify for not including the test of identification, Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> in the specification of drug product.
8.	3.2.P.5.4	Justify for not including the bacterial endotoxin test, sterility test, test of Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> while performing the batch analysis of drug product, since these test are recommended by the USP Monograph of “ Phenytoin Sodium Injection ”.
9.	3.2.P.8	Justify for not including the bacterial endotoxin test, test of Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> while performing the stability study of drug product, since these test are recommended by the USP Monograph of “ Phenytoin Sodium Injection ”.

Decision of 339th meeting of Registration Board:

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification of drug substance used for analysis by the drug product manufacturer with the clarification that which pharmacopeia has been followed for analysis of drug substance by finished product manufacturer.	Firm submitted the copy of USP monograph of Phenytoin sodium.
2.	- Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer, since the submitted analytical procedure neither included the test of free phenytoin, water content test and appearance of solution test as recommended in the specification of drug substance by drug substance manufacturer. - Justify for using different assay method for analysis of drug substance by drug product	Firm submitted the copy of USP monograph of Phenytoin sodium along with Assay detailed method which is not in accordance with USP. Chromatographic conditions, final dilution of standard and sample solution and the composition of mobile phase used by the drug product manufacturer while performing the assay the assay of drug substance was not in accordance

	manufacturer from that recommended by drug substance manufacturer.	with USP Monograph.	
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm has not submitted the verification report of drug substance performed by drug product manufacturer.	
4.	Justify the formulation without any pH adjuster, since the innovator/reference product used sodium hydroxide for pH adjustment.	Firm submitted the revised formulation of applied product in which pH adjuster (10% NaOH or 10% HCl) has been included without any clarification.	
5.	Justify for not including all the quality test as per specification of drug product in the pharmaceutical equivalence study of drug product.	Firm has not submitted the reply of this query.	
6.	Description of Manufacturing procedure given in the requisite section reflect that the drug product neither undergone any terminal sterilization process nor the manufacturing has been done under aseptic condition, justify for not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.	Firm submitted a one pager manufacturing procedure in which terminal sterilization step has been included, in which filled ampoule will undergo for autoclaving at temp 121°C for 20 minutes without any clarity that why previously not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.	
7.	Justify for not including the test of identification, Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> in the specification of drug product.	Firm submitted the particle counter report instead of replying the query.	
8.	Justify for not including the bacterial endotoxin test, sterility test, test of Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> while performing the batch analysis of drug product, since these test are recommended by the USP Monograph of “ Phenytoin Sodium Injection ”.	Firm submitted has not submitted the batch analysis report including all the test in compliance of USP monograph of “ Phenytoin Sodium Injection ”.	
9.	Justify for not including the bacterial endotoxin test, test of Particulate matter in injection and other test required under the head of <i>Injections and Implanted Drug Products</i> while performing the stability study of drug product, since these test are recommended by the USP Monograph of “ Phenytoin Sodium Injection ”.	Firm submitted has not submitted the reply of this query.	

Decision of 340th meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer, since the submitted analytical procedure is not in compliance of USP recommended specification of Phenytoin Sodium.
- Submit analytical method verification report of drug substance performed by drug product manufacturer.
- Justify for not including all the quality test as per specification of drug product in the pharmaceutical equivalence study of drug product.
- Description of Manufacturing procedure given in the requisite section reflect that the drug product neither undergone any terminal sterilization process nor the manufacturing has been done under aseptic condition, justify for not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.

- Justify for not including the test of identification, Particulate matter in injection and other test required under the head of Injections and Implanted Drug Products in the specification of drug product.
- Justify for not including all the test recommended by the USP Monograph of “Phenytoin Sodium Injection” while performing the batch analysis of drug product.
- Justify for not including the bacterial endotoxin test, test of Particulate matter in injection and other test required under the head of Injections and Implanted Drug Products while performing the stability study of drug product, since these test are recommended by the USP Monograph of “Phenytoin Sodium Injection”.

Response of the Firm:

Sr.no.	Decision of 340th	Response of the Firm
1.	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer, since the submitted analytical procedure is not in compliance of USP recommended specification of Phenytoin Sodium.	Firm submitted the analytical procedure in accordance with USP.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted that assay verification report, in which system suitability parameter is not included in accordance with USP. Further, accuracy parameter has not performed according to the standards.
3.	Justify for not including all the quality test as per specification of drug product in the pharmaceutical equivalence study of drug product.	Firm submitted pharmaceutical equivalence
4.	Description of Manufacturing procedure given in the requisite section reflect that the drug product neither undergone any terminal sterilization process nor the manufacturing has been done under aseptic condition, justify for not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.	The applied drug product is manufactured using an aseptic filling process. Terminal sterilization is not applied because the formulation and/or container-closure system cannot withstand terminal sterilization conditions (e.g., heat or radiation) without adversely affecting product quality, stability, or performance. Further, firm informed that as highlighted in Evaluation of 340 meeting it is noted that in the previously submitted master formulation, a terminal sterilization step (autoclaving at 121°C for 20 minutes) was mistakenly included due to human error. In reality, no autoclaving or terminal sterilization has ever been performed, and the product has been manufactured according to the validated aseptic filling process. Revised Master Formulation attached.
5.	Justify for not including the test of identification, Particulate matter in injection and other test required under the head of Injections and Implanted Drug Products in the specification of drug product.	Firm replied that It is noted that in the previously submitted specification of the drug product, certain tests such as Identification, Particulate Matter, and other tests required under the section for Injections and Implanted Drug Products were not included. All these tests were performed during in-process and finished product quality control; however, due to human error, they were inadvertently omitted from the specification section of the CTD submission. The omission
6.	Justify for not including all the test recommended by the USP Monograph of “Phenytoin Sodium Injection” while performing the batch analysis of drug	

	product.	does not affect the overall quality, safety, or efficacy of the product. The revised Product Specification, now including all required tests, is attached for your reference. We request that this updated specification and the above clarification be kindly considered for your review and evaluation.	
7.	Justify for not including the bacterial endotoxin test, test of Particulate matter in injection and other test required under the head of Injections and Implanted Drug Products while performing the stability study of drug product, since these test are recommended by the USP Monograph of “Phenytoin Sodium Injection”.	Firm replied that, the required tests, including Bacterial Endotoxin, Particulate Matter, and other tests recommended under the USP monograph for Injections and Implanted Drug Products, were already included in the initial stability study submission. For your convenience and reference, we are resubmitting the stability sheets, including all test parameters, along with the Particle Count Reports and Bacterial Endotoxin Reports of all batches.	

Decision: The Registration Board decided to Defer the case for on-site inspection of the firm for the authenticity/verification of submitted pharmaceutical development data and stability data.



Drug Regulatory Authority of Pakistan
(Pharmaceutical Evaluation & Registration Division)



Sr. No	Title	Description
1	Case Category	Contract Manufacturing (Abdul Mughees)
	Name, address of Applicant.	Health care pharmaceuticals 40 km lahore Road multan (000905)
	Application Form Dy. No / Tracking ID & date of submission	(D5S-JNU-YX6P, 2025-10-27)
	Detail of Fee Submitted	97200, 2025-10-25,
	The proposed proprietary name / brand name	Glulavi
	Label Claim	Each lyophilized vial contains: Glutathione as sodium 600mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's, 5's -De-Controlled
	Shelf Life (Unit)	2 YearRoom temperature
	For generic drugs (me-too Status)	Thione 600 mg Injection of M/s Friends pharma
	Pharmacotherapeutic Group of (API)	Antidotes, ATC code: V03AB32
	Name, address of Manufacturing site:	M/s Crystolite Pharmaceuticals-Plot no. 1 & 2 , S-2, National Industrial Zone, Rawat-
	The status in reference regulatory authorities	TAD 600mg Injection approved by AIFA of Italy
	Detail of previous approval	Glutalite 600mg Injection approved in PRV against tracking ID no. PVN-XHZ-S7B3
	Evaluation Remarks	
2	The firm has provided reference of a PRVC approved product dated 03-March, 2025 TID PVN-XHZ-S7B3. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
	Application Form Dy. No / Tracking ID & date of submission	(1MD-VQM-3D5B, 2025-01-14)

Detail of Fee Submitted	37000.0, 2024-11-12,
The proposed proprietary name / brand name	Cefra Injection 1gm
Label Claim	Each vial of dry substance contains: Sterile Cephadrine (with L – Arginine) USP.....1gm
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store bellows 30°C. Protect from light. Improper storage may deteriorate the medicine.
For generic drugs (me-too Status)	Brand Name: Velosef Injection Strength: 1gm Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001869 Manufacturer: GlaxoSmithKline Pakistan Limited.
Pharmacotherapeutic Group of (API)	J01DB09 First-generation cephalosporins
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Pharmagen Limited 5-A,Zafer Ali Road, Gulberg-V, Lahore, Pakistan.
Detail of stability batches of drug product	3 batches 500 vials each
Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 1g B858
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 1gm Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
GMP status of the firm	----
Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted
Evaluation Remarks	
The case was considered in 351st meeting wherein following Observations were presented.	
3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalexin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.	
Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is not present in the tested samples. The assay for Cephadrine for injection is conducted strictly as per USP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not included in assay calculations but is approximately controlled as a specified impurity under the related substances procedure. The absence of a cephalixin peak in assay chromatograms is consistent with validated method sensitivity, stability data and product quality."	
The USP 2021 has monograph of Cephadrine for injection. The definition of product given in monograph is; "Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine (C16H19N3O4S) and cephalixin (C16H17 N3O4S)"	
Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephradine (sum of cephradine and cephalixin) withdrawn from the container, or in the portion of	

constituted solution taken by the formula" Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."

Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;

"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)" was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"

Decision of 351st meeting: Deferred for clarification from the firm for queries of evaluator.

Firm has submitted renewal inspection dated 28.11.2025 wherein Ceph Injectable section is mentioned. The renewal of this section is recommended by the panel. Regarding testing as per USP monograph, firm has submitted revised Method of Analysis along with its performance report (including chromatograms). As per revised testing, firm has followed USP monograph. Firm needs to submit fee for preregistration variation. The application fulfils codal formalities and is recommended for consideration of board.

Decision

Approved

3	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
	Application Form Dy. No / Tracking ID & date of submission	(44A-7G7-91M3, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-11-12,
	The proposed proprietary name / brand name	Cefra 250mg Powder for solution for IM Injection
	Label Claim	Each vial contains: Cephadrine (with L – Arginine) 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store bellow 30°C. Protect from heat, sunlight & moisture. Improper storage may deteriorate the medicine.
	For generic drugs (me-too Status)	Brand Name: Velosef Injection Strength: 250mg Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001870 Manufacturer: GlaxoSmithKline Pakistan Limited.
	Pharmacotherapeutic Group of (API)	J01DB09 Third-generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Pharmagen Ltd. Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore-Pakistan.
	Detail of stability batches of drug product	3 batches 500 vials each

Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 250mg Injecion ML2J
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 250mg Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
GMP status of the firm	----
Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted
Evaluation Remarks	
The case was considered in 351st meeting wherein following Observations were presented.	
3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalexin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.	
Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is not present in the tested samples. The assay for Cephadrine for injection is conducted strictly as per USP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not included in assay calculations but is approximately controlled as a specified impurity under the related substances procedure. The absence of a cephalixin peak in assay chromatograms is consistent with validated method sensitivity, stability data and product quality."	
The USP 2021 has monograph of Cephadrine for injection. The definition of product given in monograph is; "Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine (C16H19N3O4S) and cephalixin (C16H17 N3O4S)"	
Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephradine (sum of cephradine and cephalixin) withdrawn from the container, or in the portion of constituted solution taken by the formula" Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."	
Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;	
"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)" was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"	
Decision of 351st meeting: Deferred for clarification from the firm for queries of evaluator.	
Firm has submitted renewal inspection dated 28.11.2025 wherein Ceph Injectable section is mentioned. The renewal of this section is recommended by the panel. Regarding testing as per USP monograph, firm has submitted revised Method of Analysis along with its performance report (including chromatograms). As per revised testing, firm has followed USP monograph. Firm needs to submit fee	

for preregistration variation. The application fulfils codal formalities and is recommended for consideration of board.

Decision

Approved

4	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	AHSONS Drug Company T/1 S.I.T.E Tando Adam (000138)
	Application Form Dy. No / Tracking ID & date of submission	(EMU-GVL-YZNH, 2025-01-14)
	Detail of Fee Submitted	37000.0, 2024-11-12,
	The proposed proprietary name / brand name	Cefra 500mg powder for solution for IM Injection
	Label Claim	Each vial contains:Cephadrine (with L – Arginine) USP.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store bellows 30°C. Protect from light. Improper storage may deteriorate the medicine.
	For generic drugs (me-too Status)	Brand Name: Velosef Injection Strength: 500mg Dosage Form: IV /IM Injection Pack Size: 1's Regn No.001866 Manufacturer: GlaxoSmithKline Pakistan Limited.
	Pharmacotherapeutic Group of (API)	J01DD04 Third-generation cephalosporins
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Pharmagen Limited 5-A,Zafer Ali Road, Gulberg-V, Lahore, Pakistan.
	Detail of stability batches of drug product	3 batches 500 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Local purchased from Pharmagen
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Velosef 500mg BF3P
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Brand Name: Velosef Injection Strength: 500mg Market Authorization: M/s Apothecon Reference Regulatory Authority: USFDA Approved medicine.
	GMP status of the firm	----
	Evidence of approval of manufacturing facility	Renewal letter dated 11.05.2022 is submitted
	Evaluation Remarks	
	The case was considered in 351st meeting wherein following Observations were presented.	
	3.2.P.5 In Assay the its mentioned that only peak of Cephadrine will be calculated, the monograph of older version of USP (which is followed as evident from your submission) states that quantity of Cephadrine and Cephalixin both needs to be considered. Further in chromatograms submitted, peak of cephalixin is not present. Please justify these deviations in analytical method and performance of assay.	

Response: The firm has stated that; "No cephalixin peak is observed because cephalixin is not present in the tested samples. The assay for Cephadrine for injection is conducted strictly as per USP Monograph with quantification based only on the Cephadrine peak. Cephalixin is not included in assay calculations but is approximately controlled as a specified impurity under the related substances procedure. The absence of a cephalixin peak in assay chromatograms is consistent with validated method sensitivity, stability data and product quality."

The USP 2021 has monograph of Cephadrine for injection. The definition of product given in monograph is; "Cephadrine for Injection contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine (C16H19N3O4S) and cephalixin (C16H17N3O4S)"

Under heading of assay, procedure to calculate quantity is give as "Calculate the quantity, in mg, of cephradine (sum of cephradine and cephalixin) withdrawn from the container, or in the portion of constituted solution taken by the formula" Further the COA of drug substance lot No. 00401/22-02/002 (used in manufacturing of drug product) does indicate cephalixin content. Drug substance manufacturer (M/s Pharmagen) has quantified it as 2.48% whereas drug product manufacturer has quantified it as 2.59%. But in their response firm is claiming that "No Cephalixin peak is observed because cephalixin is not present in the tested samples."

Firm was asked to justify that their application falls under category of new section as in renewal section Ceph dry powder inj section is not mentioned as new. The firm has replied as under;

"We M/s Ahsons Drug Company Plot No: T/1, S.I.T.E Tando Adam Sindh, wish to bring in your kind notice that, our newly established section of "Dry Powder Injection Section (Cephalosporin)" was inspected and recommended for grant on 22/02/2022 by the panel constituted by chairman Central Licensing Board. Subsequently renewal of DML was granted by the CLB with inclusion of new section of "Dry Powder Injection Section (Cephalosporin)" on 11/05/2022. Since the date of approval of our new section of "Dry Powder Injection Section (Cephalosporin)" by CLB we haven't applied for any product of the said section to the Registration Board"

Decision of 351st meeting: Deferred for clarification from the firm for queries of evaluator.

Firm has submitted renewal inspection dated 28.11.2025 wherein Ceph Injectable section is mentioned. The renewal of this section is recommended by the panel. Regarding testing as per USP monograph, firm has submitted revised Method of Analysis along with its performance report (including chromatograms). As per revised testing, firm has followed USP monograph. Firm needs to submit fee for preregistration variation. The application fulfils codal formalities and is recommended for consideration of board.

Decision

Approved

5	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	Highnoon Laboratories Ltd 17.5 KM, Multan Road, (000155)
	Application Form Dy. No / Tracking ID & date of submission	(ATJ-RU3-XDYD, 2024-07-19)
	Detail of Fee Submitted	30000.0, 2024-07-03,
	The proposed proprietary name / brand name	Tagipmet 50/850 Tablet
	Label Claim	Each Film coated tablet contains: Sitagliptin (as phosphate Monohydrate) 50mg Metformin HCl.....850mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5's, 7's, 10's, 14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not Store above 30°C
	For generic drugs (me-too Status)	Sitagen-M 50/850 Tablets(088404)

	Pharmacotherapeutic Group of (API)	A10BD07 Combinations of oral blood glucose lowering drugs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Not Applicable
	Detail of stability batches of drug product	3 batches, 2083 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted. (firm already have registration of other strengths, importing material for them)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Janumet 50/850 B. No. X006346 Mfg Patheon USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Sitagliptin Zone IVa, upto 36 months. Metformin Zone IVa upto 60 months.
	The status in reference regulatory authorities	Janumet® 50 mg/850 mg film coated tablets
	GMP status of the firm	
	Evidence of approval of manufacturing facility	DML is submitted, Tablet general section mentioned in GMP certificate.
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
6	Case Category	New Section (Adil Saeed)
	Name, address of Applicant.	shrooq pharmaceuticals pvt ltd 21km feorzpur road lahore (000577)
	Application Form Dy. No / Tracking ID & date of submission	(MP2-WRT-YV8W, 2024-10-08)
	Detail of Fee Submitted	30000.0, 7000.0 2024-09-02, 2024-10-03
	The proposed proprietary name / brand name	M.cip dry oral suspension 250mg/5ml
	Label Claim	Each 5ml reconstituted Suspension contains Ciprofloxacin 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 Year(s)below 30
	For generic drugs (me-too Status)	Novidat suspension of SAMI Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Flouroquinolone antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi.pharma (Pvt) Ltd.
	Detail of stability batches of drug product	3 batches of 150 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	--
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against Novidat Suspension
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	GMP certificate issued dated 15-12-2023

	Evidence of approval of manufacturing facility	Firm has been granted additional section of "Dry Powder suspension (General)" vide letter no. F.1-29/2001-Lic (Vol-III) issued by Secretary CLB dated 14-02-2024
	Evaluation Remarks Case was deferred in 344th meeting with following decision; "For further deliberation regarding the salt form of drug substance and requirements of diluent for applied formulation" Firm has submitted response that they have used Ciprofloxacin base as its used in innovator product. But all the attachments in response and initial Module 3 submitted indicate that firm has used Ciprofloxacin HCL salt. PE is also performed against Novidate which contains HCl salt. As per submitted data, firm has not developed their product as per innovator.	
	Decision	
	Approved	
	Subject to submission of data of drug product developed by using Ciprofloxacin base along with its diluent.	
7	Case Category Name, address of Applicant. Application Form Dy. No / Tracking ID & date of submission Detail of Fee Submitted The proposed proprietary name / brand name Label Claim Reference to Finished product specifications Proposed Pack Size Shelf Life (Unit) For generic drugs (me-too Status) Pharmacotherapeutic Group of (API) Name, address of Manufacturing site: 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 GMP status of the firm	Export Facilitation (Adil Saeed) Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012) (QLN-EZ8-R32R, 2025-04-21) 30000.0, 7000.0 2024-08-16, 2025-03-07 Prestro Each film coated tablet contains: Cyproterone Acetate.....2mg Ethinyl Estradiol.....35mcg British Pharmacopeia As per DPC-De-Controlled 2 Year(s)Store below 30 degree C. Acnot 2mg + 0.035g Tablets by Zafa Pharmaceutical Laboratories (Pvt.) Ltdby Antiandrogens and estrogens ATC code: G03HB01 Self Manufacturing Hubei Gedian Humanwell Pharmaceutical Co. Ltd ,SYMBIOTEC PHARMALAB PRIVATE LIMITED 3 batches, 500,000 tablets each clearance certificate is submitted wherein both drug substances are mentioned. Diane-35 2/0.035mg tablet B. No. KT0506P Mfg Bayer Germany Cyproterone: Zone IVb upt 60 months. Ethinylestradiol: Zone II upto 18 months. Diane-35 by Bayer Inc. Health Cananda Approved Copy of GMP certificate issued on basis of inspection dated 06.03.2024 is submitted

	Evidence of approval of manufacturing facility	Renewal letter dated 26.10.2020 is submitted wherein Tablet (Hormone) Section is mentioned.
	Evaluation Remarks	
	the application is complete as per codal formalities for consideration by the Registration Board	
	Decision	
	Approved	
8	Case Category	Priority As Per 257-M of RB (Adil 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	(TAE-A2Z-EXBM, 2024-06-27)
	Detail of Fee Submitted	300000.0, 2024-04-08,
	The proposed proprietary name / brand name	Bratoma 100mg Capsule
	Label Claim	Each capsule contains. Temozolomide 100mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C. Protect from light.
	For generic drugs (me-too Status)	Temomedac 100mg Capsule Imported and Marketed by: Amgomed
	Pharmacotherapeutic Group of (API)	Anti Neoplastic
	Name, address of Manufacturing site:	Actero Middle East -On the corner of 8th Golestan , Sarvestan Blvd. Baharestan Industrial Zone, Karaj, Iran.-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Reference Product: Temodal 100mg capsule Manufacturer: Orion Corporation Batch No: 8DZAA40013 Test Product: Bratoma 100mg Capsule Manufacturer: Actero Middle East Batch No: C1902B
	Name, address of Marketing Authorization Holder:	Actero Middle East , On the corner of 8th Golestan, Sarvestan Blvd., Baharestan Industrial zone, Karaj, Iran., Iran
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate in the name of M/s Actero Middle East issued by Islamic Republic of Iran, Ministry of Health and Education. Validity Date: May 2024. CoPP granted by Islamic Republic of Iran, Ministry of Health and Education, FDA (Ref No. 665/32511 dat
	Details of Authorization Letter :	Not Applicable
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not Applicable
	The status in reference regulatory authorities	Temodal® 100 mg Capsule (Merck Sharp & Dohme (UK) Limited). European Medicine Agency
Evaluation Remarks		
The case was deferred in 349th meeting with following decision. Deferred for above mentioned Shortcomings/observations.		

Observation: 3.2.P.5: Applied formulation is available in BP as well as USP while applied specification are "In house". As per Drug Specification Rules 1978, Pharmacopial specification to be granted (if available in official monograph). Hence Finished product specifications/analytical testing method to be revised in line with Pharmacopoeia alongwith performance report of next time point of stability studies.

Initial response; The principle has provided dated 09.07.2025 undertaking that they will update their specifications and will submit all the relevant documentation till 15th July,2025. "We are actively in the process of updating and preparing the necessary documents, and we commit to finalizing and submitting all relevant documentation by 15 July 2025."

Current response: Firm has revised their product specifications as per USP monograph and have submitted new method along with its results. The response of firm is satisfactory.

the application is complete as per codal formalities for consideration by the Registration Board

Decision

Approved

As per policy for inspection abroad.

9	Case Category	Priority As Per 257-M of RB (Adil 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	(PY7-2DQ-VP7B, 2025-02-12)
	Detail of Fee Submitted	300000.0, 2024-08-21,
	The proposed proprietary name / brand name	Zabiteron 250mg
	Label Claim	Each Uncoated Tablet Contains: Abiraterone Acetate USP ... 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	120's-As per SRO
	Shelf Life (Unit)	24 Year(s)Store protected from light and moisture at temperature not exceeding from 30°C.
	For generic drugs (me-too Status)	Zytiga (Janssen Biotech) USFDA Approved
	Pharmacotherapeutic Group of (API)	L02BX03 Other hormone antagonists and related agents
	Name, address of Manufacturing site:	Zuvius Lifesciences Pvt. Ltd.-At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.)-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Abiraterone 250mg Tablet B. No. QTA19034 M/s Qilu Pharma China.
	Name, address of Marketing Authorization Holder:	Zuvius Lifesciences Pvt. Ltd., At-Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.),(India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Abyga 250mg Tablet Composition : Each Tablet Contains: Abiraterone Acetate .. 250mg MAH: M/s Amgomed Manufacturer: DEVA Holding A.S.

Halkali Merkez Mah., Basin Ekspres Cad. No.: 1
34303 Kucukcekmece- Istanbul Turkey;
Manufacturer: DEVA Holding A.S. Cerkezkoy
Organize Sanayi Bolgesi Karaagac Mah. Fatih
Bulvari No: 26 Kapakli-Tekirdag Turkey;

Evaluation Remarks

As per COPP submitted the manufacturer and marketing authorization holder both are mentioned as M/s Zuvius LiveSciences Pvt. Ltd. At Kharuni Lodhimajra Road Vill Nandpur Baddi Distt Solan,
The Manufacturing license issued by State Drugs Controller is a Loan License to manufacture for sale drugs. In place of names of technical staff M/s Beta Drugs limited with same address as that of M/s Zuvius is mentioned. (Indicating 2 firms having same address).
The fact that product is being manufactured at facility of M/s Beta Drugs limited is not mentioned in COPP where its written that manufacturer is M/s Zuvius. This indicates that COPP submitted does not depict correct information.
There is provision of contract manufacturing of products in Drugs Act 1976 and rules made thereunder. In other countries similar practices are observed where contract manufacturing is a routine practice and is clearly mentioned on COPP when a product is being manufactured on contract basis, but there is no such provision of loaning of manufacturing site to an entity to carry out their manufacturing activities in laws of Pakistan. This has neither been identified in cases of import from other countries.
The matter is placed before the board for consideration keeping in view above 2 facts i.e 1) contradiction in information of manufacturing license and COPP, 2) Nonavailability of provision of loan license in local drug laws.

Decision

Rejected

Keeping in view the fact that there is no provision of Loan DML in laws of Pakistan, the board rejected the case.

10	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(622-LV4-MUWW, 2024-03-26)
	Detail of Fee Submitted	75000.0, 2024-02-27,
	The proposed proprietary name / brand name	Evista 60mg tablet
	Label Claim	Each Film Coated Tablet contains: Raloxifene Hydrochloride 60mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's,2x10's,2x7's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30 degree celcius
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Selective estrogen receptor modulators
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s.Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002. Gujarat, INDIA

Detail of stability batches of drug product	Stability studies both accelerated and real time for three batches of drug product are submitted by firm as per conditions of zone IVA.
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted Form 6 with following statement: "we have released the shipment on Form-6 basis."
Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies both accelerated and real time for three batches of drug substance are submitted by firm as per conditions of zone IVA.
The status in reference regulatory authorities	Raloxifene Hydorchloride 60mg tablet by M/s Aspire Pharma Ltd 4 Rotherbrook Court, Bedford Road, Pete
GMP status of the firm	GMP certificate issued to the firm based on inspection carried out on 0.3.04.2023
Evidence of approval of manufacturing facility	Tablet General Section mentioned on GMP certificate.

Evaluation Remarks

S No.	Approved in 350th RB meeting with decision	Panel Inspection Observations/Remarks and conclusion
1	Registration letter shall be issued after verification of authenticity of submitted stability data by panel constituted by Chairman Registration Board	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that "they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format" Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software not 21CFR compliant and audit trail report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

11	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(5T6-U9X-U5G4, 2024-04-24)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	ASP 100mg Tablet

Label Claim	Each Tablet contains Amisulpride.....100mg
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
For generic drugs (me-too Status)	Aisul 100mg Tablet M/s Siam Pharmaceuticals Registration #105654
Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
Detail of stability batches of drug product	930 tablets 3 batches
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 100mg Tablets)
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Solian 100mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section

Evaluation Remarks

S No.	Approved in 351st RB meeting with decision	Panel Inspection Observations/Remarks and conclusion
1	Registration Board Approved the said case subject to verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that "they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format." Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trail report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

12	Case Category		Routine (Dr. Farhad Ullah)
	Name, address of Applicant.		Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission		(44H-A4P-86J5, 2024-04-22)
	Detail of Fee Submitted		30000.0, 2024-03-19,
	The proposed proprietary name / brand name		ASP 50mgTablet
	Label Claim		Each Tablet contains Amisulpride.....50mg
	Reference to Finished product specifications		British Pharmacopeia
	Proposed Pack Size		1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)		2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)		Aisul 50mg Tablet M/s Siam Pharmaceuticals Registration #106988
	Pharmacotherapeutic Group of (API)		Dopamine receptor antagonist; neuroleptic
	Name, address of Manufacturing site:		Self Manufacturing
	Name & address of API manufacturer		Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
	Detail of stability batches of drug product		930 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)		Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Comparator drug Product (Solian 50mg Tablets)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		IV-A
	The status in reference regulatory authorities		Solian 50mg Tablets M/s Sanofi-Winthrop Industrie, United Kingdom (HPRA Approved)
	GMP status of the firm		188/2023-DRAP(AD-3489860170) 14.11.23
	Evidence of approval of manufacturing facility		No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section
Evaluation Remarks			
S No.	Approved in 351st RB meeting with decision	Panel Inspection Observations/Remarks and conclusion	
1	Registration Board Approved the said case subject to verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that "they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format." Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trail report could not be verified	

due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

13	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	Wimits Pharmaceuticals Pvt. Ltd 129-Sunder Industrial Estate, Lahore (000789)
	Application Form Dy. No / Tracking ID & date of submission	(ZXH-H5B-XWSP, 2024-04-22)
	Detail of Fee Submitted	30000.0, 2024-03-19,
	The proposed proprietary name / brand name	ASP 200mg Tablet
	Label Claim	Each Tablet contains: Amisulpride.....200mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's, 2x7's, 2x10'-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at cool &dry place below 30
	For generic drugs (me-too Status)	Amiride200mg Tablet M/s Shrooq Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Dopamine receptor antagonist; neuroleptic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Atlas Life Sciences Private Limited. Address C-1/360-361, G.I.D.C. Estate, Ahmedabad – 382415, Gujarat
	Detail of stability batches of drug product	930 tablets 3 batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from M/s Medisure letter ref No. ML/03/2022 and clearance certificate from Loan giver E-2670562245736 13.sep.22
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparator drug Product (Solian 200mg Tablets)

Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Solian 50mg Tablets M/sSanofi-Winthrop Industrie, United Kingdom(HPRA Approved)
GMP status of the firm	188/2023-DRAP(AD-3489860170) 14.11.23
Evidence of approval of manufacturing facility	No. F.1-51/2004-LIC dated 7th -02-2014 mentioning tablet section

Evaluation Remarks

S No.	Approved in 351st RB meeting with decision	Panel Inspection Observations/Remarks and conclusion
1	Registration Board Approved the said case subject to verification of loan letter of API & the authenticity of the submitted stability data by the panel constituted by the Chairman, Registration Board.	Observations/Remarks; During the on-site verification, the submitted drug product stability data was presented by the firm in archived form through the lab solution software of HPLC. Upon inquiring, the firm submitted that "they keep the data in online status till one year and since the instant study was conducted in 2023 hence the data has been shifted in the archive format." Hence the stability data of the applied product was accessible from HPLC software system in the archive section of the Lab solution software and was not available in the online report formats. Conclusion: Considering the firm's response that HPLC software was not 21CFR compliant and audit trail report could not be verified due to archiving of data, concerns remained regarding the integrity of the data. The panel recommended that this case be submitted before the Registration Board for further consideration and necessary action.

Decision

Deferred

The Registration Board decided to give an opportunity of Personal Hearing to the firm for observations noted during product specific inspection

14	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd. 154, Industrial Triangle, Kahuta Road (000393)
	Application Form Dy. No / Tracking ID & date of submission	(JJY-RT3-NSVJ, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-05-16,
	The proposed proprietary name / brand name	Cesod 250 mg IV Injection
	Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone USP.....250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	24 MonthStore at 15– 25°C
	For generic drugs (me-too Status)	Oxidil 250mg (IV) Injection Manufacturer: Sami Pharmaceuticals Generic Name: Ceftriaxone sodium Registration No: 023393
	Pharmacotherapeutic Group of (API)	

Name, address of Manufacturing site:	Arreta Pharmaceuticals (Private) Limited-Arreta Pharmaceuticals (Private) Limited ,Plot No. 13, N-5, Rawat Industrial Estate, Islamabad, Rawalpindi, Islamabad Capital Territory-
The status in reference regulatory authorities	Brand name: Rocephin 250 mg Powder for Solution for Injection Generic name: Ceftriaxone sodium Reference authorities: FDA Reference ID: 4290275
Detail of previous approval	Cefre 250 mg IV Injection (M-291)

Evaluation Remarks

S No.	Deficiencies	Firm's Response
1	You are once again advised to provide correct cross referred product as your reference could not be verified.	We applied our Toll registration in PRV on 03-06-2025, and we were granted the Cesod IV Injection "Ceftriaxone Soidum" On Contract Manufacturing range in September 2025. Therefore, kindly withdraw/cancel our request, as we do not wish to pursue this application further.

Decision

Rejected

Registration Board acceded the request of the firm

15	Case Category		Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.		Amson Vaccines & Pharma (Pvt.) Ltd. 154, Industrial Triangle, Kahuta Road (000393)
	Application Form Dy. No / Tracking ID & date of submission		(RWU-EUZ-XWDP, 2024-06-27)
	Detail of Fee Submitted		75000.0, 2024-05-07,
	The proposed proprietary name / brand name		Cesod 2 gm IV Injection
	Label Claim		Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone USP.....2 gm
	Reference to Finished product specifications		United States Pharmacopeia
	Proposed Pack Size		1's-As per SRO
	Shelf Life (Unit)		24 MonthStore at 15– 25°C
	For generic drugs (me-too Status)		Brand name: Oxidil 2gm (IV) Injection Manufacturer: Sami Pharmaceuticals Generic Name: Ceftriaxone sodium Registration No: 086609
	Pharmacotherapeutic Group of (API)		
	Name, address of Manufacturing site:		Arreta Pharmaceuticals (Private) Limited-Arreta Pharmaceuticals (Private) Limited ,Plot No. 13, N-5, Rawat Industrial Estate, Islamabad, Rawalpindi, Islamabad Capital Territory-
	The status in reference regulatory authorities		Brand name: Rocephin 2gm Powder for Solution for Injection Generic name: Ceftriaxone sodium Reference authorities: FDA
	Detail of previous approval		Cefire 2g IV Injection (M-291)
Evaluation Remarks			
S No.	Deficiencies	Firm's Response	

1	You are once again advised to provide correct cross referred product as your reference could not be verified.	We applied our Toll registration in PRV on 03-06-2025, and we were granted the CESOD IV Injection “Ceftriaxone Soidum” on Contract Manufacturing range in September 2025. Therefore, kindly withdraw/cancel our request, as we do not wish to pursue this application further.

Decision

Rejected

Registration Board acceded the request of the firm

16	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	(YVT-B89-E2UQ, 2024-03-12)
	Detail of Fee Submitted	30000.0, 2023-12-04,
	The proposed proprietary name / brand name	Pharbion injection
	Label Claim	Each 3 ml of ampoule contains: Vitamin B1 (Thiamine hydrochloride) 100 mg Vitamin B6 (Pyridoxine hydrochloride)..... 100 mg Vitamin B12 (Cyanocobalamin) 1000 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3ml-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30C
	For generic drugs (me-too Status)	Neurobion Injection by Martin Dow Marker Ltd
	Pharmacotherapeutic Group of (API)	Vitamin B1 in combination with vitamin B6 and/or vitamin B12
	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 1000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 30-04-2022 specifying 100kg Pyridoxin HCl and 100kg Thiamine HCl. Firm has also submitted copy of clearance certificate dated 30-04-2022 specifying 01kg Cyanocobalamin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Neurobion Injection by M Martin Dow Marker 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	Neurobion solution for injection Germany Approved
	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	Not submitted
	Evaluation Remarks	
	Deferred in 352nd meeting of RB;	
	S No.	Deferment Reason Firm's Response

1	The Registration Board deferred the case, as the cyanocobalamin assay was performed by the UV method instead of the required HPLC method.	Firm has submitted specifications, HPLC method for assay test of cyanocobalamin and summary report
Decision		
Deferred		
Registration Board decided to defer the case for submission of assay results of cyanocobalamin on HPLC method		
17	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	McOlson Research Laboratories Pvt. Ltd Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhpura Pakistan (000664)
	Application Form Dy. No / Tracking ID & date of submission	(YBT-Q72-SUGG, 2024-05-29)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	Thiomac 4 mg Capsule
	Label Claim	Each Capsule Contains: Thiocolchicoside: 4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's & 30's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	Colril 4 mg Capsule
	Pharmacotherapeutic Group of (API)	Centrally acting muscle relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	Provided for six months
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate uploaded by firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability studies as condition of zone IVa submitted by firm.
	The status in reference regulatory authorities	Approved in ANSM, https://thesynapse.net/wp-content/uploads/2016/02/Muscoril_4mg_SmPC.pdf
	GMP status of the firm	
	Evidence of approval of manufacturing facility	CLB letter dated 14 Feb 2024 indicate Capsule General section.
Evaluation Remarks		
Decision		
Approved		
18	Case Category	Routine (Haleema Sharif)
	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	(JRA-4YX-YV33, 2024-04-29)
	Detail of Fee Submitted	30000.0, 2024-04-22,
	The proposed proprietary name / brand name	Coxitab Tablet 120 mg
	Label Claim	Each Film Coated Tablet contains:Etoricoxib 120 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Accelerated 40°C± 2°C/75%±5%RH, Long term 30 °C± 2°C /65%±5%RH
	For generic drugs (me-too Status)	“Starcox TM Immediate Release film coated Tablet is DRAP Approved
	Pharmacotherapeutic Group of (API)	Selective COX-2 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Assurgen Pharma Private Limited.
	Detail of stability batches of drug product	Provided
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate uploaded by firm.
	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	Approved in MHRA, ARCOXIA ® Immediate Release Tablet is approved in AEMPS Spain
	GMP status of the firm	
	Evidence of approval of manufacturing facility	CLB renewal letter dated 2nd August 2021 indicate Tablet General section.
	Evaluation Remarks	
	Decision	
	Approved	
19	Case Category	Routine (Haleema Sharif)
	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	(9S3-961-2ZMP, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-05-06,
	The proposed proprietary name / brand name	Azilmed
	Label Claim	Each tablet contains Azilsartan Medoxomil (as Potassium) 40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place. Below 30 oC

	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blocker
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited and Address: Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka-Padra, District- Vadodara Gujarat, INDIA
	Detail of stability batches of drug product	Stability studies both accelerated (six month) and real time (24 months) submitted by firm
	Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice submitted by firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2-8 oC.
	The status in reference regulatory authorities	Food and Drug Administration (FDA) USA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	CLB letter dated 3rd March 2023 indicate Tablet general section of firm.
	Evaluation Remarks	
	The query and response of firm is mentioned in the table below for consideration of Board.	
	The expiry date of the submitted stability batches is 2020, while the application for registration was received in 2024. Kindly explain the reason-for this gap.	The stability batches submitted in the dossier were development batches manufactured earlier to establish the initial stability profile At the time of generation of these stability data, the product was under formulation development and internal evaluation, and commercialization was deferred due to strategic and business considerations. Therefore, the registration application was submitted at a later stage.
	Mention shelf life of drug substance and submit stability studies as per conditions of zone IVA.	Stability data as per Zone IV A is not applicable as API storage condition is 2-8 0 (cold storage).
	Residual solvent testing has not been performed by drug substance manufacturer. Please explain it.	Drug substance manufacturer has shared updated COA inclusive of residual solvent test has been Attached as Annexure II
	Upload audit trail report of 21 CFR compliant system.	Audit trail report submitted but not complete.
	Stability data of applied formulation for 24months is submitted when requirement is for 6 months only.	The 24-month stability data were submitted voluntarily as supportive and additional information, although the minimum regulatory requirement is 6 months. The rationale for submitting extended stability data is: To demonstrate stability and consistency of the formulation. To strengthen assurance regarding product quality, safety, and efficacy. To support the shelf life claim
	Decision	
	Approved	
20	Case Category	Routine (Haleema Sharif)

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	(DZ8-V4G-HLY5, 2024-06-25)
Detail of Fee Submitted	75000.0, 2024-05-06,
The proposed proprietary name / brand name	Azilmed
Label Claim	Each tablet contains Azilsartan Medoxomil (as Potassium) 80mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	14's-As per SRO, 28's-As per SRO, 30's-As per SRO, 7'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)	None
Pharmacotherapeutic Group of (API)	Angiotensin II receptor blocker
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Ami Lifesciences Private Limited and Address: Block No.82/B, ECP Road, AT & Post. Karakhadi-391 450 Taluka-Padra, District- Vadodara Gujarat, INDIA
Detail of stability batches of drug product	Stability studies both accelerated (six month) and real time (24 months) submitted by firm
Documents for the procurement of API with approval from DRAP (in case of Import)	DRAP attested commercial invoice submitted by firm.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2-8 oC.
The status in reference regulatory authorities	Food and Drug Administration (FDA) USA
GMP status of the firm	
Evidence of approval of manufacturing facility	CLB letter dated 3rd March 2023 indicate Tablet general section of firm.
Evaluation Remarks	
The query and response of firm is mentioned in the table below for consideration of Board.	
The expiry date of the submitted stability batches is 2020, while the application for registration was received in 2024. Kindly explain the reason-for this gap.	The stability batches submitted in the dossier were development batches manufactured earlier to establish the initial stability profile At the time of generation of these stability data, the product was under formulation development and internal evaluation, and commercialization was deferred due to strategic and business considerations. Therefore, the registration application was submitted at a later stage.
Mention shelf life of drug substance and submit stability studies as per conditions of zone IVA.	Stability data as per Zone IV A is not applicable as API storage condition is 2-8 0 (cold storage).
Residual solvent testing has not been performed by drug substance manufacturer. Please explain it.	Drug substance manufacturer has shared updated COA inclusive of residual solvent test has been Attached as Annexure II

	Upload audit trail report of 21 CFR compliant system.	Audit trail report submitted but not complete.
	Stability data of applied formulation for 24months is submitted when requirement is for 6 months only.	The 24-month stability data were submitted voluntarily as supportive and additional information, although the minimum regulatory requirement is 6 months. The rationale for submitting extended stability data is: To demonstrate stability and consistency of the formulation. To strengthen assurance regarding product quality, safety, and efficacy. To support the shelf life claim
	Decision	
	Approved	
21	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	(88V-NX4-6TP2, 2025-09-30)
	Detail of Fee Submitted	97200.0, 2025-09-03,
	The proposed proprietary name / brand name	Teagra 25mg Tablets
	Label Claim	Each Film coated tablet contains: Sildenafil citrate 35.1125mg equivalent to Sildenafil 25mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degrees Celsius
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of Cyclic Gmp-Specific Phosphodiesterase (Type V) With Vasodilator Action; Urologicals; Drugs Used In Erectile Dysfunction (ED).
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd -Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan. -
	The status in reference regulatory authorities	Viagra 25mg Tablets, Manufactured By: VIATRIS US FDA Approved
	Detail of previous approval	RIPPLE 25MG TABLETS ; 345 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	
22	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(3BW-2WZ-BGZX, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Gabasen 2.5mg Tablet
	Label Claim	Each film coated tablet contain: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No. 129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
23	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(4N4-VZA-G8YW, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	ELM Plus Tablet 25mg/5mg/1000mg
	Label Claim	Each Film Coated Tablet Contains: Empagliflozin (Immediate Release layer)...25mg Linagliptin (Immediate Release layer)...5mg Metformin HCl (Extended Release Core)...1000mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10s-As per SRO,2x10s-As per SRO,2X7s-As per SRO,3x10s-As per SRO,4x7s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-340
	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	
24	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(4PD-5UX-1N1R, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Sildew 4mg Capsule
	Label Claim	Each capsule contains: Silodosin.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
25	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat -

	Islamabad (000889)																						
Application Form Dy. No / Tracking ID & date of submission	(78Q-WS5-RYBY, 2026-01-12)																						
Detail of Fee Submitted	97200, 2025-12-09,																						
The proposed proprietary name / brand name	ELM Plus Tablet 10mg/5mg/1000mg																						
Label Claim	Each Film Coated Tablet Contains: Empagliflozin (Immediate Release layer)...10mg Linagliptin (Immediate Release layer)...5mg Metformin Hcl (Extended Release Core)...1000mg																						
Reference to Finished product specifications	As per Innovators Specification																						
Proposed Pack Size	1x10s-As per SRO,2x10s-As per SRO,2X7s-As per SRO,3x10s-As per SRO,4x7s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -																						
The status in reference regulatory authorities	Attached																						
Detail of previous approval	M-340																						
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																							
26	<table> <tr> <td>Case Category</td><td>Contract Manufacturing (Incharge Evaluation Cell)</td></tr> <tr> <td>Name, address of Applicant.</td><td>Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)</td></tr> <tr> <td>Application Form Dy. No / Tracking ID & date of submission</td><td>(7SY-5AL-VWVL, 2026-01-12)</td></tr> <tr> <td>Detail of Fee Submitted</td><td>97200, 2025-12-16,</td></tr> <tr> <td>The proposed proprietary name / brand name</td><td>Amlodew 5/160mg Tablet</td></tr> <tr> <td>Label Claim</td><td>Each film coated tablet contains: Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/ 160mg</td></tr> <tr> <td>Reference to Finished product specifications</td><td>United States Pharmacopeia</td></tr> <tr> <td>Proposed Pack Size</td><td>As Per SRO-As per SRO</td></tr> <tr> <td>Shelf Life (Unit)</td><td>2 Year15-30c</td></tr> <tr> <td>For generic drugs (me-too Status)</td><td>Attached</td></tr> <tr> <td>Pharmacotherapeutic Group of (API)</td><td>Attached</td></tr> </table>	Case Category	Contract Manufacturing (Incharge Evaluation Cell)	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)	Application Form Dy. No / Tracking ID & date of submission	(7SY-5AL-VWVL, 2026-01-12)	Detail of Fee Submitted	97200, 2025-12-16,	The proposed proprietary name / brand name	Amlodew 5/160mg Tablet	Label Claim	Each film coated tablet contains: Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/ 160mg	Reference to Finished product specifications	United States Pharmacopeia	Proposed Pack Size	As Per SRO-As per SRO	Shelf Life (Unit)	2 Year15-30c	For generic drugs (me-too Status)	Attached	Pharmacotherapeutic Group of (API)	Attached
Case Category	Contract Manufacturing (Incharge Evaluation Cell)																						
Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)																						
Application Form Dy. No / Tracking ID & date of submission	(7SY-5AL-VWVL, 2026-01-12)																						
Detail of Fee Submitted	97200, 2025-12-16,																						
The proposed proprietary name / brand name	Amlodew 5/160mg Tablet																						
Label Claim	Each film coated tablet contains: Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/ 160mg																						
Reference to Finished product specifications	United States Pharmacopeia																						
Proposed Pack Size	As Per SRO-As per SRO																						
Shelf Life (Unit)	2 Year15-30c																						
For generic drugs (me-too Status)	Attached																						
Pharmacotherapeutic Group of (API)	Attached																						

	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
27	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(83S-PLU-MHTJ, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Gabasen 10mg Tablet
	Label Claim	Each film coated tablet contain: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
28	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)

	Application Form Dy. No / Tracking ID & date of submission	(96X-4U8-AXH1, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	CECATRIL (Racecadotril) 10 mg Sachet
	Label Claim	Each sachet contains: Racecadotril 10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,16's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Racedo 10mg sachet (Highnoon laboratories ltd.)
	Pharmacotherapeutic Group of (API)	antidiarrheals. WHO ATC Code: A07XA04
	Name, address of Manufacturing site:	M/s. Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Approved by HPRA, Ireland.
	Detail of previous approval	Product Name: Acetril 10mg Sachet, Meeting No.: 347th 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	
29	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(9H3-728-XPBQ, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-11,
	The proposed proprietary name / brand name	Avinal 100mg Tablet
	Label Claim	Each tablet contains: Avanafil..... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Avala 100mg Tablet, Manufacturer: Medizan Laboratories Approved in: 351st DRB Meeting
	Pharmacotherapeutic Group of (API)	Urologicals: Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 100 mg Initial U.S. Approval: 2012

		Company: Manufactured for VIVUS, Inc. Mountain View, CA 94040 Manufactured in Osaka Japan
	Detail of previous approval	Avala 100mg Tablets, Approved in 351st 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	
30	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(9JR-ZYX-8T8D, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-21,
	The proposed proprietary name / brand name	Tamsopin-D Capsule
	Label Claim	Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) 0.5 mg Tamsulosin hydrochloride (as modified release pellets) 0.4 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Maxflow-D Capsule CCL Pharmaceuticals (Pvt.) Ltd. Reg. 091571
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules Milpharm Limited Medicines and Healthcare products Regulatory Agency (MHRA)
	Detail of previous approval	335th 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	
31	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(9T7-V32-WP8Z, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Tofdin 5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib...5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	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	
32	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(AMT-VJ5-SS41, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Amlodew 5/80mg Tablet
	Label Claim	Each film coated tablet contains: Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....5mg/ 80mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c

	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No. 8 Street No S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
33	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(B2X-WTE-R63Y, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	DESRIN 0.5MG/ML SYRUP
	Label Claim	Each ml of Syrup contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Neo-Antial Syrup 0.5mg/ml by M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Data Already approved in 331 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	Clarinx Syrup 0.5mg/ml ,(US-FDA) Approved
	Detail of previous approval	Kardine Syrup in 331 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	

34	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(B68-YJE-32MV, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Gabasen 5mg Tablet
	Label Claim	Each film coated tablet contain: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,14s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
35	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(E5M-VBP-925W, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-10-02,
	The proposed proprietary name / brand name	avanalet 50mg tablet
	Label Claim	Each tablet contains: Avanafil 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	medizan laboratory
	Pharmacotherapeutic Group of (API)	phosphodiesterase 5 (PDE5) inhibitors
	Name, address of Manufacturing site:	medizan laboratroy-Plot No 313, Kahuta Road Islamabad-
	The status in reference regulatory authorities	FDA APPORVED

	Detail of previous approval	M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
36	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(H7Q-H4U-XER5, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Tofdin 10mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib...10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	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	
37	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	(HMR-AWP-AV36, 2026-01-12)

	Detail of Fee Submitted	97200, 2025-12-12,
	The proposed proprietary name / brand name	DYDROTAB 10MG TABLET
	Label Claim	Each Film coated tablet contains: Dydrogesterone.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10x10's (100's)-As per SRO, 1x10's (10's)-As per SRO, 2x10's (20's)-As per SRO, 3x10's (30's)-As per SRO, 4x10's (40's)-As per SRO
	Shelf Life (Unit)	24 MonthStore below 30°C
	For generic drugs (me-too Status)	Ovagest Tablets 10mg by Aries (Reg. No. 086481)
	Pharmacotherapeutic Group of (API)	G03DB01 Pregnadien derivatives
	Name, address of Manufacturing site:	ARIES PHARMACEUTICAL (PRIVATE) LIMITED -FACTORY/ 1-W, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR-
	The status in reference regulatory authorities	Duphaston 10mg Tablets by Abbott (Medicines Evaluation Board, Netherlands)
	Detail of previous approval	Dydrova Tablets 10mg, Toll for Martin Dow Limited - Approved in 352nd RB 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	
38	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(J8R-R53-M6MB, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Dewferric Injection
	Label Claim	Each 10ml Ampoule Contains: Ferric Carboxymaltose Equivalent to Elemental Iron.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10ml-As per SRO, 1x20ml-As per SRO, 1x2ml-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -

	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
39	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	(JBY-PEG-J91R, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-29,
	The proposed proprietary name / brand name	Ripple 25mg Tablet
	Label Claim	Each Film coated Tablet: Sildenafil as Citrate 25mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s, 1x10s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade
	For generic drugs (me-too Status)	Ripple 25mg tablet M/s by Solaris Life Sciences Pvt Ltd. plot no.08 street no S-1 RCCI industrail estate Rawat.Pakistan
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of Cyclic GMP-Specific Phosphodiesterase (Type V) with Vasodilator Action.
	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	Viagra 25mg tablet Mfg by Viatris EI thawra St.almazia Cairo Egypt US FDA approved,
	Detail of previous approval	345 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	
40	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
Application Form Dy. No / Tracking ID & date of submission	(JE9-53G-8SQJ, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-09,
The proposed proprietary name / brand name	Remobect 1g Injection
Label Claim	Each vial contains: Cefoperazone (as Sodium) 500mg Sulbactam (as Sodium) 500mg
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:	Seraph Pharmaceuticals-Plot No.210 Industrial Triangle Kahuta Road Islamabad-
The status in reference regulatory authorities	Attached
Detail of previous approval	M-326
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	
41	Case Category
Name, address of Applicant.	Semos Pharmaceuticals PVT LTD Plot No.11, Sector 12-A North Karachi, Industrial Area, Karachi, Pakistan (000335)
Application Form Dy. No / Tracking ID & date of submission	(LLV-SDT-Z7EP, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-10,
The proposed proprietary name / brand name	Kast Sachet 4mg
Label Claim	Each sachet contains: Montelukast Sodium equivalent to.....4mg of Montelukast (USP Specifications)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2X7's, 4x7's-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Montika Sachet 4mg (Reg No: 050744) By Sami Pharmaceuticals (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Montelukast Sodium (M/s Dhanuka Laboratory Ltd.,)

	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved Brand name: Singulair (Montelukast sodium) oral granules
	Detail of previous approval	Meeting No: Minutes of 336th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
42	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(MLA-PU5-M8SG, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-19,
	The proposed proprietary name / brand name	EsoNap DR
	Label Claim	Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR.....20mg Naproxen as enteric coated core 375mg
	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 YearDon't store above 30C
	For generic drugs (me-too Status)	Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338
	Pharmacotherapeutic Group of (API)	esomeprazole : Proton Pump Inhibitor Naproxen: Nonsteroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals -Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/375mg USFDA
	Detail of previous approval	324 DRB Minutes of meeting (Esonyp DR 20/375Tablet)
	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	
43	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Seraph Pharmaceutical Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860)
	Application Form Dy. No / Tracking ID & date of submission	(MPQ-UV3-JJ5H, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-23,
	The proposed proprietary name / brand name	Tadil 20mg Tablet
	Label Claim	Each film-coated tablet contains: Tadalafil..... 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 30C
	For generic drugs (me-too Status)	Culis 20mg Tablet by Solaris Life Sciences
	Pharmacotherapeutic Group of (API)	Urologicals
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	FDA Approved drug
	Detail of previous approval	Culis 20mg Tablet , 352nd 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	
44	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(NPB-2JG-1H26, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-21,
	The proposed proprietary name / brand name	Fospin Ultra 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	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C

	For generic drugs (me-too Status)	Focin Ultra sachet Manufacturer: Tabros Pharma (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	antibiotics. WHO ATC Code: J01XX01
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Monurol 3g Sachet Manufacturer: Zambon Switzerland Ltd., Address: 6814 Cadempino, Switzerland
	Detail of previous approval	347th 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	
45	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(NWX-YA1-NTV4, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Amlodew 10/160mg Tablet
	Label Claim	Each film coated tablet contains: Amlodipine besylate (equivalent to Amlodipine)/ Valsartan.....10mg/ 160mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No. 8 Street No S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-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	
46	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Tovida Pharmaceuticals (Pvt) Ltd Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad (000996)
	Application Form Dy. No / Tracking ID & date of submission	(P7W-9QV-P6V5, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-27,
	The proposed proprietary name / brand name	ROLAC INJECTION 30MG/ML
	Label Claim	Each ml contains: Ketorolac Tromethamine 30mg USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Toradol 30mg/ml injection by Martin dow
	Pharmacotherapeutic Group of (API)	Anti-Inflammtory
	Name, address of Manufacturing site:	Carer Pharmaceuticals Industries -Plot #27,Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	Ketorolac Tromethamine injection 30mg/ml Peck fortan Pharmaceuticals Limited MHRA Approved
	Detail of previous approval	333th minutes of meeting held on 19th to 20th dec 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	
47	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(PZ7-MLU-ME16, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-11,
	The proposed proprietary name / brand name	Avinal 50mg Tablet
	Label Claim	Each tablet contains: Avanafil..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C

	For generic drugs (me-too Status)	Avala 50mg Tablet, Manufacturer: Medizan Laboratories Approved in: 351st DRB Meeting
	Pharmacotherapeutic Group of (API)	Urologicals; Drugs used in erectile dysfunction
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, Initial U.S. Approval: 2012,. Company: Manufactured for VIVUS, Inc. Mountain View, CA 94040 Manufactured in Osaka Japan
	Detail of previous approval	Avala 50mg Tablets, Approved in 351st 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	
48	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pine Pharmaceuticals Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955)
	Application Form Dy. No / Tracking ID & date of submission	(Q38-WRU-Y744, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-21,
	The proposed proprietary name / brand name	Montipin 4mg sachet
	Label Claim	Each sachet contains. Montelukast Sodium (equivalent to Montelukast).....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Myteka 4mg Tablet Manufacturer: Hilton Pharma (Private) Limited
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Singulair 4mg Sachet Manufacturer: MERCK & CO., INC Address: Whitehouse Station, NJ 08889, USA
	Detail of previous approval	339th 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	
49	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Winlet Pharmaceuticals (Pvt) Ltd. 30-Km, Lahore Sargodha Raod, Sargodha (000874)
	Application Form Dy. No / Tracking ID & date of submission	(QB5-PXA-QTNU, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-10-02,
	The proposed proprietary name / brand name	avanalet 100mg tablet
	Label Claim	Each tablet contains: Avanafil 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 °C
	For generic drugs (me-too Status)	medizan laboratory
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	medizan laboratroy-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	FDA APPORVED
	Detail of previous approval	M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
50	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(RBL-924-BADG, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Etoxib 60mg Tablet
	Label Claim	Each film coated tablet contains: Etoricoxib.....60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO

	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(RWN-9JR-B2WY, 2026-01-12)
51	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	Ondew 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	1x10s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-326
	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	

52	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(SSM-JT1-XY39, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Resdew 80mg Tablet
	Label Claim	Each Film Coated Tablet contains: Resmetirom.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,12s-As per SRO,20s-As per SRO,28s-As per SRO,30s-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:	Wimits Pharmaceuticals (Pvt) LTD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
53	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(TVR-RZ6-MMWE, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	T-Lide 12.5mg/ml Injection
	Label Claim	Each ml ampoule Contains: Levosulpride 12.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x2ml-As per SRO,5x2ml-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:	Wimits Pharmaceuticals (Pvt) ITD-Plot No.129 Sundar Industrial Estate Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-340
	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	
54	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(U4E-GMH-WDYN, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	Faster 1% Cutaneous Solution
	Label Claim	Each Gram contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Terbisil Lotion by M/s Saffron Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Data already approved in 343 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	343 meeting, LAMICAL 1% Cutaneous Solution
	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	
55	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Semos Pharmaceuticals PVT LTD Plot No.11, Sector 12-A North Karachi, Industrial Area, Karachi, Pakistan (000335)

Application Form Dy. No / Tracking ID & date of submission	(U7S-PY6-7NM9, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-10,
The proposed proprietary name / brand name	Sonion 20mg Soft Gel Capsule
Label Claim	Each Soft Gel Capsule contains: Isotretinoin.....20mg (BP Specifications)
Reference to Finished product specifications	British Pharmacopeia
Proposed Pack Size	2x10's, 3x10's, 5x10's-As per SRO
Shelf Life (Unit)	2 YearRoom Temperature
For generic drugs (me-too Status)	Altrezam 20mg Soft Gel Capsule By Biogen Life Sciences
Pharmacotherapeutic Group of (API)	API Name: Isotretinoin (Manufacturer name: Chongqing Huapont Shengchem Pharmaceuticals Co. Ltd. China)
Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
The status in reference regulatory authorities	MHRA Approved, Brand name: Isotretinoin 20mg Soft Capsule (Isotretinoin)
Detail of previous approval	Meeting No: Minutes of 312th Meeting of Registration Board
Evaluation Remarks	
In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
Decision	
Approved	
56	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
	(V1D-SH8-VB3J, 2026-01-12)
	Detail of Fee Submitted
	97200, 2025-11-25,
	The proposed proprietary name / brand name
	Tazowl 2.25gm Injection
	Label Claim
	Each Vial contains: Piperacillin (as Piperacillin Sodium)..... 2.0 g Tazobactam (as Tazobactam Sodium)..... 0.25 g
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	1's-As per SRO
	Shelf Life (Unit)
	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)
	Tanzo Injection 2.25gm by Bosch Pharmaceuticals.
	Pharmacotherapeutic Group of (API)
	β-Lactamase inhibitor

	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II , Sheikhpura Road Lahore. -
	The status in reference regulatory authorities	Zosyn ® Injection is Approved in USFDA
	Detail of previous approval	Minutes of 335th meeting of Registration Board (25th April, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
57	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	(V4J-GEY-78XJ, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-10,
	The proposed proprietary name / brand name	Esoren 500mg/20mg Tablet
	Label Claim	Each modified release tablet contains: Naproxen..... 500mg (Enteric coated Core) Esomeprazole as Magnesium trihydrate.... 20mg (immediate release Coat)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade
	For generic drugs (me-too Status)	Glomov 500/20mg tablet by M/s Global Pharmaceuticals Pvt Ltd. Reg.no 109338
	Pharmacotherapeutic Group of (API)	Nonsteroidal Antiinflammatory drug and proton pump inhibitor
	Name, address of Manufacturing site:	Solaris life Sciences (PVT) Ltd.-Plot No.08, Street no S-1 RCCI industrial Estate, Rawat Pakistan-
	The status in reference regulatory authorities	Vimovo 500/20mg tablet M/s by Astrazeneca Pharmaceutical industry biomedical campus Cambridge CB2 0AA UK MHRA approved.
	Detail of previous approval	343 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	
58	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(VPL-16G-DPP7, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	ONFAS 4MG/5ML SYRUP
	Label Claim	Each 5ml contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Onseron Syrup 4mg/5ml by M/s Indus Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Data already approved in 331 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Zofran Syrup 4mg/5ml. USFDA Approved
	Detail of previous approval	331 st meeting, Brand Name: Calsetron 4mg/5ml syrup
	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	
59	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	UNISON CHEMICAL WORKS POST OFFICE ARAIAN 15-km RAIWIND ROAD LAHORE (000174)
	Application Form Dy. No / Tracking ID & date of submission	(VUE-SJ5-D8QS, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-04,
	The proposed proprietary name / brand name	Acnefon 20mg Soft Gel Capsules
	Label Claim	Each Soft Gel Capsule Contain
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10's-As per SRO,28's-As per SRO,30's-As per SRO,56's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	3 YearBelow 30°C

	For generic drugs (me-too Status)	BIOTAN 20mg Capsule (Reg No 111034)
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	BIOTAN 20mg Capsule (Reg No 111034), Approved in Minutes of 312th meeting of Registration Board on 5
	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	
60	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Neomedix Plot #5, N-5, National Industrial Zone, Rawat (000539)
	Application Form Dy. No / Tracking ID & date of submission	(X1M-V4N-AMPN, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-10-08,
	The proposed proprietary name / brand name	Neonal Injection
	Label Claim	Each ml contains Nalbuphine Hydrochloride 10mg/ml (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Kinz inj . Reg No 018686 By Sami Pharmaceuticals (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Opioid agonist-antagonist..
	Name, address of Manufacturing site:	carer Pharmaceuticals Industries-Plot #27, Main Road, Industrial Estate, Rawat-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Nubin Injection 10mg/ml. Meeting NO 326
	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	

61	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Pharmedic Laboratories (Pvt.) Ltd Lahore 16-Km Multan Road, Lahore (000228)
	Application Form Dy. No / Tracking ID & date of submission	(XBP-TU1-1TME, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-19,
	The proposed proprietary name / brand name	EsoNap DR
	Label Claim	Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR.....20mg Naproxen (as enteric coated core) 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Pack size: 10's, 14's,20's, 28's, 30's,-As per SRO
	Shelf Life (Unit)	2 YearDon't store above 30C
	For generic drugs (me-too Status)	Glomov 20/500mg tablet by M/s Global Pharmaceutical (Pakistan)
	Pharmacotherapeutic Group of (API)	esomeprazole : Proton Pump Inhibitor Naproxen: Nonsteroidal anti-inflammatory drug (NSAID)
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals -Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg USFDA
	Detail of previous approval	Esonyp 20/500mg DR Tablet in 324 DRB Minutes of Meeting
62	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	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(XR1-H4S-H76T, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Rosotec 10mg Tablet
	Label Claim	Each film coated tablet contains: Rosuvastatin Calcium.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c

	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
63	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(XTQ-B74-PH72, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-11,
	The proposed proprietary name / brand name	Drogest 10mg Tablet
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE 10mg
	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:	Skywin Pharmaceutical-., Plot No.01 A1 Badar Industrial Estate Phase II Sheikhpura Road Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

64	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Dew-Max Pharmaceuticals (Pvt) Ltd Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad (000889)
	Application Form Dy. No / Tracking ID & date of submission	(YXR-E8X-ZMBZ, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-16,
	The proposed proprietary name / brand name	Etoxib 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 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt) Ltd-Plot No.8 Street No. S-1 RCCI Industrial Estate Rawat-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
65	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
	Application Form Dy. No / Tracking ID & date of submission	(3YZ-S9Y-7B3S, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	OMESTURN
	Label Claim	Each Vial contains: Omeprazole Sodium E.ph equivalent to Omeprazole 40 mg (BP SPECIFICATIONS)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's & 25's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Risek 40 mg IV
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)

	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Minutes of 312th DRAP 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.	
66	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(4M8-386-ADU6, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-18,
	The proposed proprietary name / brand name	Genvoid Tablet 25 mg
	Label Claim	Each Tablet contains: Bethanechol Chloride..... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Cholinergic agonist
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	Amneal Pharmaceuticals LLC
	Detail of previous approval	Bethanechol Chloride, M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
67	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)

	Application Form Dy. No / Tracking ID & date of submission	(54B-7HN-G39A, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	CLOBETA CREAM
	Label Claim	Each gram contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10g; 15g; 20g; 30g-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Lotricort Cream by M/s Dermagen Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Data already approved in 352 MoM , please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Lotriderm 0.05% w/w /1.0% w/w Cream, EMC Approved
	Detail of previous approval	Caltrim-B cream in 352MoM.
	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.	
68	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(6DV-SDJ-43UT, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Linza 100mg Tablets
	Label Claim	Linzagolix Choline eq. to Linzagolix..... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Linzagolix 100 mg Tablets
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-

	The status in reference regulatory authorities	Ysely 100 mg film-coated tablets
	Detail of previous approval	Linzagolix 100 mg Tablets, M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
69	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(8R1-QX8-TG5W, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-03,
	The proposed proprietary name / brand name	Linza 200mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix..... 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Linzagolix 200 mg Tablets
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	Ysely 200 mg film-coated tablets
	Detail of previous approval	Linzagolix 200 mg Tablets, M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
70	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)

Application Form Dy. No / Tracking ID & date of submission	(ANB-E9Z-P3Q6, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-09,
The proposed proprietary name / brand name	DOMAX
Label Claim	Each Film coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin....250mg (USP)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's -As per SRO
Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
For generic drugs (me-too Status)	CIPROXIN 250mg Tablet
Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
The status in reference regulatory authorities	USFDA
Detail of previous approval	Minutes of 312th DRAP 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

71	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	fozan pharmaceuticals Industries (Pvt) Ltd 36-A hayatabad Industrial estate, Peshawar (000567)
	Application Form Dy. No / Tracking ID & date of submission	(BMW-6WT-413Y, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	Artem 120mg
	Label Claim	Each Vial Contains: Artesunate.....120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Gen-M Injection by Genix Pharma
	Pharmacotherapeutic Group of (API)	Antimalarial
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd-Plot # 145, Industrial Triangle, Kahuta Road. Islamabad.-
	The status in reference regulatory authorities	FDA
	Detail of previous approval	BIOART 120MG IV INJECTION, 331 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	
72	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Hoechst Pakistan Limited Plot 23, Sector 22, Korangi Industrial Area, (000007)
	Application Form Dy. No / Tracking ID & date of submission	(D1T-U17-J4TU, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-19,
	The proposed proprietary name / brand name	Tamu 0.4mg Capsules
	Label Claim	Each Capsule Contains: Tamsulosin HCl as Extended Release Pellets 0.2% eq. to Tamsulosin...0.4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO, 1x7's-As per SRO, 2x10's-As per SRO, 2x7's-As per SRO, 3x10's-As per SRO, 4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Tamsol 0.4mg Capsule by Global Pharmaceuticals Pvt. Ltd (Reg No. 075421)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Name, address of Manufacturing site:	Global Pharmaceutical Pvt. Ltd-Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	TAMSULOSIN ARROW LP 0.4 mg Capsules approved by ANSM France
	Detail of previous approval	Relitams 0.4mg Capsule, 343rd DRB dated 3-5th December, 2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
73	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(DBJ-PJT-Z8MN, 2026-01-12)

	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	FLUCINIC OINTMENT 0.025% w/w
	Label Claim	Each gram contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10g; 15g; 20g; 30g-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Synalar 0.025%w/w Ointmen byM/s PHARMA HEALTH PAKISTAN (PVT) LTD
	Pharmacotherapeutic Group of (API)	Data already approved in 347 MoM , please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	SYNALAR® EDIMETRIKS PHARMACEUTICALS, INC. FDA Approved
	Detail of previous approval	Flucical Oinment in 347 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	
74	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	(DUV-56H-D6ZW, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	Noxidil 5% Topical Solution
	Label Claim	Each ml Contains: Minoxidil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Hair Max 5% w/v Topical Solution M/s Elko organization (Pvt)Ltd. Reg. No. 027592
	Pharmacotherapeutic Group of (API)	vasodilator
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.-Plot No 129, Sundar Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	BOSLEY MEN 5 MINOXIDIL TOPICAL SOLUTION M/s Bosley, inc. (USFDA Approved) Made in USA

	Detail of previous approval	REGAIN 5% Topical Solution Minutes for 343rd meeting of Registration Board (3rd-5th December, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
75	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	(L6B-WUV-1E7D, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	MIZOTEC TABLET
	Label Claim	Mizotec 50mg/200mcg Tablet Diclofenac Sodium/Misoprostol
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Rotec 50mg/200mcg Tablet of M/s. Searle Pakistan
	Pharmacotherapeutic Group of (API)	NSAIDs/Prostaglandin analogue
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot No. 129 Sundar Industrial Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Artec 50mg/200mcg Tablet Minutes of 343rd meeting of Registration Board (3rd-5th December, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
76	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Nicholas Pharmaceuticals Plot 34, Street SS-2, National Industrial Zone, Rawat (000886)
	Application Form Dy. No / Tracking ID & date of submission	(LAU-R1T-L11Z, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-02,
	The proposed proprietary name / brand name	FLUCINIC CREAM 0.025% w/w
	Label Claim	Each gram contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10g,15g,20g,30g,45g.. -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	ucin 0.025%w/w Cream by M/s Bio-Labs Pharma.
	Pharmacotherapeutic Group of (API)	Data already approved in 349 MoM , please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	SYNALAR® EDIMETRIKS PHARMACEUTICALS, INC. FDA Approved
	Detail of previous approval	Flucical Cream in 349 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	
77	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Rogen Pharmaceuticals Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. (000692)
	Application Form Dy. No / Tracking ID & date of submission	(LNU-9RP-DQP7, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-10-22,
	The proposed proprietary name / brand name	Robactum Injection 4.5gm IV
	Label Claim	Each Glass Vial Contains: Piperacillin Sodium eq. to Piperacillin 4gm Tazobactum Sodium eq. to Tazobactum 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1'S-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature
	For generic drugs (me-too Status)	TANZO
	Pharmacotherapeutic Group of (API)	piperacillin and beta-lactamase inhibitor ATC Code: J01CR05

	Name, address of Manufacturing site:	Evolution Pharmaceuticals Pvt Ltd-Plot # 25-26, Street No. S-3, National Industrial Zone, Rawat.-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	TAZO-P 4.5gm IV Inj; 343rd meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
78	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(LRE-U62-6EQE, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-18,
	The proposed proprietary name / brand name	Upaib 15 mg PR Tablet
	Label Claim	Each Film Coated Extended-Release Tablet contains: Upadacitinib Hemihydrate equivalent to Upadacitinib 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	JAK inhibitors
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	Rinvoq (upadacitinib) 15mg Extended-release Tablet
	Detail of previous approval	Upadacitinib, M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
79	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
	Application Form Dy. No / Tracking ID & date of submission	(R8G-Q9Z-APBP, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-09,
	The proposed proprietary name / brand name	DOMAX
	Label Claim	Each Film coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin....500mg (USP)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	CIPROXIN 500mg Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 312th DRAP 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	
80	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
	Application Form Dy. No / Tracking ID & date of submission	(RVJ-462-DVQ6, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	Levosyl
	Label Claim	Each Tablet contains: Levosulpiride....50mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's 20's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	LEVOPRAID 50 mg tab
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	AIFA APPROVED

	Detail of previous approval	Minutes of 323rd meeting of Registration Board (6th to 8th December, 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	
81	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	(RWD-EPT-SB71, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	Miraba 5mg Tablet
	Label Claim	Each Film coated tablet contains: Mirogabalin besilate equivalent to Mirogabalin..... 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*10's-As per SRO,2*10's-As per SRO,2*7's-As per SRO,3*10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	N02BF Gabapentinoids indicated for Neuropathic pain
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.-Plot No 129, Sundar Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 5mg Tablet Minutes of 344th meeting of Registration Board (31st December, 2024 – 02nd Januar
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
82	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
Application Form Dy. No / Tracking ID & date of submission	(SB2-92A-NRD3, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-08,
The proposed proprietary name / brand name	OMESTURN
Label Claim	Each Capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole....20 mg USP SPECIFICATIONS
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	2 X 7's, 10's, 20's,30's,&100's-As per SRO
Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
For generic drugs (me-too Status)	Risek 20mg Capsule
Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
The status in reference regulatory authorities	USFDA
Detail of previous approval	Minutes of 297th DRAP 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

83	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
	Application Form Dy. No / Tracking ID & date of submission	(SZ2-2LT-8HMR, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	Levosyl
	Label Claim	Each Tablet contains: Levosulpiride....25mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's 20's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	LEVOPRAID 25 mg tab
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-

	The status in reference regulatory authorities	AIFA APPROVED
	Detail of previous approval	Minutes of 323rd meeting of Registration Board (6th to 8th December, 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.	
84	Decision	
	Approved	
	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	(U2N-XT3-4UZ7, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-25,
	The proposed proprietary name / brand name	EBAWL SYRUP
	Label Claim	Ebawl 5mg/5ml Syrup (Ebastine)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 25 Degree Centigrade
	For generic drugs (me-too Status)	Kestine 5mg/5ml oral liquid by M/s Highnoon Labortories Ltd, Reg. No. 028369
	Pharmacotherapeutic Group of (API)	Histamine H ₁ -receptor antagonist, Anti allergic agent
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd.-Plot No 129, Sundar Estate, Raiwind Road, Lahore.-
	The status in reference regulatory authorities	USFDA Approved.
	Detail of previous approval	Ebatrix 5mg/5ml syrup Minutes of 320th meeting of Registration Board (29th-31st August, 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	
85	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)

Application Form Dy. No / Tracking ID & date of submission	(VGV-XWJ-3B9G, 2026-01-12)
Detail of Fee Submitted	97200, 2025-12-08,
The proposed proprietary name / brand name	LEVOSAT
Label Claim	Each film coated tablet contains: Levofloxacin hemihydrate eq. to Levofloxacin....500mg (USP SPECIFICATIONS)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	10's -As per SRO
Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
For generic drugs (me-too Status)	TAVANIC 500 mg tab
Pharmacotherapeutic Group of (API)	Quinolone antibiotic
Name, address of Manufacturing site:	v-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
The status in reference regulatory authorities	USFDA
Detail of previous approval	Minutes of 335th meeting of Registration Board (25th April, 2024)

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.

Decision

Approved

86	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(VH9-TMA-HY3A, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-29,
	The proposed proprietary name / brand name	Avil 100 mg Tablets
	Label Claim	Each tablet contains: Avanafil 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Avala 100 mg Tablets
	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	STENDRA™ (avanafil) tablets

	Detail of previous approval	Avala 100 mg Tablets, M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
87	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	MEDPHARM RESEARCH LAB 28 KM FEROZPUR ROAD LAHORE (000878)
	Application Form Dy. No / Tracking ID & date of submission	(VJ1-BXA-BPAQ, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-03,
	The proposed proprietary name / brand name	Pantocid Sterile Powder Injection
	Label Claim	Each vial contains: Pantoprazole as sodium sesquihydrate.....40mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 24 degree
	For generic drugs (me-too Status)	Protonix
	Pharmacotherapeutic Group of (API)	PPI'S
	Name, address of Manufacturing site:	May & Baker Pvt Ltd-45Km Multan road Lahore-
	The status in reference regulatory authorities	EMA
	Detail of previous approval	Mayclon 40mg sterile dry powder Injection IV., approved in333 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	
88	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(YBE-Q43-2BGS, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-29,

	The proposed proprietary name / brand name	Avil 50 mg Tablets
	Label Claim	Each tablet contains: Avanafil..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per Sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Avala 50 mg Tablets
	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	STENDRA™ (avanafil) tablets
	Detail of previous approval	Avala 50 mg Tablets, M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
89	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd , Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(YQB-D7A-NUDW, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-11-18,
	The proposed proprietary name / brand name	Genvoid Tablet 10 mg
	Label Claim	Each Tablet contains: Bethanechol Chloride..... 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Wimits Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Cholinergic agonist
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt) Ltd -Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore -
	The status in reference regulatory authorities	Amneal Pharmaceuticals LLC
	Detail of previous approval	Bethanechol Chloride, M-344
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
90	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	SATURN Pharmaceuticals Pvt Ltd 23km Thorar Raiwind Road Lahore (000734)
	Application Form Dy. No / Tracking ID & date of submission	(ZHD-SGP-HWBL, 2026-01-12)
	Detail of Fee Submitted	97200, 2025-12-08,
	The proposed proprietary name / brand name	MOXISAT
	Label Claim	Each film coated tablet contains: Moxifloxacin HCl eq. to Moxifloxacin 400mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	MOXIGET 400 mg tab
	Pharmacotherapeutic Group of (API)	Quinolone antibiotic (ATC Code: J01MA14)
	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 313th meeting of Registration Board (16-18 Nov, 2021)
	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	
91	Case Category	New Section (Incharge Evaluation Cell)
	Name, address of Applicant.	MAFINS PHARMA A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (000820)
	Application Form Dy. No / Tracking ID & date of submission	(GWH-8E6-DTP7, 2024-09-09)
	Detail of Fee Submitted	30000.0, 2024-07-24,
	The proposed proprietary name / brand name	Wellsef 125mg/5ml oral suspension
	Label Claim	Each 5ml (reconstituted) suspension contains: Cephadrine (anhydrous).....125mg

Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	60ml-As per SRO
Shelf Life (Unit)	2 Year(s)Store below 30 degree centigrade
For generic drugs (me-too Status)	Velosef suspension by GSK
Pharmaceutical Group of (API)	Antibiotic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Pharmagen Limited
Detail of stability batches of drug product	3 batches: 132 bottles
Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial invoice dated 14-09-2023 for 15kg cefradine
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefrinex suspension of Bosch: PE studies performed
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	3 batches as per Zone IV-A
The status in reference regulatory authorities	Not available
GMP status of the firm	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section.
Evidence of approval of manufacturing facility	Additional section approval letter dated 25-10-2023 for Dry powder suspension (Cephalosporin) section.

Evaluation Remarks

Registration Board in its 344 meeting deferred the above product for: "for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting" Accordingly, the firm was asked to submit reply in accordance with decision of the Registration Board for which first reminder was given on 18.02.2025 and second reminder was given on 30.12.2024. In response to the second reminder the firm has submitted that in 339th meeting: "Approved as per decision of the 179 meeting of the Authority as the formulation is already registered/ available in Pakistan." The actual decision of the Registration Board taken in its 339th meeting of Registration Board held from 6th to 8th August, 2024 under Case 4 for renewal cases of M/s Shazal's Pharmaceuticals is reproduced below: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. a. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. b. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. c. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Submitted for consideration of the Board.

Decision

Deferred

The Registration Board deferred the case for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.

92	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(ASY-1Q8-1XMT, 2025-06-20)
	Detail of Fee Submitted	93000.0, 2025-04-28,
	The proposed proprietary name / brand name	GenRes 60mg Tablet
	Label Claim	Each Film Coated Tablet contains: Resmetirom 60mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearProtect from heat light and moisture
	For generic drugs (me-too Status)	Manufacturer Name: Solaris Life Sciences Private Limited Address: Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat,(000992) Brand Name & Strength: Resmet (Resmetirom) 60mg Tablets Compos
	Pharmacotherapeutic Group of (API)	Thyroid hormone receptor-beta (THR-β)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Name: Wimits Pharmaceuticals (Pvt.) Ltd. Address: Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Reference Regulatory Authority: U.S. FDA Manufactured For and Distributed by: Madrigal Pharmaceutical,Inc.. West Conshohocken, PA Composition: Each tablet contains Resmetirom.....60mg NDC: 82576-060-30
	Detail of previous approval	345
	Evaluation Remarks	
	Company provided the reference of 345 meeting which is wrong as the referred product was approved in 347th meeting of DRB. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
93	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(1AT-8LY-H5B1, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	Aurodex 30MG Capsules
	Label Claim	Each Capsule contains:

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Razodex Capsule 30mg (Reg No. 086976) by getz pharma.
	Pharmacotherapeutic Group of (API)	Data Already approved in 308 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Dexilant Capsule , US-FDA
	Detail of previous approval	Lasila Capsule 30mg in 308 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	
94	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(WPZ-XGN-A6ZQ, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	Aurodex 60MG Capsules
	Label Claim	Each Capsule contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Razodex Capsule 60mg (Reg No. 086976) by getz pharma.
	Pharmacotherapeutic Group of (API)	Data Already approved in 308 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Dexilant Capsule , US-FDA
	Detail of previous approval	Lasila Capsule 60mg in 308 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	
95	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(6P6-1HB-DDXN, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Pipragen 4.5g Injection
	Label Claim	Label Claim: Each vial contains: Sterile Piperacillin Sodium eq. to Piperacillin.....4.0g, Sterile Tazobactam Sodium eq. to Tazobactam.....0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Product Name:: PIPRAL-T 4.5gm Injection (IV) Registration No: 117576 Company Name: Nimrall Laboratories Company Address: Plot No. 24, Street SS-3, Rawat Industrial Estate, Rawat Route of Admin: Intrav
	Pharmacotherapeutic Group of (API)	Piperacillin and tazobactam combination is an antibiotic that belongs to the group of medicines known as penicillins 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	Talzon Injection 4.5g, Minutes of 350th Meeting of Registration
96	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	
96	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Biogen PHarma 8-KM, Chak Beli Road, Rawat, (000639)
	Application Form Dy. No / Tracking ID & date of submission	(74R-W9E-7JNM, 2026-01-12)

	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Pipragen 2.25g Injection
	Label Claim	Each vial contains: Sterile Piperacillin Sodium eq. to Piperacillin.....2.0g Tazobactam Sodium eq. to Tazobactam.....0.25g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Product Name:: Tazonem Injection 2g/250mg Registration No: 117576 Company Name: Medera Pharmaceuticals Company Address: Plot No. 2, Street N-4, National Industrial Zone, Rawat Route of Admin: Intraven
	Pharmacotherapeutic Group of (API)	Piperacillin and tazobactam combination is an antibiotic that belongs to the group of medicines known as penicillins 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	350th 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	
97	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(A56-VMP-WB3X, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	SATOUR 4MG/5ML SYRUP
	Label Claim	Each 5ml contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Onseron Syrup 4mg/5ml by M/s Indus Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Data Already approved in 331 MoM, Please see attached.

	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Zofran Syrup 4mg/5ml , USFDA Approved
	Detail of previous approval	Calsetron 4mg/5ml Syrup in 331 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.	
98	Decision	
	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TN PHARMACEUTICALS 264-C SUNDAR INDUSTRIAL ESTATE LAHORE (000868)
	Application Form Dy. No / Tracking ID & date of submission	(AMU-7NW-495E, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	ON-TN 4mg/2 ml Injection
	Label Claim	ON-TN 4mg/2 ml injection Each 2ml contains: Ondansetron HCl Dihydrate eq. to Ondansetron 4mg (As Per 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°C in a cool and dry place.
	For generic drugs (me-too Status)	Ondit 4mg/2ml Injection by Hi-Med Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiemetic
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals.-208-C Sundar Industrial Estate Raiwind Road Lahore, Punjab, Pakistan. -
	The status in reference regulatory authorities	MHRA Approved.
	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	
99	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TN PHARMACEUTICALS 264-C SUNDAR INDUSTRIAL ESTATE LAHORE (000868)

	Application Form Dy. No / Tracking ID & date of submission	(XXN-RTX-28Y4, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	ON-TN 8mg/ 4ml Injection
	Label Claim	ON-TN 8 mg/4 ml injection Each 4ml contains: Ondansetron HCl Dihydrate eq. to Ondansetron 8mg (As Per 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°C in a cool and dry place.
	For generic drugs (me-too Status)	Denorta 8mg/4ml Injection by Nicholas Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiemetic
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals.-208-C Sundar Industrial Estate Raiwind Road Lahore, Punjab, Pakistan. -
	The status in reference regulatory authorities	MHRA Approved.
	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	
100	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TN PHARMACEUTICALS 264-C SUNDAR INDUSTRIAL ESTATE LAHORE (000868)
	Application Form Dy. No / Tracking ID & date of submission	(USY-55Q-82Y7, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	Tenfer 500mg /10 ml Injection
	Label Claim	Each 10ml contains: Iron as Ferric Carboxymaltose 500mg (As Per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	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)	Ferojin 500mg/10ml Injection by Jinnah 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, Punjab, Pakistan. -
	The status in reference regulatory authorities	MHRA Approved.
	Detail of previous approval	IN 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	
101	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medizan Laboratories (Pvt) Ltd Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572)
	Application Form Dy. No / Tracking ID & date of submission	(WSN-8RT-247G, 2026-01-12)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Aprotan-12.5mg Tablets
	Label Claim	Each film-coated tablet contains: Aprocitentan.....12.5mg
	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)	SOLARIS LIFE SCIENCES (PVT.) LTD
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Endothelin receptor antagonist (ETRA) WHO ATC Code: C02KN01
	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	SRA Registration Status: Registered in US FDA NDA:217686 Brand Name: TRYVIO 12.5mg tablets Company: Idorsia Pharmaceuticals US Inc Address: One Radnor Corporate Center Suite 101, Radnor, PA 19087, United States. https://www.accessdata.fda.gov/scripts/cder/daf/indexevent=BasicSearch.process
	Detail of previous approval	345th 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	
102	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(VQM-47J-Q6TE, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	ACINAP TABLET 375MG/20MG
	Label Claim	Each modified release tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	roxen-ES DR 375mg/20mg Tablet by /s Martin Dow Limited.
	Pharmacotherapeutic Group of (API)	Data Already approved in 340 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	VIMOVO 375mg/20mg Tablet, US-FDA
	Detail of previous approval	ASPEC 500/20 Tablet in 340 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	
103	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(SGX-DJZ-VM9X, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	VONOFAS 20MG TABLET
	Label Claim	Each film coated tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Vonozan Tablet 20mg by getz pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 322 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Takecab 20mg Tablet , PMDA Japan.

	Detail of previous approval	322 meeting, Brand Name: Vonocal 20mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
104	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(S2N-U47-4EL1, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	WONIZA 20MG TABLET
	Label Claim	Each film coated tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	vonozan Tablet 20mg by getz pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 322 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-lot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	Takecab 20mg Tablet , PMDA Japan
	Detail of previous approval	Vonocal Tablet in 322 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	
105	Case Category	Contract Manufacturing (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	(RV2-ZR6-ANQR, 2026-01-13)
	Detail of Fee Submitted	93000, 4200 2024-12-04, 2025-12-18

	The proposed proprietary name / brand name	Rig 25mg Tablet
	Label Claim	Each Film Coated Tablet contains: Omarigliptin.....25mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C
	For generic drugs (me-too Status)	Omatin Tablet by Helix Pharma
	Pharmacotherapeutic Group of (API)	DPP-4 inhibitor
	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	Omergo 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	
106	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(R3E-H1R-AT3U, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	ONFAS 8MG TABLET
	Label Claim	Each Film Coated tablet contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Zofran Tablet 8mg by M/s Novartis Pharma (Pakistan) Limited.
	Pharmacotherapeutic Group of (API)	Data already approved in 322 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	322 meeting, Brand Name: Calsetron 8mg tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
107	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(N6Z-9YD-HZ8R, 2026-01-13)
	Detail of Fee Submitted	93000, 4200 2025-07-10, 2025-12-22
	The proposed proprietary name / brand name	Vancin 1g Injection
	Label Claim	Each vial contains: (Sterile Powder for reconstitution) Vancomycin as HCl 1000mg (50mg/ml after dilution in 20ml WFI)
	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)	Brand Name: VINJEC 1g Injection,. Registration holder: BOSCH PHARMACEUTICALS (PVT) LTD., Registration number: 024115
	Pharmacotherapeutic Group of (API)	Antibacterial agent for the treatment of certain bacterial infections, such as infections caused by Clostridium difficile and Staphylococcus aureus.
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-KM, Chak Beli Road, Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	Brand Name: Vancomycin 1gm powder for concentrate for solution for infusion vials Company: Bowmed Ibisqus Limited Address : The Old Dairy, Brynkinalt Business Centre, Brynkinalt, Chirk, Wrexham, LL14 5NS, UK (MHRA approved)
	Detail of previous approval	Product name: GENOCIN 1G INJECTION, Approved in 339th DRB Meeting
108	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	
108	Approved	
	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)

	Application Form Dy. No / Tracking ID & date of submission	(MEV-PHZ-ARN7, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	CECATRIL (Racecadotril) 30 mg Sachet
	Label Claim	Each sachet contains 30 mg of Racecadotril.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,16's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Racedo 30mg sachet (Highnoon laboratories Ltd.) Reg No. 104704
	Pharmacotherapeutic Group of (API)	antidiarrheals. WHO ATC Code: A07XA04
	Name, address of Manufacturing site:	M/s. Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Approved by HPRA, Ireland.
	Detail of previous approval	Product Name: Acetril 30mg Sachet, Meeting No.: 347th 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	
109	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(L8W-HT3-2UZY, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	ASLOR 0.5MG/ML SYRUP
	Label Claim	Each ml of Syrup contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c
	For generic drugs (me-too Status)	Neo-Antial Syrup 0.5mg/ml
	Pharmacotherapeutic Group of (API)	Data already approved in 331 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Clarinex Syrup 0.5mg/ml, US FDA Approved

	Detail of previous approval	331 st meeting, Brand Name: Kardine 0.5MG/ML SYRUP
	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	
110	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(ZJD-TVY-4QH8, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Avalfin 50mg Tablets
	Label Claim	Each tablet contains: Avanafil 50mg (As per Innovators Specification)
	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)	Medizan Laboratoreis 351th meeting (132422 Aval)
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta road Islamabad-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
111	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(YWN-5MU-6UDT, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	WONIZA 10MG TABLET
	Label Claim	Each Film Coated tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	Vonozan Tablet 10mg by getz pharma
	Pharmacotherapeutic Group of (API)	Data Already approved in 322 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Takecab 10mg Tablet. PMDA Japan.
	Detail of previous approval	Vonocal 10mg Tab, in 322 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	
112	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Searle Pakistan Limited C-14, Manghopir Road, SITE, Karachi (000012)
	Application Form Dy. No / Tracking ID & date of submission	(URN-HW6-MMMB, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	OVALET (Letrozole) 2.5 mg Tablet
	Label Claim	Each film coated tablet contains: Letrozole.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Selet 2.5mg Tablets, Seraph Pharmaceutical
	Pharmacotherapeutic Group of (API)	Endocrine therapy. Hormone antagonist and related agents: aromatase inhibitor

	Name, address of Manufacturing site:	M/s. Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Approved by US FDA.
	Detail of previous approval	The product, Letrozole 2.5 mg Tablet has already been approved by the Registration Board in its 343rd meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
113	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	(UPN-EN5-UBAX, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-05,
	The proposed proprietary name / brand name	Feritol 30 mg Capsule
	Label Claim	Each capsule contains: Iron (as Ferric Maltol.) 30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year 15 °C - 30 °C
	For generic drugs (me-too Status)	Ferric Maltol 30mg Capsule
	Pharmacotherapeutic Group of (API)	Iron Supplement
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Accrufer 30 mg Capsules
	Detail of previous approval	Solafer 30mg Capsule (351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
114	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(TBU-TJU-UP2Q, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Avalfin 100mg Tablets
	Label Claim	Each tablet contains: Avanafil 100mg As per Innovators Specification
	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)	Medizan Laboratories pvt Lts (132423 Aala)
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
115	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(S1R-W7U-Y49J, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	SATOUR 8MG TABLET
	Label Claim	Each Film Coated tablet contains:
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c

	For generic drugs (me-too Status)	Zofran Tablet 8mg M/s Novartis Pharma (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	Data Already approved in 322 MoM, Please see attached.
	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 , United States Food and Drug Administration (US-FDA)
	Detail of previous approval	Calsetron 8mg tablet in 322 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	
116	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	(JJW-RM4-GTWL, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-29,
	The proposed proprietary name / brand name	Ripple 100mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil as Citrate 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s, 1x10s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade
	For generic drugs (me-too Status)	Ripple 100mg tablet M/s by Solaris Life Sciences Pvt Ltd. plot no.08 street no S-1 RCCI industrail estate Rawat.Pakistan
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of Cyclic GMP-Specific Phosphodiesterase (Type V) with Vasodilator Action.
	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	Viagra 100mg tablet Mfg by Viatris EI thawra St.almaza Cario Egypt US FDA approved,
	Detail of previous approval	345 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	
117	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	(EZ6-5A6-DGBS, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-29,
	The proposed proprietary name / brand name	Ripple 50mg Tablet
	Label Claim	Each film coated tablet contains: Sildenafil as Citrate 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4s, 1x10s-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 centigrade
	For generic drugs (me-too Status)	Ripple 50mg tablet M/s by Solaris Life Sciences Pvt Ltd. plot no.08 street no S-1 RCCI industrail estate Rawat.Pakistan
	Pharmacotherapeutic Group of (API)	Selective Inhibitor of Cyclic GMP-Specific Phosphodiesterase (Type V) with Vasodilator Action.
	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	Viagra 50mg tablet Mfg by Viatris EI thawra St.almaza Cario Egypt US FDA approved,
	Detail of previous approval	345 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	
118	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Aurik Pharmaceuticals Pvt Ltd PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI (000802)
	Application Form Dy. No / Tracking ID & date of submission	(DPX-7R7-LT1N, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-07,
	The proposed proprietary name / brand name	ACINAP TABLET 500MG/20MG
	Label Claim	Each modified release tablet contains:

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30c
	For generic drugs (me-too Status)	roxen-ES DR 500mg/20mg Tablet by /s Martin Dow Limited.
	Pharmacotherapeutic Group of (API)	Data Already approved in 340 MoM, Please see attached.
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd-lot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	VIMOVO 500mg/20mg Tablet, US-FDA
	Detail of previous approval	NASPEC 500/20 Tablet in 340 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	
119	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	(6DJ-U5V-XN7H, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	Depra 30 mg Capsule
	Label Claim	Each capsule contains: Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole 30 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15 °C - 30 °C
	For generic drugs (me-too Status)	Razodex capsules 30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Dexilant 30mg delayed release capsules
	Detail of previous approval	Exilo 30mg Capsule (M-344)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation,	

	specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
120	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	(1QR-PJA-5WB1, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-31,
	The proposed proprietary name / brand name	Depra 60 mg Capsule
	Label Claim	Each capsule contains: Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole 60 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year 15 °C - 30 °C
	For generic drugs (me-too Status)	Razodex capsules 60mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Dexilant 60mg delayed release capsules
	Detail of previous approval	Exilo 60mg Capsule (M-344)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
121	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(7R3-AGM-3M53, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2024-12-05,
	The proposed proprietary name / brand name	Cibact 1g Injection
	Label Claim	Each vial contains: Cefoperazone (as sodium).....500mg Sulbactam (as

		sodium).....500mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	2SUM 1g Injection, (Regn. No. 047002), Healthtek Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Sulperazon for Intravenous Use 1 g, Pfizer Japan Inc.
	Detail of previous approval	
	Evaluation Remarks	
	The firm has informed vide General Request Form TID ML2-9DD-92ML that their contract manufacturer has recently obtained registration of Cefoperazone + Sulbactam 1g & 2g Injection for another toll client vide PRVC letter Tracking ID: H6R-GVW-B5Z6 dated 12 August 2025. 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	
122	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(R88-ZZ3-X9DW, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2024-12-05,
	The proposed proprietary name / brand name	Cibact 2g Injection
	Label Claim	Each vial contains: Cefoperazone as sodium.....1 gm Sulbactam as sodium.....1 gm
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	2SUM 2g Injection, Regn. No. 047003, Healthtek Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Sulperazon for Intravenous Use 2 g, Pfizer Japan Inc.
	Detail of previous approval	

Evaluation Remarks		
The firm has informed vide General Request Form TID ML2-9DD-92ML that their contract manufacturer has recently obtained registration of Cefoperazone + Sulbactam 1g & 2g Injection for another toll client vide PRVC letter Tracking ID: 21J-GDT-ZYS4 dated 12th August 2025. 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		
123	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(TQA-NM9-HH1P, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Cibapride 25mg Tablet
	Label Claim	Each tablet contains: Levosulpiride.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand name: Scipride 25mg Tablet (Levosulpiride), Manufacturer/Registration holder: Getz Pharma (Pvt) Limited, Registration number: 057902
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Brand Name: Levosulpiride Aristo 25 mg tablets EFG (Levosulpiride), Manufacturer: Aristo Pharma GmbH Wallenroder Street 8-1013435 Berlin, Germany, Marketing Authorisation Number: 84561, Approved by: AIFA.
	Detail of previous approval	
Evaluation Remarks		
The firm has informed vide General Request Form TID DA5-JR2-X3BT that their contract manufacturer has recently obtained registration of Cefoperazone + Sulbactam 1g & 2g Injection for another toll client vide PRVC letter Tracking ID: Tracking ID: VEB-2QH-AXNG dated 5th June 2025. 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	
124	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CIBA Pharmaceuticals (Pvt) Ltd. A-371, Nooriabad S.I.T.E., Karachi, Hyderabad Super Highway, District Jamshoro (000825)
	Application Form Dy. No / Tracking ID & date of submission	(39P-YJS-BSJZ, 2025-05-02)
	Detail of Fee Submitted	93000.0, 2024-12-30,
	The proposed proprietary name / brand name	Cibapride 50mg Tablet
	Label Claim	Each tablet contains: Levosulpiride.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand name: Scipride 50mg Tablet (Levosulpiride), Manufacturer/Registration holder: Getz Pharma (Pvt) Limited, 29-30/27, Korangi Industrial Area karachi, Registration number: 057903.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
	The status in reference regulatory authorities	Brand Name: Levosulpiride Aristo 50mg tablets (Levosulpiride), Manufacturer: M/s. MEDOCHEMIE LTD, 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus, Marketing Authorisation Holder/Number: Aristo Pharma GmbH Wallenroder Straße 8-10 13435 Berlin Germany, Approved by: AIFA (Italian Medicines Agency)
	Detail of previous approval	
	Evaluation Remarks	
	The firm has informed vide General Request Form TID DA5-JR2-X3BT that their contract manufacturer has recently obtained registration of Levosulpiride 25 & 50 mg Injection for another toll client vide PRVC letter Tracking ID: Tracking ID: Tracking ID: 6GW-RNN-L1TG dated 5th June 2025. 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	
125	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	(Q4T-YPJ-2B5W, 2024-11-30)
Detail of Fee Submitted	93000.0, 2024-11-01,
The proposed proprietary name / brand name	Silage 50mg Tablet
Label Claim	Each tablet contains: Levosulpiride 50mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	As Per SRO-As per SRO
Shelf Life (Unit)	2 YearStore Below 30°C
For generic drugs (me-too Status)	Scipride 50mg Tablet (Levosulpiride) by Getz Pharma (Pvt) Limited, 29-30/27,Korangi Industrial Area karachi (020855)
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	M/s. Swiss Pharmaceutiucals Pvt. Ltd.-A/159, S.I.T.E. II Super Highway, Karachi – Pakistan-
The status in reference regulatory authorities	Levosulpiride Aristo 50mg tablets (Levosulpiride) MEDOCHEMIE LTD, 110 Constantinoupoleos street, 3011 Limassol, Cyprus
Detail of previous approval	
Evaluation Remarks	
The firm has informed vide General Request Form TID BUJ-MUS-3NB5 that their contract manufacturer has recently obtained registration of Levosulpiride for another toll client vide PRVC letter Tracking ID: Tracking ID: VEB-2QH-AXNG dated 5th June 2025. 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	
126	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
	(4TV-ZTJ-JJ1N, 2025-03-21)
	Detail of Fee Submitted
	93000.0, 2024-11-01,
	The proposed proprietary name / brand name
	Silage 25mg Tablet
	Label Claim
	Each tablet contains: Levosulpiride.....25mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	As per SRO-As per SRO
	Shelf Life (Unit)
	2 YearStore below 30°C
	For generic drugs (me-too Status)
	Scipride 25mg Tablet (Levosulpiride) by Getz Pharma (Pvt) Limited (057902)
	Pharmacotherapeutic Group of (API)

	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	The status in reference regulatory authorities	Levosulpiride Aristo 25 mg tablets EFG (Levosulpiride) by Aristo Pharma GmbH Wallenroder Street 8-1013435 Berlin, Germany
	Detail of previous approval	
	Evaluation Remarks	
	The firm has informed vide General Request Form TID BUJ-MUS-3NB5 that their contract manufacturer has recently obtained registration of Levosulpiride for another toll client vide PRVC letter Tracking ID: Tracking ID: VEB-2QH-AXNG dated 5th June 2025. 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	
127	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CKD Pharmaceuticals Pakistan Pvt. Ltd Plot No. 50, Sector No. 28, Korangi Industrial Area (000144)
	Application Form Dy. No / Tracking ID & date of submission	(46J-5SA-U5VH, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-10-23,
	The proposed proprietary name / brand name	Feriron Max 50mg/ml
	Label Claim	Each vial contains: Iron as Ferric Carboxymaltose.....50mg/ml
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	Ferinject
	Pharmacotherapeutic Group of (API)	Nanjing Hancer Pharmaceutical Co., Ltd.
	Name, address of Manufacturing site:	English Pharmaceuticals Industries-Link Kattar Road, Thokar Niaz Baig, Multan Road, Lahore-
	The status in reference regulatory authorities	Injectafer® solution for injection of M/s Luitpold Pharmaceuticals, Inc is USFDA Approved.
	Detail of previous approval	
	Evaluation Remarks	
	Initially, the firm selected the data already approved status as no, but later on provided the reference minutes. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved	
128	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Welmed Pharmaceutical Industries (Pvt) Ltd. Plot No. 108/1 Road No. R-2 I.E. Gadoon. (000546)
	Application Form Dy. No / Tracking ID & date of submission	(VAS-QTY-JGYT, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-05-09,
	The proposed proprietary name / brand name	Veda 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 at room temperature below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 100mg, Ajanta Pharma USA Inc. Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Neogra 100mg Tablet approved in 345th meeting
	Evaluation Remarks	
	The firm initially selected No in data already approved. Later on, the firm applied vide General Request Form TID MWH-DHH-3845 that you are requested to please take-up our following applications as cross reference of M/s Wimits Pharmaceuticals products which are approved in M-350 & M-351 instead of 345th Meeting. 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	
129	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(AQD-9ZB-9D8T, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-04-29,
	The proposed proprietary name / brand name	Tadalafil Tablet.
	Label Claim	Each Film coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	10's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
For generic drugs (me-too Status)	Not Available
Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
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 vy Ajanta Pharma USA Inc., Bridgewater, NJ 08807
Detail of previous approval	Procial 2.5mg Tablet approved in DRB-345 held on 19-21-Feb, 2025

Evaluation Remarks

The firm initially selected Yes in data already approved but provided reference of 345 RB meeting. Later on, the firm applied vide General Request Form TID 8WS-WUG-6653 We would like to bring to your attention that the Registration Board, in its 351st meeting, has already granted registration to M/s Wimits Pharmaceutical Pvt. Ltd. for their Tadalafil range 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

130	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(LUL-N7M-A4PB, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-04-29,
	The proposed proprietary name / brand name	Tadalis Tablet.
	Label Claim	Each Film coated Tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	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 vy Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	Procial 5mg Tablet approved in DRB-345 held on 19-21-Feb, 2025

Evaluation Remarks		
The firm initially selected Yes in data already approved but provided reference of 345 RB meeting. Later on, the firm applied vide General Request Form TID 8WS-WUG-6653 We would like to bring to your attention that the Registration Board, in its 351st meeting, has already granted registration to M/s Wimits Pharmaceutical Pvt. Ltd. for their Tadalafil range 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		
131	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(HL9-4BY-SWQX, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-04-29,
	The proposed proprietary name / brand name	Tadalafil Tablet.
	Label Claim	Each Film coated Tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 10mg by Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	Procial 10mg Tablet approved in DRB-345 held on 19-21-Feb, 2025
Evaluation Remarks		
The firm initially selected Yes in data already approved but provided reference of 345 RB meeting. Later on, the firm applied vide General Request Form TID 8WS-WUG-6653 We would like to bring to your attention that the Registration Board, in its 351st meeting, has already granted registration to M/s Wimits Pharmaceutical Pvt. Ltd. for their Tadalafil range 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	
132	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Atco Laboratories Limited B-18 SITE KARACHI (000188)
	Application Form Dy. No / Tracking ID & date of submission	(8UM-RUB-5NES, 2025-05-22)
	Detail of Fee Submitted	93000.0, 2025-04-29,
	The proposed proprietary name / brand name	Tadalafil Tablet.
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 YearDon't store & transport above 30degree centigrade
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Phosphodiesterase (PDE) inhibitors
	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 by Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	Procial 20mg Tablet approved in DRB-345 held on 19-21-Feb, 2025
	Evaluation Remarks	
	The firm initially selected Yes in data already approved but provided reference of 345 RB meeting. Later on, the firm applied vide General Request Form TID 8WS-WUG-6653 We would like to bring to your attention that the Registration Board, in its 351st meeting, has already granted registration to M/s Wimits Pharmaceutical Pvt. Ltd. for their Tadalafil range 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	
133	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CORTEX PHARMACEUTICALS PLOT NO.16-A, SS-4,NATIONAL INDUSTRIAL ZONE,RAWAT,ISLAMABAD. (000826)
	Application Form Dy. No / Tracking ID & date of submission	(LX2-7GP-VDGD, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Cordena Tablets

	Label Claim	Each Film coated tablet contains: Sildenafil Citrate USP equivalent to 50mg Sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*5's,1*10's,2*10's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	NOT AVAILABLE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-PLOT NO.129 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE-
	The status in reference regulatory authorities	SILDENAFIL TABLET USP 50MG OF MASSES Rubicon Research Private Limited Ambarnath Dist. Thane, 421506(USFDA APPROVED)
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected No in data already approved. Later on, the firm applied vide General Request Form TID HRE-X4Z-X7RM that you are requested to please take-up our following applications as cross reference of M/s Wimits Pharmaceuticals products which are approved in M-350 & M-351 instead of 345th Meeting. 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	
134	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	CORTEX PHARMACEUTICALS PLOT NO.16-A, SS-4,NATIONAL INDUSTRIAL ZONE,RAWAT,ISLAMABAD. (000826)
	Application Form Dy. No / Tracking ID & date of submission	(MDW-PBE-1U5V, 2025-05-12)
	Detail of Fee Submitted	93000.0, 2025-01-28,
	The proposed proprietary name / brand name	Cordena Tablets
	Label Claim	Each Film coated tablet contains: Sildenafil Citrate USP equivalent to 100mg Sildenafil
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*5's,1*10's,2*10's,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	NOT AVAILABLE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-PLOT NO.129 SUNDAR INDUSTRIAL ESTATE RAIWIND ROAD LAHORE-
	The status in reference regulatory authorities	SILDENAFIL TABLET USP 100MG OF MASSES Rubicon Research Private Limited

		Ambernath Dist. Thane, 421506(USFDA APPROVED)
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected No in data already approved. Later on, the firm applied vide General Request Form TID HRE-X4Z-X7RM that you are requested to please take-up our following applications as cross reference of M/s Wimits Pharmaceuticals products which are approved in M-350 & M-351 instead of 345th Meeting. 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	
135	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(1G4-DU7-A7EH, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Linza 100mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg As per Innovators Specification
	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)	Medizan Laboratoreis 351th meeting (132401)Linza
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	Approval: MHRA in January, 2025
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved	
136	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(4U6-VQH-MTQ6, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Linza 200mg Tablets
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg As per Innovators Specification
	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)	Medizan Laboratoreis 351th meeting (132402Lingolix 200mg Tablets)
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	Approval: MHRA in January, 2025
	Detail of previous approval	351th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
137	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	FAAS Pharmaceuticals (Pvt)Ltd F-748 L, S.I.T.E, Karachi (000767)
	Application Form Dy. No / Tracking ID & date of submission	(687-SJ9-6A6A, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	VONOFAS 10MG TABLET
	Label Claim	Each Film Coated tablet contains:
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year25c

	For generic drugs (me-too Status)	Vonozan Tablet 10mg by getz pharma
	Pharmacotherapeutic Group of (API)	Data already approved in 322 MoM, please see attached
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Takecab 10mg Tablet , PMDA Japan.
	Detail of previous approval	322 meeting, Brand Name: Vonocal 10mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
138	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	(7S5-PS7-XXQZ, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Montage 10mg tablet
	Label Claim	Each film-coated tablet contains Montelukast sodium eq. to Montelukast 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25 °C.
	For generic drugs (me-too Status)	myteka tablet of M/S Hilton pharma
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	singulair tablet of USFDA Approved
	Detail of previous approval	DRAP Meeting No 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	

139	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(A2E-XGW-UZBP, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-26,
	The proposed proprietary name / brand name	Anafil-50mg Tablets
	Label Claim	Each tablet contains: Avanafil.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Avala 50mg Tablet By Medizan Labs Reg. No. 132422
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterasetype5(PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5,whichisanenzymethat plays a role in The development of erections.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200mg Initial U.S.A Approval: 2012
	Detail of previous approval	Avala 50mg Tablet (DRB Meeting M-351)
140	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
140	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(EGE-QDA-UN83, 2026-01-13)
	Detail of Fee Submitted	93000, 4200 2025-07-10, 2025-12-22
	The proposed proprietary name / brand name	Vita-E 400mg Soft Gelatin Capsule
	Label Claim	Each soft gelatin capsule contains: Dl alpa tocopheryl acetate.....400mg
	Reference to Finished product specifications	United States Pharmacopeia

Proposed Pack Size	10 x 10's-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C
For generic drugs (me-too Status)	Product Name: Zescap Capsule 400mg Registration No: 030626 Company Name: M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd.
Pharmacotherapeutic Group of (API)	Fat soluble vitamin (antioxidant).
Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-KM, Chak Beli Road, Rawat, Islamabad-Pakistan-
The status in reference regulatory authorities	Not Verifiable
Detail of previous approval	Tocogen 400mg Soft gelatin Capsule, Approved in 345th 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

141	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	TN PHARMACEUTICALS 264-C SUNDAR INDUSTRIAL ESTATE LAHORE (000868)
	Application Form Dy. No / Tracking ID & date of submission	(M1M-NWL-BB6D, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-12,
	The proposed proprietary name / brand name	SOLA-D Injection 5mg/ml
	Label Claim	Each 1ml Contains: Cholecalciferol (Vitamin D3).....5mg (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 30°C in a cool and dry place.
	For generic drugs (me-too Status)	New-D injection BY NP News
	Pharmacotherapeutic Group of (API)	Vitamin D Analogs
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals.-208-C Sundar Industrial Estate Raiwind Road Lahore, Punjab, Pakistan.-
	The status in reference regulatory authorities	FDA approved
	Detail of previous approval	D3 Vibe Injection 5mg/ml in Minutes of 351st Meeting of Registration Board (23rd – 24th September, 2

Evaluation Remarks

In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned

	notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
142	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	(MMG-TJQ-JNLV, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Montage 4mg chewable tablet
	Label Claim	Each chewable tablet contains Montelukast sodium eq. to Montelukast 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25 °C.
	For generic drugs (me-too Status)	myteka tablet of M/S Hilton pharma
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	Singulair Tablet USFDA Approved
	Detail of previous approval	DRAP Meeting No 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	
143	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	(MVY-B24-GW6B, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Montage 4mg Sachet
	Label Claim	Each filled sachets contains Montelukast sodium eq to Montelukast 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO

	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	Myteka sachets of M/S Hilton Pharma
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	singulair sachets USFDA Approved
	Detail of previous approval	DRAP Meeting No 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	
144	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Solaris Life Sciences Private Limited , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
	Application Form Dy. No / Tracking ID & date of submission	(MW8-PQW-96WT, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-26,
	The proposed proprietary name / brand name	Anafil-100mg Tablets
	Label Claim	Each tablet contains: Avanafil.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Avala 100mg Tablet By Medizan Labs Reg. No. 132423
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd,-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012
	Detail of previous approval	Avala 100mg Tablet (DRB Meeting M-351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a	

	declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
145	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(PZX-UHB-UNWW, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Frimay 50mg Injection
	Label Claim	Each ml contains: Iron as Ferric Carboxymaltose...50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year25° C
	For generic drugs (me-too Status)	Product Name: FCM Injection 500mg/10ml Composition: Each 10ml vial contains: Ferric Carboxymaltose 500mg Reg. No.: 108583 Manufactured by: Genix Pharma Limited, Karachi
	Pharmacotherapeutic Group of (API)	Haematinics
	Name, address of Manufacturing site:	Bio-Labs(Pvt).Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan -
	The status in reference regulatory authorities	FDA
	Detail of previous approval	331st
	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.	Swiss Pharmaceuticals Pvt. Ltd. A/159, S.I.T.E.-II, Super Highway (000438)
	Application Form Dy. No / Tracking ID & date of submission	(Q3S-14J-3886, 2026-01-13)
	Detail of Fee Submitted	93000, 4200 2025-07-10, 2025-12-22
	The proposed proprietary name / brand name	Vita-E 600mg Soft Gelatin Capsule

	Label Claim	Each soft gelatin capsule contains: DI alpha tocopheryl acetate 600mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Product Name: Zescap Capsule 600mg Registration No: 030627 Company Name: M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd .
	Pharmacotherapeutic Group of (API)	Fat soluble vitamin (antioxidant).
	Name, address of Manufacturing site:	M/s Biogen Life Sciences-8-KM, Chak Beli Road, Rawat, Islamabad-Pakistan-
	The status in reference regulatory authorities	Not Verifiable
	Detail of previous approval	Tocogen 600mg Soft gelatin Capsule, Approved in 345th 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	
147	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	(R53-9S2-8HHT, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-06,
	The proposed proprietary name / brand name	Montage 5mg chewable tablet
	Label Claim	Each chewable tablet contains Montelukast sodium eq. to Montelukast 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25 °C.
	For generic drugs (me-too Status)	myteka tablet of M/S Hilton pharma
	Pharmacotherapeutic Group of (API)	leukotriene receptor antagonists (LTRAs)
	Name, address of Manufacturing site:	Solaris Life Sciences-Plot 8, Street S-1, RCCI industrial estate rawat-
	The status in reference regulatory authorities	singulair tablet of USFDA Approved
	Detail of previous approval	DRAP Meeting No 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	
148	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Medwell Pharmaceuticals 1 km, terbellla road, lawrencepur, faqirabad Attock (000699)
	Application Form Dy. No / Tracking ID & date of submission	(TJ3-BH1-955B, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-27,
	The proposed proprietary name / brand name	Betawel Lotion
	Label Claim	Each ml of lotion contains: Betamethasone as valerate.0.1%w/v (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree
	For generic drugs (me-too Status)	Betnogen 0.1% Cream Reg 111971
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Biogen Life Sciences-8-KM Chakbeli Road Rawat Rawalpindi Pakistan -
	The status in reference regulatory authorities	Company: SENORES PHARMS USFDA Approved
	Detail of previous approval	Valbe lotion 313 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	
149	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Genetics Pharmaceuticals Pvt. Ltd 539-A Sundar Industrial Estate Raiwind Road Lahore (000845)
	Application Form Dy. No / Tracking ID & date of submission	(VA8-7DQ-A3BV, 2026-01-13)
	Detail of Fee Submitted	97200, 2025-12-26,
	The proposed proprietary name / brand name	Aprovia 12.5mg Tablet
	Label Claim	Each Film Coated Tablet Contains: Aprocitentan 12.5mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearProtect from heat light and moisture
	For generic drugs (me-too Status)	Manufacturer name: • Manufactured By: Solaris Life Sciences Brand name: Aprocent Strength: Aprocitentan 12.5mg Composition: Each Film Coated Tablet contains: Aprocitentan 12
	Pharmacotherapeutic Group of (API)	Anti Hypertensive
	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	SRA Registration Status: Registered in US FDA NDA:217686 Brand Name: TRYVIO 12.5mg tablets Company: Idorsia Pharmaceuticals US Inc
	Detail of previous approval	Aprocent, 345 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	
150	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	Maybush Pharmaceuticals (Pvt) Ltd Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad (000501)
	Application Form Dy. No / Tracking ID & date of submission	(WNB-2GG-DD67, 2026-01-13)
	Detail of Fee Submitted	97200, 2026-01-09,
	The proposed proprietary name / brand name	Ketorein Tablets
	Label Claim	Each film coated tablet contains; α -Ketoanalogue to isoleucine (Calcium-salt)... 67 mg α -Ketoanalogue to leucine (Calcium-salt)... 101 mg α -Ketoanalogue to phenylalanine (Calcium-Salt) 68 mg α -Ketoanalogue to valine (Calcium-Salt) 86 mg α -hydroxyanalogue to DL-methionine (Calcium-Salt)....59 mg L-lysine acetate...105mg corresponding to L-lysine 75 mg L-threonine 53 mg L-tryptophan 23 mg L-histidine 38 mg L-tyrosine 30 mg Total nitrogen content per tablet 36 mg Calcium content per tablet 1.25mmol = 50 mg (Innovator Spec's)
	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)	Me To Registration Status: Registered in Pakistan Brand Name: Ketoalfa tablets Manufacturer: M/s Genome Pharmaceuticals (Pvt.) Ltd. Address: Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Ha
	Pharmacotherapeutic Group of (API)	Amino acids, including combinations with polypeptides. WHO ATC Code: V06DD L-lysine acetate: V06DD L-threonine: V06DD L- tryptophan: N06AX02 L-histidine: V06DD L- Tyrosine: V06DD
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat,-
	The status in reference regulatory authorities	SRA Registration Status: Bfarm Approved Brand Name: Ketosteril Tablets Manufacturer: M/s Fresenius Kabi, Germany Address: Siemensstraße 27, 61352 Bad Homburg vor der Höhe, Germany
	Detail of previous approval	336th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
151	Case Category	New License (Incharge Evaluation Cell)
	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	(D2V-ENM-NG76, 2025-11-18)
	Detail of Fee Submitted	38700, 2025-11-04,
	The proposed proprietary name / brand name	Ketorex shampoo
	Label Claim	Each ml contains: Ketoconazole 20mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1,S-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	Conaz lotion(shampoo based) M/s ATCO Laboratories Ltd. Karachi
	Pharmacotherapeutic Group of (API)	Antifungals for topical use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED MANUFACTURING FACILITY Plot No. E – 21, M.I.D.C., Tarapur, Tal. – Palghar, Dist.: Palghar- 401 506,

		Maharashtra,INDIA. TEL.: +91-2525-275 841 FAX: +91-2525-260 930
	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	MHRA
	GMP status of the firm	Attached
	Evidence of approval of manufacturing facility	Attached
	Evaluation Remarks	
	The firm was communicated following shortcomings also the firm needs to revise label claim as per MHRA i.e. Ketoconazole 2% w/w (20 mg/g) with relevant fee.	
	S. No	Observation
	1	BP monograph specifies that assay test shall be performed by performing system suitability with Ketoconazole Impurity standard BPRCRS. Provide COA and Purchasing documents for aforementioned standard.
	2	COA and testing record for pharmaceutical Equivalence for test and reference product
	3	COA of Ketoconazole API by Drug Product Manufacturer
	4	Submission of Loan intimation to DRAP
		Justification
		The COA for the requisite impurities has already been provided in the main CTD dossier. Regarding, the documents of purchase of reference standard, our firm has requested M/S Caliph for the provision of the same.
		The requisite record for pharmaceuticals equivalence for test and reference product is attached.
		COA of Ketoconazole API by Drug Product Manufacturer is attached.
		The API for the applied product was obtained from M/S Caliph Pharmaceuticals (Pvt) Ltd. The loan along with other documents has been submitted in the CTD dossier. However regarding prior intimation to DRAP, M/S Nagarsons Pharmaceutical Pvt Ltd is a new licensee and had no knowledge as to intimate DRAP before initiation of trial/Stability on loan basis API. It is pertinent to mention that the CTD dossier of the instant product has been submitted before issuance of the present directives DRAP with regard to the loan matters. We therefore request our inability to observe this procedural requirement with the assurance that in future we will strictly observe this requirement. It is therefore requested that our product may kindly be processed for registration.
	Decision	
	Approved	
	Approved subject to submission of requisite fee for revised label claim and verification of API loan letter.	
152	Case Category	Routine (Muhammad Sarfraz Nawaz)

	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(D95-4RL-ZZR5, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommendation of the Sub-committee: Recommended	
	Decision	
	Approved	
153	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(74W-A9Z-BRHN, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Recommendation of the Sub-committee: Recommended	

	Decision	
	Approved	
154	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	QAS International Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan (000968)
	Application Form Dy. No / Tracking ID & date of submission	(6QW-X39-WM8R, 2024-11-04)
	Detail of Fee Submitted	37000.0, 2024-10-08,
	The proposed proprietary name / brand name	TYLVALOZONE FEED PREMIX
	Label Claim	Each 100gram contains: Tylvalosin tartrate 20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 20gm, 50gm, 10-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room Temperature. Protect from direct sunlight.
	For generic drugs (me-too Status)	Quantasol 20% Premix with Reg. # 125697 of M/S U.M Enterprises
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Firm has demanded the following pack sizes: 10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 25Kg	
	Decision	
	Approved	
	upto 1Kg pack size.	
155	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
	Application Form Dy. No / Tracking ID & date of submission	(M2L-1L3-YJP8, 2024-08-02)
	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	Artham Dry Suspension 15mg/90mg (30ml)
	Label Claim	Each 5ml of reconstituted suspension contains: Artemether ... 15mg Lumefantrine ... 90mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 15°C to 30°C
	For generic drugs (me-too Status)	ARCEVA 15mg+90mg / 5ml Dry Suspension of M/s SAMI Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	P01BF01: ANTIMALARIALS
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Vital Laboratories Pvt. Ltd. Plant No-I, Plot No 1416 -21 ,1507 1&2, 1601, GIDC Estate, Phase III, Vapi – 396 195 Gujarat, India
Detail of stability batches of drug product	03 Batches, 100 Bottles each.
Documents for the procurement of API with approval from DRAP (in case of Import)	Loan from Ms Demont Research Laboratories.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence conducted against ARCEVA 15mg+90mg / 5ml Dry Suspension of M/s SAMI Pharmaceuticals Pvt. Ltd.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability Studies conducted on Zone IV by Drug Substance Manufacturer.
The status in reference regulatory authorities	Could not be confirmed from WHO or USFDA
GMP status of the firm	New License w.e.f. 28-04-2022
Evidence of approval of manufacturing facility	Section approval letter from Licensing Division for Oral Dry Powder Suspension Section (General) has been submitted.

Evaluation Remarks

Sr. No.	Shortcomings as per decision of M-347	Firm's response
1	Evidence of RRA status for applied dosage form and strengths.	EMA-approved CO-ARTESIANE Suspension (poudre pour suspension orale containing 180 mg Artemether and 1080 mg Lumefantrine per 60 mL) manufactured by M/s PF B.V., Appelhof 13, 8465 RX Oudehaske, The Netherlands. The relevant EMA approval weblink is as follows: https://www.ema.europa.eu/en/documents/orphan-designation/eu309702-public-summary-opinion-orphan-designation-beta-artemether-lumefantrine-powder-oral-suspension-treatment-malaria_en.pdf Furthermore, the same RRA reference has already been accepted in the 350th meeting of DRAP for Skywin Pharmaceuticals' product "Artemet 15+90 mg/5 mL Powder for Oral Suspension."
2	Drug Product Data as per International Pharmacopeia	The current ongoing stability time point is the 18th month. Testing has been performed in accordance with the International Pharmacopeia method, and the method has been duly verified.

Firm shall submit prescribed fee Rs. 9400/- for pre-registration variation in FPP specifications from as per innovator specifications to International Pharmacopoeia specifications.

Decision

Approved

Firm shall submit prescribed fee Rs. 9400/- for pre-registration variation in FPP specifications from as per innovator specifications to International Pharmacopoeia specifications, before issuance of registration letter.

156	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	(W5W-TZ6-867B, 2024-08-29)
	Detail of Fee Submitted	75000.0, 225000 2024-08-28, 2025-08-19
	The proposed proprietary name / brand name	Ifflurin
	Label Claim	Ifflurin 100ml/bottle Composition: Isoflurane 100ml Chinese Veterinary Pharmacopoeia
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	100ml/bottle-De-Controlled
	Shelf Life (Unit)	2 Year(s)Keep away of the light and store in sealed container and a cool place
	For generic drugs (me-too Status)	New Registration in Pakistan
	Pharmacotherapeutic Group of (API)	Inhalation anesthetic
	Name, address of Manufacturing site:	Ringpu (Tianjin) Bio-Pharmacy Co., Ltd.-No. 6 Liuqing 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):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted 6 months accelerated and 24 months real time stability studies data as per zone IV-A conditions.
	Evaluation Remarks	
	Scanned copies of GMP valid till 21-11-2026, FSC and LOA valid till 17-08-2029 are submitted. Firm shall submit fee for pre-approval variation in FPP specifications and since scanned copies of FSC, GMP certificate and LOA submitted, firm shall submit original legalized documents before issuance of registration letter.	
	Decision	
	Deferred	
	for review of formulation by the Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
157	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(EUR-2XY-7ZSE, 2024-11-27)
	Detail of Fee Submitted	37000.0, 2024-11-25,
	The proposed proprietary name / brand name	ONYX LA INJECTION (50ML)
	Label Claim	Each ml contains: Oxytetracycline HCL 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ML-De-Controlled

Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	ANAOXY-CP INJECTION Reg. No. 043563 (CHERISHED PHARMACEUTICALS (PVT.)LTD.LAHORE)
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	cGMP compliance (Satisfactory)
Evidence of approval of manufacturing facility	Liquid Injection Vet General confirmed from GMP certificate based on the evaluation conducted on 27-05-2025

Evaluation Remarks

Decision

Approved

with following label claim:

Each ml contains:

Oxytetracycline.....200mg

The firm shall submit revised form 5 and fee for pre-approval revision/correction of label claim in line with USP monograph before issuance of registration letter.

158	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	(GZ8-EBM-W44N, 2025-05-29)
	Detail of Fee Submitted	37000.0, 2025-05-22,
	The proposed proprietary name / brand name	Oxy-Pro LA Injection
	Label Claim	Each mL Contains: Oxytetracycline Hydrochloride eq. to Oxytetracycline Base.....300mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at 25 Degree C
	For generic drugs (me-too Status)	Bio-Oxy 30% Injection by M/s. Bio-Labs (Pvt.) Ltd., (Reg. No.: 088833)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated conditions their current GMP compliance level is rated as good.
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Decision

Approved

with following label claim:

	Each ml contains: Oxytetracycline.....300mg The firm shall submit revised form 5 and fee for pre-approval revision/correction of label claim in line with USP monograph before issuance of registration letter.	
159	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	(Q43-P6J-4B5L, 2025-05-29)
	Detail of Fee Submitted	37000.0, 2025-05-22,
	The proposed proprietary name / brand name	Amprowan-90 Oral Powder
	Label Claim	Each Kg Contains: Amprolium Hydrochloride.....900gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,100 gm-De-Controlled,2.5 Kg-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 Degree C in Dry Place.
	For generic drugs (me-too Status)	Amprovil Powder by M/s. Symans Pharmaceuticals (Pvt.) Ltd., (Reg. No.: 023438)
	Pharmacotherapeutic Group of (API)	Anticoccidial (Antiprotozoal Agent)
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the stated conditions their current GMP compliance level is rated as good.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	upto 1Kg pack.	
160	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	(RA3-W5P-GVP5, 2025-05-21)
	Detail of Fee Submitted	37000.0, 2025-05-13,
	The proposed proprietary name / brand name	Floro-C Oral Liquid
	Label Claim	Each 100ml contains: Florfenicol.....23gm Colistin 50MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml,-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	125939 Flor Vet-23 oral liquid of M/s. Vetnicare Pharmaceutical 8-Km Sheikhpura Road, Muridke-Pakistan

	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on inspection conducted on 27-12-2023 their current GMP compliance level is rated as Good.
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has submitted that by mistaken the storage condition are written 30 °C instead of below 25 °C. Kindly consider storage condition is "Store below 25 °C". The firm has also demanded 1L, 2.5L and 5L pack sizes. The firm shall submit fee for pre-registration variation/correction of storage conditions before issuance of registration letter.	
	Decision	
	Approved	
	upto 1Litre pack size. The firm shall submit fee for pre-registration variation/correction of storage conditions before issuance of registration letter.	
161	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(4YX-6ZS-WR3T, 2024-11-01)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	Tide Injection 50 mL
	Label Claim	Each ml contains: Tylosin tartrate.....50mg, Colistin sulfate.....10mg, Streptomycin as Sulfate.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store Cool and Dry place below 25 degree centigrade
	For generic drugs (me-too Status)	CETICIN Injection
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted differential fee Rs. 7000/- vide challan No. 392542991264 and fee Rs. 9000/- vide challan no. 821750821 for correction/revision of FPP specifications from manufacturer's specifications to as per innovator's specifications.	
	Decision	
	Approved	
	with as per Innovator's specifications. The firm shall submit differential fee Rs. 400/- for correction/revision of FPP specifications before issuance of registration letter.	
162	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)

Application Form Dy. No / Tracking ID & date of submission	(G7Q-XDB-2ST7, 2024-10-28)
Detail of Fee Submitted	37000.0, 2024-10-24,
The proposed proprietary name / brand name	ETER PHENYLDOX POWDER
Label Claim	Each 1000gm contains:- Tylosin tartrate..... 100gm Doxycycline HCL 200gm Colistin sulphate..... 500MIU Phenylbutazone 12gm Bromhexine HCL 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
Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	RESCO POWDER Reg. # 044965 (LEADS PHARMA PVT, LTD, ISLAMABAD)
Pharmacotherapeutic Group of (API)	Antibiotics, mucolytic
Name, address of Manufacturing site:	--
GMP status of the firm	cGMP compliance (Satisfactory)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Target species: Poultry and calves.	
Decision	
Rejected	
since the Sub-committee on Veterinary Drugs recommended use of Phenylbutazone primarily in non-food-producing animals restricting its use to equine animals only while the firm has mentioned target species poultry and calves,	
Case Category	Routine (Najia Saleem)
Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
Application Form Dy. No / Tracking ID & date of submission	(P84-9NB-WL8X, 2024-07-13)
Detail of Fee Submitted	30000.0, 2024-07-11,
The proposed proprietary name / brand name	HEPANOL LIQUID
Label Claim	Each litre contains:- Carnitine..... 25000mg Methionine..... 10000mg Choline chloride..... 19000mg Magnesium sulphate..... 10000mg Sorbitol..... 200000mg (As per Innovator's specs.)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,500ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light

	For generic drugs (me-too Status)	INTERVAC (PVT) LTD. SHEIKHUPURA (HEPASOL LIQUID REG. No. 069657)
	Pharmacotherapeutic Group of (API)	Amino acids/ electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has also demanded the following pack sizes: 100ml,200ml,500ml,1000ml & 2500ml	
	Decision	
	Approved	
	upto 1L pack size.	
164	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(LWA-16V-LT7V, 2024-07-13)
	Detail of Fee Submitted	30000.0, 2024-07-11,
	The proposed proprietary name / brand name	HEPANOL LIQUID
	Label Claim	Each litre contains:- Carnitine..... 25000mg Methionine..... 10000mg Choline chloride..... 19000mg Magnesium sulphate..... 10000mg Sorbitol..... 200000mg (As per Innovator's specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	INTERVAC (PVT) LTD. SHEIKHUPURA (HEPASOL LIQUID REG. No. 069657)
	Pharmacotherapeutic Group of (API)	Amino acids/ electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Same formulation is also applied against tracking ID P84-9NB-WL8X, hence the instant case may be disposed of.	
	Decision	
	Rejected	
	the instant application as same formulation has been applied twice against tracking ID P84-9NB-WL8X and LWA-16V-LT7V.	
165	Case Category	Routine (Najia Saleem)

Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
Application Form Dy. No / Tracking ID & date of submission	(RW6-7WU-M9R6, 2024-11-01)
Detail of Fee Submitted	30000.0, 2024-06-27,
The proposed proprietary name / brand name	SPINCO Injection 100 mL
Label Claim	Each ml contains: Lincomycin HCL - 75 mg Spiramycin Adipate - 125 mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	100 ml-De-Controlled
Shelf Life (Unit)	24 Month(s)Store Cool and Dry place below 25 Degree Centigrade
For generic drugs (me-too Status)	LISPIRACIN Injection
Pharmacotherapeutic Group of (API)	Antibacterial
Name, address of Manufacturing site:	--
GMP status of the firm	Approved
Evidence of approval of manufacturing facility	
Evaluation Remarks	
The firm has submitted differential fee Rs. 7000/- vide challan number 1676798034 and fee Rs. 9000/- vide challan number 97711663136 for pre-registration variation in FPP specifications from manufacturer's to as per innovator's specifications.	
Decision	
Approved	
with as per Innovator's specifications. The firm shall submit differential fee Rs. 400/- for correction/revision of FPP specifications before issuance of registration letter.	
Case Category	Routine (Najia Saleem)
Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
Application Form Dy. No / Tracking ID & date of submission	(YRV-EA1-VLZX, 2024-11-02)
Detail of Fee Submitted	30000.0, 2024-06-27,
The proposed proprietary name / brand name	Vitabolase Solution
Label Claim	Each 1000ml contains: L-Carnitine - 500 mg Vitamin B6 (Pyridoxin HCL) - 500 mg Vitamin B12 - 15 mg Nicotinamide - 1500 mg Calcium Pantothenate - 1000 mg Sorbitol - 100000 mg DL-Methionine - 100,000 mg L-Arginine - 3,000 mg L-Citrulline - 2,000 mg L- Glycin - 2,000 mg L-Aspartic Acid - 1,500 mg L- Lysin - 1,000 mg L- Glutamic Acid - 1,500 mg L-Ornithine - 2,000 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml, -De-Controlled
Shelf Life (Unit)	24 Year(s)Store Cool and Dry place below 25 Degree Centigrade

For generic drugs (me-too Status)	Megabolase Solution Reg No 043231
Pharmacotherapeutic Group of (API)	Multivitamins
Name, address of Manufacturing site:	--
GMP status of the firm	Approved
Evidence of approval of manufacturing facility	
Evaluation Remarks	
The firm has revised formulation in line with reference product i.e. Megabolase solution 043231, as per following label claim. EACH 1000ml CONTAINS:- L-CARNITINE 500.00mg VITAMIN 6.....500.00mg VITAMIN B12..... 15.00mg NICOTINAMIDE..... 150.00mg CALCIUM PANTOTHENATE ..1000.00mg SORBITOL 100000.00mg DL-METHIONINE 10000.00mg L-ARGNINE 3000.00mg L-CITRULLINE 2000.00mg L-GLYCINE 2000.00mg L-ASPARTIC ACID.....1500.00mg L-LYSINE 1000.00mg L-GLUTAMIC ACID ...1500.00mg L-ORNITHINE 2000.00mg The firm has submitted differential fee Rs. 7000/- vide challan No. 9209527573 and fee Rs. 9000/- vide challan no. 2755962815 for correction/revision of FPP specifications from manufacturer's specifications to as per innovator's specifications.	
Decision	
Approved	
upto 1Litre pack with as per Innovator's specifications and following label claim: EACH 1000ml CONTAINS:- L-CARNITINE 500mg VITAMIN 6.....500mg VITAMIN B12..... 15mg NICOTINAMIDE..... 150mg CALCIUM PANTOTHENATE ..1000mg SORBITOL 100000mg DL-METHIONINE 10000mg L-ARGNINE 3000mg L-CITRULLINE 2000mg L-GLYCINE 2000mg L-ASPARTIC ACID.....1500mg L-LYSINE 1000mg L-GLUTAMIC ACID ...1500mg L-ORNITHINE 2000mg The firm shall submit differential fee Rs. 400/- for correction/revision of label claim and FPP specifications before issuance of registration letter.	

167	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Decent Pharma Plot No. 30, Street No. SS-3, RCCI, RAWAT (000766)
	Application Form Dy. No / Tracking ID & date of submission	(M7P-BG1-85GV, 2024-11-01)
	Detail of Fee Submitted	30000.0, 2024-06-27,
	The proposed proprietary name / brand name	Megamine Injection 10 mL
	Label Claim	Each ml contains: Flunixin as Meglumine.....83mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 mL-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store Cool and Dry place below 25 Degree Centigrade
	For generic drugs (me-too Status)	NIXYM Injection
	Pharmacotherapeutic Group of (API)	Anti-inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Approved
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted differential fee Rs. 7000/- vide challan No. 73381428354 and fee Rs. 9000/- vide challan no. 54960304161 for correction/revision of label claim in line with USP monograph.	
	Decision	
	Approved	
	The firm shall submit differential fee Rs. 400/- for correction/revision of label claim in line with USP monograph before issuance of registration letter.	
168	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(DN9-RHR-4MXB, 2024-10-26)
	Detail of Fee Submitted	37000.0, 9400 2024-10-22, 2025-12-16
	The proposed proprietary name / brand name	ETER IVER SOLUTION
	Label Claim	Each ml contains:- Ivermectin.....0.24%
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1 Litre-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	ACTIVER-S Reg. No. 117383 (ACME PHARMA (PVT.)LTD. RAWAT ISLAMABAD)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
169	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(XE1-B24-2REM, 2024-07-15)
	Detail of Fee Submitted	30000.0, 2024-07-12,
	The proposed proprietary name / brand name	ETER BROILER POWDER,
	Label Claim	Each Kg Contains:- L-Lysine..... 26000mg DL-Methionine..... 18500mg Ethoxyquin..... 1000mg Vitamin A 75000IU Vitamin D3..... 15000IU Vitamin E..... 100mg Vitamin K3..... 23mg Vitamin B1..... 5mg Vitamin B2..... 45mg Vitamin B6..... 10mg Vitamin B12..... 200mcg Pantothenic acid.....68mg Niacin.....20mg Folic acid.....5mg Choline chlorid3e.....3000mg Iron.....440mg Zinc.....500mg Copper.....50mg Iodine.....13mg Manganese.....620mg Selenium.....2.2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10KG-De-Controlled,25KG-De-Controlled,50KG-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	U.M Enterprises Karachi. (PROVIMI BROILER PACK POWDER REG. # 019028)
	Pharmacotherapeutic Group of (API)	Minerals/vitamins/immune booster
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted fee for registration of applied product vide challan No. 392709251.The firm has demanded following pack sizes: 100gm,500gm,1 Kg,5Kg,10Kg & 25,50Kg.	
	Decision	
	Approved	

	upto 1Kg pack size.	
170	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(ES7-9XR-L1NR, 2024-08-26)
	Detail of Fee Submitted	30000.0, 9400 2024-08-20, 2025-12-16
	The proposed proprietary name / brand name	DIARO STOP WATER SOLUBLE POWDER
	Label Claim	Each 100gm contains:- Sulphadimerazine 86gm Diaveridine 10.5gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,1kg-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	FUL STOP WATER SOLUBLE POWDER REG. No. 049524 (NOBLE PHARMA (PVT.) LTD. MIRPURAJ & K.)
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
171	Case Category	Import (Najia Saleem)
	Name, address of Applicant.	Hilton Pharma (Pvt.) Limited Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area Karachi, Pakistan (0647.)
	Application Form Dy. No / Tracking ID & date of submission	(U4A-E2P-LLQY, 2025-04-24)
	Detail of Fee Submitted	300000.0, 2025-04-07,
	The proposed proprietary name / brand name	LD
	Label Claim	Each ml contains: Phosphate buffer pH 7.0 (KCl 0.19 mg, NaCl 5.86 mg, KH ₂ PO ₄ 6.81 mg, NaOH 1.16 mg)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 doses-De-Controlled,1000 doses-De-Controlled,200 doses-De-Controlled,2000 doses-De-Controlled,2500 doses-De-Controlled,50 doses-De-Controlled,500 doses-De-Controlled

Shelf Life (Unit)		3 Year(s)Stored in a tightly closed container in a dry, protected from direct sunlight
For generic drugs (me-too Status)		NA
Pharmacotherapeutic Group of (API)		Diluent
Name, address of Manufacturing site:		PT MEDION FARMA JAYA-Office Address: Jl. Babakan Ciparay No. 282, Babakan Ciparay, Bandung – Indonesia Plant Address: Jl. Raya Batujajar No. 29, Cimareme, Ngamprah, Bandung Barat – Indonesia-Indonesia
Name, address of Marketing Authorization Holder:		Hilton Pharma (Pvt) Ltd , Plot No. 13, 14 & 43 Sector-15, Korangi Industrial Area 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		
Sr. No.	Shortcomings	Firms reply
1	Submit evidence of approval of applied product in any RRA	approved in Vietnam
2	Submit relevant sole agency/ distribution agreement duly notarized from the country of origin since the applied product is not included in the list of products mentioned in the already submitted agreement.	Submitted
3	State list of vaccines for which the applied diluent shall be used	033213 Medivac IB H-120 Vaccine033210 Medivac ND Lasota Vaccine033208 Medivac ND-IB Vaccine084987 Medivac ILT Vaccine033209 Medivac ND Clone 45 Vaccine039940 Medivac IB H-52033212 Medivac ND Hitchner B1 Vaccine107895 Medivac AE Pox131630 Medivac ND La Sota 5000 doses126158 Medivac IB Variant Vaccine
Decision		
Deferred		
Since the Board was apprised by the Division of Pharmaceutical Evaluation & Registration (PE&R) that the applied product is diluent for vaccines, the Board deferred the case and directed the Division of PE&R to forward the application to Division of BE&R for further evaluation and processing.		
Case Category		Import (Najia Saleem)
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		(12H-2GQ-EMPA, 2024-03-25)

	Detail of Fee Submitted	150000.0, 300000.0 2024-01-23, 2024-01-05
	The proposed proprietary name / brand name	DINOLYS
	Label Claim	Each ml contains; Prostaglandin F2 α Tromethamine...5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5 Vials per Box -De-Controlled
	Shelf Life (Unit)	24 Month(s)Store at a cool and dark place
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	Synthetic Prostaglandin Analogue
	Name, address of Manufacturing site:	M/s Ningbo Sansheng Biological Technology Co., Ltd-No.159, Buzheng East Road, Haishu District, Ningbo, Zhejiang, China-China
	GMP status of the firm	Valid Legalized CoPP & GMP has been submitted
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm shall submit fee for pre-approval variation in FPP specifications and since scanned copies of FSC, GMP certificate and LOA submitted, firm shall submit original legalized documents before issuance of registration letter.	
	Decision	
	Deferred	
	for review of formulation by the Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
173	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	ONE HEALTH PHARMA Plot# 28/2-A, SITE Kotri, sindh. (000993)
	Application Form Dy. No / Tracking ID & date of submission	(ARQ-RHQ-WZ16, 2024-05-29)
	Detail of Fee Submitted	30000.0, 2024-05-22,
	The proposed proprietary name / brand name	Tetrasone Aerosol Spray
	Label Claim	Each mL ContainsOxytetracycline HCL 5 mgHydrocortisone 1.6 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 mL-De-Controlled,150 mL-De-Controlled,200 mL-De-Controlled,250 mL-De-Controlled,300 mL- De-Controlled,50 mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Cortisel Aerosol Spray (071079) Star
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The case was deferred in M-344 meeting for submission of evidence of separate dispensing booth for steroids. The firm has submitted that 1. The Route of administration of combination of Oxytetracycline Hcl and Hydrocortisone Aerosol Spray is "Topical". The spray is applied on directly affected skin surface of the animal. This combination is used for various allergic, infectious and traumatic skin conditions. 2. This product combination will be manufactured at our dedicated approved section for Aerosol Sprays " Aerosol Spray Section"	
	Decision Rejected the instant application since the firm does not possess approval of required manufacturing facility / section i.e. Aerosol (Steroid) section from Licensing Division, DRAP.	
174	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate, Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(NXA-3RL-J8LU, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	GUMBO OFF POWDER
	Label Claim	Each 100gm contains:- Ammonium chloride.....30gm Sorbitol.....5gm DL-methionine.....10gm Vitamin A.....15,00,00 iu Vitamin C.....10gm Acetyl salicylic acid.....10gm (As Per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm,-De-Controlled, 10gm-De-Controlled, 10Kg -De-Controlled, 1Kg-De-Controlled, 25 Kg-De-Controlled, 5 Kg -De-Controlled, 500gm-De-Controlled, 50gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	GUMBOSOL POWDER. REG. NO. 063752 (M/S WESTMONT PHARMACEUTICAL INDUSTRY RAWALPINDI)
	Pharmacotherapeutic Group of (API)	Multivitamines /Vitamin-suppliment
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
175	Case Category	Routine (Sabahat Zehra)

Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
Application Form Dy. No / Tracking ID & date of submission	(RDV-XDU-9T1B, 2025-07-06)
Detail of Fee Submitted	37000.0, 2025-07-03,
The proposed proprietary name / brand name	SUPER LYTE C POWDER
Label Claim	Each 100 gm contains:- Paracetamol 2gm Vitamin C(ascorbic acid) 20gm Calcium Carbonate 4.5gm Magnesium Sulphate 3.5gm Potassium Chloride 4gm
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10Kg - De-Controlled,1Kg-De-Controlled,25Kg-De- Controlled,500gm-De-Controlled,50gm-De- Controlled,5Kg-De-Controlled
Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
For generic drugs (me-too Status)	SPIN-C POWDER. Reg. No. 078239 (M/S.LEADS PHARMA (PVT.) LTD. ISLAMABAD)
Pharmacotherapeutic Group of (API)	Anti-Inflammatory/Vitamin
Name, address of Manufacturing site:	--
GMP status of the firm	cGMP compliance (Satisfactory)
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Approved upto 1 KG pack size.	
176	Case Category
	Routine (Sabahat Zehra)
	Name, address of Applicant.
	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission
	(ENZ-A5Q-DQ3A, 2025-07-06)
	Detail of Fee Submitted
	37000.0, 2025-07-03,
	The proposed proprietary name / brand name
	ETER HYDRA WSP
	Label Claim
	Each 100 gm contains:-Glucose.....80gm Chloride 198mg Sodium 170mg Potassium 10mg Calcium 19mg
	Reference to Finished product specifications
	As per Innovators Specification
	Proposed Pack Size
	100gm-De-Controlled,10gm-De-Controlled,10Kg - De-Controlled,1Kg-De-Controlled,25 Kg-De-

		Controlled,500gm-De-Controlled,50gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	HYDRAVET-DMG POWDER REG. NO. 043548 LEADS PHARMA (PVT) LTD., ISLAMABAD
	Pharmacotherapeutic Group of (API)	Vitamin/Supplement
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
177	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	Eterna Pharma Pvt Ltd plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K (000923)
	Application Form Dy. No / Tracking ID & date of submission	(169-M17-L4LT, 2025-07-06)
	Detail of Fee Submitted	37000.0, 2025-07-03,
	The proposed proprietary name / brand name	PARATIN ORAL POWDER
	Label Claim	Each 100gm contains:- Paracetamol..... 20.0gm Vitamin C..... 5.0gm Potassium Carbonate..... 12.5gm Sodium bicarbonate..... 12.5gm Vitamin E..... 12.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10kg - De-Controlled,1Kg,-De-Controlled,25kg-De- Controlled,500gm-De-Controlled,50gm-De- Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25 °C. Protect from light
	For generic drugs (me-too Status)	PARA CE ORAL POWDER. REG. NO. 063812 (M/S BIOGEN PHARMA ISLAMABAD)
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory/Vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP compliance (Satisfactory)
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
	Approved upto 1 kg pack size.	
178	Case Category	Contract Manufacturing (Saima Hussain)

Name, address of Applicant.	Amson Vaccines & Pharma (Pvt.) Ltd. 154, Industrial Triangle, Kahuta Road (000393)
Application Form Dy. No / Tracking ID & date of submission	(9GR-BV3-ED3G, 2024-06-07)
Detail of Fee Submitted	75000.0, 2024-05-08,
The proposed proprietary name / brand name	Cesod 250 mg IM Injection
Label Claim	Each vial contains: Ceftriaxone sodium equivalent to Ceftriaxone USP.....250 mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	24 MonthStore at 15– 25°C
For generic drugs (me-too Status)	Brand name: Oxidil 250 mg (IM) Injection Manufacturer: Sami Pharmaceuticals Generic Name: Ceftriaxone sodium Registration No: 023073
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Arreta Pharmaceuticals (Private) Limited-Arreta Pharmaceuticals (Private) Limited ,Plot No. 13, N-5, Rawat Industrial Estate, Islamabad, Rawalpindi, Islamabad Capital Territory-
Name & address of API manufacturer	Company name: Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China Tel: 0352-7698888 Fax: 0352-7695555
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: Rocephin 250 mg Powder for Solution for Injection Generic name: Ceftriaxone sodium Reference authorities: FDA
GMP status of the firm	
Evidence of approval of manufacturing facility	
Evaluation Remarks	
You are advised to provide correct cross referred product as your reference could not be verified. Firm informed that, "We applied our Toll registration in PRV on 03-06-2025, and we were granted the CESOD IV INJECTION "CEFTRIAZONE SODIUM" ON CONTRACT MANUFACTURING range in September 2025. Therefore, kindly withdraw/cancel our request, as we do not wish to pursue this application further".	
Decision	
Rejected	

	Registration Board acceded the request of the firm regarding the withdraw/cancellation of their instant application.	
179	Case Category	New Section (Saima Hussain)
	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	(D4U-PMV-L9ML, 2024-12-16)
	Detail of Fee Submitted	75000.0, 2024-10-18,
	The proposed proprietary name / brand name	Menaquin K2 180mcg soft gelatin capsule
	Label Claim	Each soft gelatin capsule contains: Menaquinone-7 (vitamin K2) 180mcg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	20's-As per SRO,30's-As per SRO,60'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)	Vitamin K analogue
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Anthem Biosciences Pvt. Ltd, Unit-IV. & Address: Plot No. 276-P, 277-P, Sy No. 20, Bannikuppe Road Harohalli Industrial area, phase-II, Kanakapura Taluk, Ramanagara District.
	Detail of stability batches of drug product	3 batches of 600 capsules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 (License to import Drugs) issued by DRAP I&E Office, Karachi dated 14-04-2023
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence & CDP performed against reference product Vitamin K2 Max of Herbs of Gold
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone IV conditions from Submitted as per Zone IV conditions from Anthem Biosciences , India
	The status in reference regulatory authorities	TGA - Therapeutic Goods Administration
	GMP status of the firm	GMP certificate issued dated 26-06-2023
	Evidence of approval of manufacturing facility	Firm has been granted additional section of "Soft gelatin capsule (General)" vide letter no. F.2-5/2009-Lic (Vol-I) issued by Secretary CLB dated 18-05-2021
Evaluation Remarks		
Registration Board in its 344th meeting decided to deferred due to following reasons: Clarification regarding the status of applied formulation in reference regulatory authorities whether as a drug or otherwise. Documents of procurement of drug substance with approval of DRAP I&E office Firm in their reply stated that, "We would like to intimate to your good office that the RDA value of vitamin K is 150mcg, below this value the product shall proceed with enlistment number but our product strength is 180mcg, therefore the product shall be considered as therapeutic category. However, the drug is approved as listed drug in TGA Australia and according to the TGA, "Listed medicines are low-risk, non-prescription products. They include medicines with ingredients like vitamins, minerals, herbal substances and fish oil. They must be included in the Australian Register of Therapeutic Goods (ARTG) before supply. Listed medicines are not individually assessed by us before supply. They can		

only contain low-risk ingredients and only make low-level health claims. As a sponsor (product owner), you need to self-certify that you comply with all the safety, quality and efficacy requirements that apply to your medicine". Furthermore, vitamin policy has been revised and notified dated 06th August, 2025 and according to the revised policy, formulations containing ingredients above the Tolerable Upper Intake Level (UL) will now be registered as drugs, based on their status with Reference Regulatory Authorities. All other formulations, with ingredients at or below the Tolerable Upper Intake Level (uL), may be enlisted by the Health & OTC (non-drug) Division under their respective rules. According to the UL List, the UL limit vitamin K is 10mg.

Decision

Rejected

The Registration Board rejected the instant application because the approval status of the applied formulation as a pharmaceutical drug has not been confirmed in any Reference Regulatory Authority (RRA) declared by the Registration Board in its 275th meeting.

180	Case Category	New Section (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	Systears Lubricant Eye Drop (0.4 % Polyethylene Glycol 400 and 0.3% Propylene Glycol Lubricant Eye Drop)
	Label Claim	Each mL contains: Polyethylene glycol 400 ----- -----4mg Propylene 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.
	Pharmaceutical 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		
Sr.no.	Decision of 344th meeting of Registration Board	Response of the Firm
1.	Valid DML/GMP certificate of drug substance manufacturers shall be submitted.	Firm submit the Certificate for Registration of DONGYING HI-TECH SPRING CHEMICAL INDUSTRY CO., LTD. No. 23, Zoucheng Road Dongying High-tech Industrial Development Area Dongying Shandong 257100 China in place of GMP certificate of Shandong Shida Shenghua Chemical. In place of GMP Certificate Anhui Eapearl Chemical (Polyethylene Glycol 400), firm submit the safety datasheet of polyethylene glycol of Supplier Anhui Eapearl Chemical Co.Ltd. Economic Development Zone Tongling City, Anhui Province CHINA and the safety datasheet section 1.4 mentioned that “For R&D use only. Not for pharmaceutical, household or other uses.”
2.	Clarification shall be submitted for the method applied for the Assay test of propylene glycol.	The firm submitted an analytical method that is neither in accordance with the USP nor the BP, despite initially claiming that the API (propylene glycol) complies with the USP monograph. Furthermore, both USP and BP monographs require testing for diethylene glycol (DEG) and ethylene glycol (EG) impurities; however, these tests have not been included in the drug substance specification by the drug product manufacturer. In addition, the firm has not submitted the assay validation report for the drug product.
3.	Analytical method verification studies of drug substances and drug product shall be submitted from the drug product manufacturer.	
4.	Batch manufacturing record of stability batches shall be submitted	Firm submitted an incomplete document mentioning only the composition procedure without any performance record.
5.	Documents confirming procurement of drug substance shall be submitted	Firm submit the unendorsed commercial invoice of polyethylene glycol only.
6.	Provide the approval status of applied formulation in the approved RRA ,since the applied formulation has not available on the official website of USFDA.	Initially, the firm provided evidence of the availability of the applied formulation on DailyMed. Upon request to submit evidence from other reference regulatory authorities (RRAs), the firm provided evidence from Health Canada. However, the status of the applied formulation in Health Canada is “Cancelled Post-Market.”
Decision		

Deferred

Deferred for submission of the following documents and clarifications:

1. Justification for not procuring pharmaceutical-grade APIs from GMP-certified sources.
2. Provide complete specifications and detailed analytical methods for both active pharmaceutical ingredients (APIs). Additionally, justify for not performing diethylene glycol (DEG) and ethylene glycol (EG) impurity testing for propylene glycol API, as recommended by both USP and BP monographs.
3. Submit the analytical method validation report of the drug product.
4. Submit complete Batch Manufacturing Records (BMRs) of all stability batches.
5. Submit DRAP-attested documents confirming procurement of both drug substances.
6. Provide approval status of the applied formulation in an approved Reference Regulatory Authority (RRA).

181	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	ACME PHARMACEUTICALS Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat (000967)
	Application Form Dy. No / Tracking ID & date of submission	(EB1-TR1-V2X1, 2025-01-16)
	Detail of Fee Submitted	37000.0, 2025-01-13,
	The proposed proprietary name / brand name	Vita-12 WSP
	Label Claim	Each gram contains: Vitamin A..... 20,000 IU Vitamin B2..... 20mg Vitamin D..... 4000 IU Vitamin B6..... 6mg Vitamin E BP..... 8mg Vitamin B12 BP..... 30mcg Vitamin K..... 9mg Folic Acid..... 2mg Vitamin C coated..... 10mg Nicotinic Acid BP..... 100mg Vitamin B1 1.25mg Calcium Pantothenate BP.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50gm, 100gm, 250gm, -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	SOLUVIT SUPER 04666 by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Multivitamins & Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certificate was granted dated 27.05.2024.
	Evidence of approval of manufacturing facility	
Evaluation Remarks		

	Decision	
	Approved	
182	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(5DH-RYD-18HX, 2025-11-21)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	GAMMAZAN DS PLUS DRENCH
	Label Claim	Each ml Contains: Levamisole HCL BP.....30mg Oxyclozanide BP.....60mg Cobalt Sulphate 3.34mg Sodium Selenite BP.....1.00mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	HELMEX GOLD DRENCH by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
183	Evaluation Remarks	
	Decision	
	Approved	
183	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(7MH-3QS-Z7R3, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Fosfosin Oral Powder
	Label Claim	Each 100gm Contains: Fosfomycin Calcium BP ... 20gm Tylosin as Tartrate USP... 10gm Fructose

		USP... 18gm Sodium Phosphate USP... 15gm Magnesium Phosphate USP... 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	FOSFOVET Oral Powder
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
184	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(7N6-8J2-D9W4, 2025-11-20)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-MECTIN 0.8% Drench
	Label Claim	Each ml Contains: Ivermectin USP.....0.8mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	SUPERMEC DRENCH by M/s Mylab
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
185	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(84J-HXH-1BVT, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Mole- C Oral Powder
	Label Claim	Each 100gm contains: Paracetamol BP... 2 gm Vitamin C (Ascorbic acid) USP ... 20 gm Calcium Carbonate USP... 4.5 gm Potassium Chloride USP... 4 gm Magnesium Sulphate USP... 3.5 gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg- De-Controlled,500Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Paralite-C by M/s Vetz Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antipyretic, Analgesic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
186	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(RU6-9YR-ZRNB, 2025-11-21)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	FLUKE SUPER DRENCH
	Label Claim	Each ml Contains: Oxfendazole USP ... 22.65mg Oxyclozanide BP..... 62.50 mg Cobalt Sulphate

		1.67mg Sodium Selenite BP ... 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	FLUKE FREE SC Oral Liquid by Vetz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
187	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(9BY-9QY-HQML, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	Gamma-NFO Oral Powder
	Label Claim	Each kg Contains: Neomycin Sulphate USP.....14gm Furaltadone as Hcl BP.....30gm Oxytetracycline as Hcl USP.....50gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	O-NEFUR POWDER by A&K Pharmaceutical
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE

		Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
188	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(Y79-9A9-ZPLH, 2025-11-21)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	GAMMAZAN PLUS DRENCH
	Label Claim	Each 100ml Contains: Levamisole Hcl USP ... 1.5gm Oxytoclozanide BP... 3.0gm Cobalt Sulphate Heptahydrate... 0.382gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Oxymisole Oral Liquid by M/s
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
189	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)

	Application Form Dy. No / Tracking ID & date of submission	(DXX-8Q9-L5BU, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Bronex Oral Powder
	Label Claim	Each gm Contains: Bromhexine Hcl USP.....10mg Tartaric Acid USP.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	BRONCHOFIT Powder by Selmore Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
190	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(G83-7TL-LQ74, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Doxytyl Oral Powder
	Label Claim	Each 100gram Contains: Tylosin Tartrate USP 20gm Doxycycline Hyclate USP 40gm Colistin Sulphate USP.....10gm Bromhexine Hcl USP.....2gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Brocotyd Water soluble Powder by M/s Univet Pharmaceutical Rawalpindi
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
191	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	HAAKS Vethum (Pvt) Ltd. Plot No. 60 (B-II), M-3 Industrial City, FIEDMC, Faisalabad (001002)
	Application Form Dy. No / Tracking ID & date of submission	(S86-ARN-WG2Q, 2025-06-28)
	Detail of Fee Submitted	37000.0, 2025-06-27,
	The proposed proprietary name / brand name	NEPHRA GOLD
	Label Claim	Each 1000gm. contains: Furosemide 20 gm Sodium chloride 35 gm Magnesium Sulphate 35 gm Manganese Sulphate 1 gm Calcium Carbonate 45 gm Potassium Chloride 400 mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg, 100 gm, 250gm, 500 gm, 5 Kg, 10 Kg, 20Kg, 25-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature. Avoid exposure to direct sunlight.
	For generic drugs (me-too Status)	Neyphralyte Powder
	Pharmacotherapeutic Group of (API)	Diuretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	DML was granted vide letter dated 03.02.2025.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm was asked to change finished product specifications from manufacturer to innovator specifications, Page of application where specification reference is written as Manufacturer was attached with query, but they replied as "We already write innovator specification in submitted dossier". In Form-5, it is mentioned as manufacturer specifications.	
	Decision	
	Approved	
	Approved subject to change of specifications and submission of pre-registration variation fee.	
192	Case Category	Routine (Sara Mehreen)

Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
Application Form Dy. No / Tracking ID & date of submission	(8XH-54P-H7YY, 2025-06-12)
Detail of Fee Submitted	37000.0, 2025-05-31,
The proposed proprietary name / brand name	OXYTOCIN INJECTION
Label Claim	Each ml Contains Oxytocin USP..... 10.0 IU
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	250ml & 500ml-De-Controlled
Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2 - 8°C). Protect from light.
For generic drugs (me-too Status)	OXYTOCIN
Pharmacotherapeutic Group of (API)	Hormone
Name, address of Manufacturing site:	--
GMP status of the firm	As per inspection conducted on 26.09.2024 "Good compliance was noted at time of inspection".
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Firm was asked to provide product relevant challan as product name on challan is different along with evidence of approval of hormone section. They replied, "IT IS TYPOGRAPHIC MISTAKE The fee paid to DRAP against product this challan is not used in other product. This is to inform you that if there is any requirement to change the specification challan, we have already made the payment and re-deposited the oxytocin challan. The updated challan has already been submitted in the above-mentioned dossier. Additionally, we have received the registration letter from DRAP. We have already registered product of OXYTOXIN INJECTION". However, they neither updated product relevant challan not they provided hormone section approval letter. Submitted for consideration of Board, please.	
Decision	
Rejected	
Rejected due to non-confirmation of hormonal injection section and non-provision of product relevant fee challan.	
193	Case Category
	Routine (Sara Mehreen)
	Name, address of Applicant.
	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission
	(7W8-Z8V-QB4G, 2025-05-02)
	Detail of Fee Submitted
	37000.0, 2025-04-24,
	The proposed proprietary name / brand name
	JF-AMPROX W/S POWDER
	Label Claim
	Each gram Contains Amprolium HCl.....900mg
	Reference to Finished product specifications
	United States Pharmacopeia
	Proposed Pack Size
	500g/1000g/250g/100g-De-Controlled
	Shelf Life (Unit)
	2 Year(s)below 30 degree celcius
	For generic drugs (me-too Status)
	Amprohawk-90 Oral Powder (Reg. No. 118432)
	Pharmacotherapeutic Group of (API)
	Anticoccidial

194	Name, address of Manufacturing site:	--
	GMP status of the firm	Found comply with cGMP in Control, Process and documentation
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm was asked to provide product relevant registration fee challan. They replies as, "The Registration application is attached as uitable challan No 588177748458 dated 22-04-2025. Hence, the fee is deposited to DRAP then it proceeds. The Registration application is attached as challan No 588177748458 dated 22-04-2025. is another product as per your observation but this challan is not used in that product so the fee is paid to DRAP in this product Hence, the fee is deposited to DRAP then it proceeds. For your convenience, we have re-uploaded the challan for the above-mentioned product on the e-portal. The earlier upload contained a minor naming discrepancy; however, we confirm that the full fee has been paid without any shortfall". Firm didn't provide product relevant registration fee challan. Case is submitted for consideration of the Board, please.	
	Decision	
	Rejected	
	Rejected due to non-provision of product relevant registration fee challan.	
	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	DMAARSON PHARMACTUICALS PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD (000744)
	Application Form Dy. No / Tracking ID & date of submission	(UVX-EP8-T8HT, 2025-02-20)
	Detail of Fee Submitted	37000.0, 2024-10-23,
	The proposed proprietary name / brand name	MAXMECTIN 3.15% INJECTION
	Label Claim	Each ml contains (BP) Ivermectin BP..... 31.5 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	ELVOMEK STAR INJECTION 3.15% (063728) ELKO ORGANIZATION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	At the time of inspection firm was operating according to GMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Application was considered and decided as follow in 352nd meeting of Registration Board, "Deferred for review of sub-committee on veterinary drugs regarding therapeutic requirements & dose keeping in view safety efficacy & quality parameters". Case was considered in 8th meeting of Sub-Committee on Veterinary Drugs held on 08-01-2026 and decided as following: "Recommendation of the Sub-committee: Recommended".	
	Decision	
	Approved	

195	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(1N3-GRB-WMDZ, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	Gamma-TFC Powder
	Label Claim	Each kg Contains: Tylosin Tartrate USP.....200gm Furaladone Hcl BP 200gm Colistin Sulphate USP.....10MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled, 100 Gm-De-Controlled, 5 Kg-De-Controlled, 500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s) Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	TY-CO – FURA WATER SOLUBLE POWDER by M/s FARM AID GROUP PAKISTAN, HATTAR, HARIPUR, N.W.F.P.
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
196	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
196	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(3GZ-TU4-URRY, 2025-11-25)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Enrostin Oral Solution
	Label Claim	Each ml Contains: Enrofloxacin USP.....100mg Colistin Sulphate USP..... 500,000IU

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Coliflox Solution by M/s Selmore Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
197	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(EVA-HU4-H485, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Hepa Oral Solution
	Label Claim	Each ml Contains: L-Carnitine BP.....50mg Betain USP.....20mg Inositol USP.....7mg Choline Chloride USP.....100mg Sorbitol USP.....200mg Magnesium Sulphate USP.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Hepawin Solution by M/s Univet Pharmaceutical Rawalpindi
	Pharmacotherapeutic Group of (API)	Liver Tonic
	Name, address of Manufacturing site:	--

	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
198	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(WRS-SZG-J5T1, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Lyzovit-E Oral Powder
	Label Claim	Each 100gm Contains: Lysozyme.....22gm Vitamin E USP: 0.5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	VITOZYME Oral Powder by m/s Selmore Pharmaceutical Pvt Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
199	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)

	Application Form Dy. No / Tracking ID & date of submission	(35M-413-EPYD, 2025-11-21)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-MECTIN 1% Drench
	Label Claim	Each ml Contains: Ivermectin BP 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	GRAND IVERMEC DRENCH ORAL LIQUID M/s Grand pharma
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
200	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(WLD-B6E-2AEQ, 2025-11-27)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Mycin 72% Oral Powder
	Label Claim	Each 100gm Contains: Neomycin Sulfate USP.....72gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	NEOSULPH by M/s ICI Pakistan Ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--

	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
201	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(4AZ-UU6-8PNV, 2025-11-26)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-NFloroxo Oral Powder
	Label Claim	Each gm Contains: Florfenicol 100mg Oxytetracycline HCL USP.....300mg Neomycin Sulphate USP.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	FLOXY-N MAK Water Soluble powder by M/s M.A.kamil Farma Pvt Limited
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
202	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(LLM-QAY-RA2H, 2025-11-20)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Trimizole Oral Drench
	Label Claim	Each ml Contains: Trichlabendazole (USP).....120mg Levamisole (As Hydrochloride) (USP)..75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	LEVATRISOL DRENCH by M/s A & K PHARMACEUTICAL, 94-A PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA ROAD, FAISALABAD.
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
203	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(AYD-QZJ-MM35, 2025-11-20)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Triverzole Drench
	Label Claim	Each 100ml Contains: Trichlabendazole USP.....12gm Ivermectin USP.....0.2gm Albendazole USP.....10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled,50ml-De-

		Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	ABENTIN DRENCH by M/s Selmore
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
204	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	GAMMA PHARMACEUTICAL (PVT) LTD. PLOT#N-28/III S.I.T.E, KOTRI SINDH. (001016)
	Application Form Dy. No / Tracking ID & date of submission	(EMA-14J-L652, 2025-11-24)
	Detail of Fee Submitted	38700, 2025-11-17,
	The proposed proprietary name / brand name	G-Trizole Oral Solution
	Label Claim	Each ml Contains: Trichlabendazole USP.....85 mg Oxfendazole USP 22.65 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	VORCID SUSPENSION (063563) by m/s BREEZE PHARMA
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
205	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(3QE-M8R-X982, 2025-12-05)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Bronate Oral Powder
	Label Claim	Each 1000gm Contain Amoxicillin as Trihydrate BP..... 160gm Clavulanic Acid as Potassium Clavulanate USP 40gm Bromhexine HCL BP.....5gm (As per innovator specifications)}
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container.
	For generic drugs (me-too Status)	calmox powder by evergreen pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic, Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
206	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(4UH-ZP8-RUGV, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Biomencil WSP
	Label Claim	Each kg Contain Amoxicillin as trihydrate BP..... 160gm Colistin Sulphate BP..... 40gm Clavulanic Acid USP..... 40gm (As per innovator specifications)}
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children
	For generic drugs (me-too Status)	augmencil wsp by decent pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
207	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(5MA-L8U-D7TN, 2025-12-01)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	LevaWorm 50 Oral Powder
	Label Claim	Each gm Contain Levamisol HCL BP..... 500mg (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children
	For generic drugs (me-too Status)	Levafic-500 Oral Powder BY M/s Biorific Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
208	Case Category	New License (Sara Mehreen)

	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(5UZ-NAE-G6QT, 2025-12-01)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Medific WSP
	Label Claim	Each gm Contain Amantadine HCL BP..... 100mg (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	ANTAMITS WATER SOLUBLE POWDER by M/s Wimits Pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	Antiviral
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has mentioned proposed dosage in Form-5 as under: "For oral administration = Calves, goats and sheep: Twice daily, 5 g per 100 kg body weight for 3 – 5 days. Poultry: 1 g per 6-8 liters of drinking water for 3 – 5 days. As directed by veterinary prescriber".	
	Decision	
	Deferred	
	The applicant shall revise the target species in light of recommendations of the Expert Working Group.	
209	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(6JV-EV9-G25J, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	TechnoCool WSP
	Label Claim	Each kg Contain Aspirin BP..... 67gm Vitamin C BP..... 200gm Sodium Citrate BP..... 0.7gm Calcium Carbonate BP..... 50gm Sodium Chloride BP..... 40gm Magnesium Sulfate BP..... 40gm } (As per innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	acelyte WSP by decent pharma
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
210	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(898-BW4-LAZE, 2025-12-02)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Techno SB Oral Powder
	Label Claim	{Each 100gm Contain Sulfachlorpyrazine sodium USP.....30gm (As per innovator specifications)}
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Sp-Cox Dry Powder by M/s Biorific Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
211	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)

	Application Form Dy. No / Tracking ID & date of submission	(9AG-LWD-PZZH, 2025-12-01)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Medisol Oral powder
	Label Claim	Each gram Contain Furosemide BP..... 20mg Calcium Carbonate BP 40mg Sodium Chloride BP 35mg Magnesium Sulphate BP 35mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Furisol Oral Powder BY M/s Biorific Pharma
	Pharmacotherapeutic Group of (API)	Diuretic, Electrolyte
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
212	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(AP2-1GA-PL3V, 2025-12-02)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Amcol Water Soluble Powder
	Label Claim	Each kg Contain Amoxicillin as trihydrate BP..... 230gm Colistin Sulphate BP..... 1000Miu (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Senacilin Water Soluble Powder by M/s Decent Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic

	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
213	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(DRW-D78-QD99, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	CoxiCare Oral Powder
	Label Claim	Each kg Contain Sulphaquinoxaline Sodium USP.....200gm Sulphadimidine Sodium EP.....82.5gm Diaveridine Hcl 50gm Vitamin A USP..... 2.5Miu Vitamin k3 BP..... 5g Vitamin E USP..... 5g (As per innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	coxiquake oral powder by decent pharma
	Pharmacotherapeutic Group of (API)	Antibiotic, multivitamins
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
214	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(G2Z-NBQ-2VAT, 2025-12-17)
	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	Enro-10 Oral Liquid

	Label Claim	Each 100ml contains: Enrofloxacin BP 10g (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children
	For generic drugs (me-too Status)	Enro-10 Oral Solution by M/s IPP ISLAMABAD
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
215	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(JUD-22E-81XJ, 2025-12-05)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Techno Prim Oral Liquid
	Label Claim	Each 100ml liquid Contain: Trimethoprim BP..... 8g Sulphadiazine USP..... 40g (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	trimzin suspension by biorific pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
216	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(L1R-PPW-V85V, 2025-12-05)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Aspron Care Oral Powder
	Label Claim	Each 100gm Contain Asprin BP..... 6.8gm Vitamin C BP..... 20gm (As per innovator specifications)}
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container.
	For generic drugs (me-too Status)	asrin-c powder by biorific pharma
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
217	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(MPB-46Y-ASBX, 2025-12-17)
	Detail of Fee Submitted	38700, 2025-12-10,
	The proposed proprietary name / brand name	Curiflush Oral powder
	Label Claim	Each gram Contain: Furosemide BP..... 20mg, Potassium chloride USP 4mg, Calcium Carbonate BP 45mg, Manganese Sulphate BP 1mg, Sodium Chloride BP 35mg, Magnesium Sulphate BP 35mg (As per innovator specification)"
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	arch flush powder by nawal pharmaceuticals
	Pharmacotherapeutic Group of (API)	Diuretic, Electrolyte
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
218	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(NBQ-HXH-HAUB, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Zimself Oral Liquid
	Label Claim	Each 1000ml Contain Selenium BP..... 1670mg Vitamin E USP..... 150000mg Zinc BP..... 8000mg (As per innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	biomix liquid by biorific pharma
	Pharmacotherapeutic Group of (API)	Minerals & vitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
219	Case Category	New License (Sara Mehreen)

Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
Application Form Dy. No / Tracking ID & date of submission	(PTD-RNW-4QDN, 2025-12-17)
Detail of Fee Submitted	38700, 2025-12-10,
The proposed proprietary name / brand name	Technoflox-P Solution
Label Claim	Each 100ml Contain: Pefloxacin methanesulfonate (BP)13.96g eq to Pefloxacin).....10g } (As per innovator specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
For generic drugs (me-too Status)	p-floxasel solution by selmore pharmaceuticals
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	Recommended for DML
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	New License (Sara Mehreen)
Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
Application Form Dy. No / Tracking ID & date of submission	(RSL-TUX-XV8G, 2025-12-10)
Detail of Fee Submitted	38700, 2025-11-26,
The proposed proprietary name / brand name	TechnoQuad Oral Powder
Label Claim	Each gram Contains: Chlortetracycline HCL BP..... 200mg Neomycin Sulphate BP.....60mg Streptomycin Sulphate BP.....20mg Colistin Sulphate BP..... 10mg (As per innovator specifications)}
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.

	For generic drugs (me-too Status)	chlorocept water soluble powder by dmaarson pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
221	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(TU4-UQ9-RBP6, 2025-12-17)
	Detail of Fee Submitted	38700, 2025-12-10,
	The proposed proprietary name / brand name	Nortech AG Solution
	Label Claim	Each 100ml Contain: Norfloxacin BP..... 20g Guaifenesin BP..... 20g Aminophylline BP 8g (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	nor+AG Solution by biogen pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
222	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)

	Application Form Dy. No / Tracking ID & date of submission	(UH2-A8N-RMTP, 2025-12-01)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Medilinc Oral Powder
	Label Claim	{Each 1000gm Contain Lincomycin HCL BP 44g (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Preline Powder BY M/s Biorific Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
223	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(W28-JM4-9A77, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Techo Vita Oral Powder
	Label Claim	Each kg Contain Vitamin A USP 0.8gm Vitamin D3 USP..... 0.16gm Vitamin E USP.....0.38gm Vitamin B1 USP..... 1gm Vitamin B2 USP..... 1.25gm Vitamin B12 USP..... 0.001gm Vitamin B3 USP..... 6.25gm Copper Sulphate BP..... 0.25gm Magnesium Sulphate BP..... 25gm Calcium chloride BP.....0.023gm Zinc Sulphate USP..... 2.17gm Manganese Sulphate BP..... 10gm Potassium Iodide BP..... 0.5gm Sodium Selenite BP..... 0.01gm Dicalcium Phosphate USP 150gm Sodium Chloride BP 120gm Vitamin B6 USP 4gm (As per innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled

	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	white gold powder by leads pharma
	Pharmacotherapeutic Group of (API)	Multivitamin & minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
224	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(YBP-SJH-4VGM, 2025-12-05)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	TecnoCina Oral Liquid
	Label Claim	Each ml Contain Enrofloxacin BP.....75mg Sulphamethoxy pyridazine 75mg Sulphamethazine USP.....50mg Trimethoprim BP.....25mg (As per innovator specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Ensufic Liquid by biorific pharma
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred	
	Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of valid international reference in support of their product.	
225	Case Category	New License (Sara Mehreen)

Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
Application Form Dy. No / Tracking ID & date of submission	(Z89-44V-QAW5, 2025-12-10)
Detail of Fee Submitted	38700, 2025-11-26,
The proposed proprietary name / brand name	Mediotic oral powder
Label Claim	Each 100gm Contain Amoxycillin Trihydrate BP..... 20gm Lincomycin HCL BP.....8.8gm Spectinomycin 2HCL USP..... 8.8gm (As per innovator specifications)
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
For generic drugs (me-too Status)	tribiotic oral powder by decent pharma
Pharmacotherapeutic Group of (API)	Antibiotic
Name, address of Manufacturing site:	--
GMP status of the firm	Recommended for DML
Evidence of approval of manufacturing facility	
Evaluation Remarks	
Decision	
Approved	
Case Category	Routine (Sara Mehreen)
Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
Application Form Dy. No / Tracking ID & date of submission	(MZ5-VH2-JU95, 2025-05-23)
Detail of Fee Submitted	37000.0, 9400 2025-05-21, 2026-01-12
The proposed proprietary name / brand name	JF-FOSTY
Label Claim	Each 100g Contains Fosfomycin Calcium ... 20g Tylosin Tartrate ... 5g Fructose 1,6 Diphosphate ...18g Sodium Phosphate ... 15g Magnesium Phosphate ... 10g Sodium Chloride QS.....100GM
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	Jar 1 Kg & 500 gm-De-Controlled
Shelf Life (Unit)	2 Year(s)Store dry and below 25°C. Do not freeze.
For generic drugs (me-too Status)	FOFACT POWDER by M/s UNIVET PHARMACEUTICALS, 14KM ADYALA ROAD, POST OFFICE DAHGAL, RAWALPINDI.

	Pharmacotherapeutic Group of (API)	Antibacterial & Minerals
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
227	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Jfrin Pharmaceuticals Laboratories Plot No. 16, 17 & 20 Hub Industrial Trading Estate (000580)
	Application Form Dy. No / Tracking ID & date of submission	(HB4-YEW-ZXY7, 2025-05-02)
	Detail of Fee Submitted	37000.0, 2025-04-24,
	The proposed proprietary name / brand name	JF TOLD INJECTION 10%
	Label Claim	Each ml contains Toldimfos Sodium 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml in amber glass -De-Controlled
	Shelf Life (Unit)	2 Year(s)below 30 degree celcius
	For generic drugs (me-too Status)	Metafos Injection
	Pharmacotherapeutic Group of (API)	RESTORATIVE TONIC
	Name, address of Manufacturing site:	--
	GMP status of the firm	cGMP certificate was granted on 26.09.2024.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm was asked to "deposit requisite fee for registration of product and update challan on eAPP interface. Name of product on challan is mentioned as JFCEFTI while applied product is JF-TOLD INJECTION". Firm replied that "it is typographic mistake the fee is paid to DRAP and attached a challan of JF Told Injection" The same JF Told Injection challan (same No. 0213934616) is attached in application of JF Told20% injection. Submitted for consideration of the Board, please.	
	Decision	
	Rejected	
	Rejected due to non-submission of product relevant registration fee challan.	
228	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(TNT-LU2-MGXB, 2025-12-01)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Oflox -10 Oral Liquid
	Label Claim	Each 1000ml Contain Ofloxacin BP 100g (As per Innovator's Specifications*)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50ml,100ml,120ml,200ml,250ml,450ml,500ml and 1000ml / 1Ls.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	Eter Oflo-Cin Oral Liquid by M/s Eterna Pharma
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
229	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(G66-H6Y-282U, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Medrate Oral Powder
	Label Claim	Each gram Contain Fosfomyim Calcium BP.....200mg Tylosin as Tartrate BP 100mg Fructose 1.6 Diphosphate 180mg Sodium Phosphate USP..... 150mg Magnesium Sulphate BP.....100mg (As per innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children.
	For generic drugs (me-too Status)	fostrate powder by biorific powder
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
230	Case Category	New License (Sara Mehreen)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(LE3-V55-G1JN, 2025-12-10)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	Peradal C Oral Powder
	Label Claim	Each 100gm Contain Paracetamol BP..... 2gm Vitamin C (Ascorbic Acid) BP.....20gm Calcium Carbonate BP..... 4.5gm Magnesium Sulphate BP..... 3.5gm Potassium Chloride BP 4gm (As per innovator specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1Kg.-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 degree
	For generic drugs (me-too Status)	paralite-c powder by vetz pharmaceuticals ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
231	Case Category	Routine (Sara Mehreen)
	Name, address of Applicant.	Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454)
	Application Form Dy. No / Tracking ID & date of submission	(933-UYG-XXQ6, 2025-08-22)
	Detail of Fee Submitted	37000.0, 2025-02-06,
	The proposed proprietary name / brand name	Levetram XR 1000mg Tablets
	Label Claim	Each extended release tablet contains; Levetiracetam 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-As per SRO
	Shelf Life (Unit)	24 Year(s)Below 30°C
	For generic drugs (me-too Status)	Xeticam XR 1000mg Tablet
	Pharmacotherapeutic Group of (API)	Antiepileptic

	Name, address of Manufacturing site:	Self Manufacturing
	GMP status of the firm	cGMP certificate was granted on 06.06.2023.
	Evidence of approval of manufacturing facility	DML was renewed vide letter dated 07.07.2021.
	Evaluation Remarks	
	Application was considered in 352nd meeting of the Registration Board and decided as following: "Deferred for evidence of approval of product in RRA". Decision of board was communicated to firm and they replied as., "We would like to further clarify that we had developed our product Levetiracetam XR 1000mg against reference product Xeticam XR 1000 by Getz pharma having Batch number 002FN8, Xeticam XR1000mg is also in Pakistan market rently.However I am providing link of "Media Statement on levetiracetam (KEPPRA® and KEPPRA XR®) where UCB claims that KEPPRA received FDA approval 24 years ago and UCB brands KEPPRA and KEPPRA XR are no longer marketed in the U.S, however across oral, injectable and tablet, over 45 generic versions are available for levetiracetam. No safety or efficacy concerned mentioned by UCB or FDA here for Keppra XR discontinuity". The marketing status of applied formulation (Levetiracetam XR 1000mg) on USFDA website is Discontinued. No other generic of same formulation (Levetiracetam XR 1000mg) is approved by USFDA. Applied formulation (Levetiracetam XR 1000mg) is not present in any other RRA. Moreover, As per FDA Drug Safety Communication, The U.S. FDA is warning that the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, we are requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines. This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas. Case is submitted for consideration of Board, please.	
	Decision	
	Deferred	
	Case was presented in 353rd meeting of Registration Board. The Boad after through deliberations decided to defer the case because of non-confirmation of RRA status of Levetiracetam XR 1000mg. It was further decided to issue show cause notice to already registered Levetiracetam XR 1000mg.	
232	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	ICU Pharmaceuticals (SMC-Private) Limited Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura, (000956)
	Application Form Dy. No / Tracking ID & date of submission	(DB6-DUW-S4W3, 2024-07-18)
	Detail of Fee Submitted	30000.0, 2024-06-14,
	The proposed proprietary name / brand name	Artham Tablets (Artemether 80mg/Lumefantrine 480mg)
	Label Claim	Each Tablet Contains:Artemether.....80mgLumefantrine. Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight

For generic drugs (me-too Status)		Arceva 80/480 Tablets manufactured by SAMI Pharmaceuticals Pvt. Ltd (Reg. No. 058381)
Pharmaceutical 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		WHO prequalified productUSFDA Approved
GMP status of the firm		
Evidence of approval of manufacturing facility		
Evaluation Remarks		
Sr. No	Shortcomings	Replies
1.	Justification shall be submitted for claiming innovator specifications, since Pharmacopoeial monograph is available for applied formulation in International Pharmacopoeia.	Firm stated that they use in-house method for finished product and stability study testing. Once we get registration after we will follow the International Pharmacopoeia method.
2.	Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation since the submitted limits are in contrary to the provision of Pharmacopoeia general monographs for immediate release formulations.	Firm stated that they follow the in-house method for dissolution test. Further There is no dissolution test specified for Artemether Lumefantrine tablet in International pharmacopoeia. Firm submitted literary reference.
3.	Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis.	Firm stated that they follow the in-house method for dissolution. Further There is no dissolution test specified for Artemether Lumefantrine tablet in International pharmacopoeia. Firm submitted literary reference.
4.	Justification shall be submitted that how the “specificity” of the applied drug product analytical method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.	Peak purity submitted by taking RSD of standard. System suitability/RSD submitted
5.	Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed.	Firm stated that their software set upon channel description. Our instrument method has desired wavelength. Instrument method evidence is submitted
6.	Readable copy of the commercial invoice attested by DRAP I&E office shall be submitted for evidence of import of drug substance.	Readable copy of the commercial invoice & commercial invoice with ADC 1731/2022-DRAP dated 3.02.22

7.	Evidence of approval of change of Qualified person form Licensing division shall be submitted.	approval of change of Qualified person record is attached Annex-5
Decision		
Deferred		
Deferred for change of specification's as per International Pharmacopoeia and revise dissolution limits as per Pharmacopoeia general monographs for immediate release formulations.		
233	Case Category	Routine (Shahrukh Ali)
	Name, address of Applicant.	Medezia pharma plot no 20 road ss-1 national industrial zone rawat (001014)
	Application Form Dy. No / Tracking ID & date of submission	(HWB-QUX-146N, 2025-10-07)
	Detail of Fee Submitted	38700, 2025-09-25,
	The proposed proprietary name / brand name	Sulphalium Oral powder
	Label Claim	Each kg contains: Amprolium HCl BP.....300g, Sulphaquinoxaline sodium Bp.....200g, Vitamin K-3 BP..... 6g (As per Innovator's Specifications*)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 50gm,100gm,200gm,250gm,500gm and 1000g / 1K-De-Controlled
	Shelf Life (Unit)	2 Yearstore at room temperaure
	For generic drugs (me-too Status)	Dyecox Water Soluble Powder by decent pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	
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	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	(8ZY-98H-TARU, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.
	Detail of stability batches of drug product	Stability conducted on 3 batches.
	Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability conducted on 3 batches.
	The status in reference regulatory authorities	EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.
Evaluation Remarks		

After evaluating the dossier, certain queries were raised with the firm. The firm's responses, along with the evaluator's remarks, are tabulated below:

Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4 does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Revised Certificate of analysis of API including all test attached in Annexure-1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was issued to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real	Raw data and chromatograms of assay performed at 0, 3 and 6months intervals at both real time	Chromatograms of 5mg injection assay is provided. Audit trail is

	time and accelerated conditions on all applied strengths of Miztide PFP is required along with audit trail.	and accelerated conditions attached in Annexure-4.	provided of single dose strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6month stability, that's why not included. But later on after receiving impurities we performed 9month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.
10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.

Decision

Deferred

Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.

2	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	(DN9-1ZU-MN1U, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16		
Name, address of Manufacturing site:	Self Manufacturing		
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.		
Detail of stability batches of drug product	Stability was conducted on 3 batches.		
Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.		
The status in reference regulatory authorities	EMA Approved		
GMP status of the firm			
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.		
Evaluation Remarks			
After evaluating the dossier, certain queries were raised with the firm. The firm's responses, along with the evaluator's remarks, are tabulated below:			
Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4 does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Revised Certificate of analysis of API including all test attached in Annexure-1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head. All tests are also not performed in stability studies of drug substance.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved.

			Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions on all applied strengths of Miztide PFP is required along with audit trail.	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions attached in Annexure-4.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6 month stability, that's why not included. But later on after receiving impurities we performed 9 month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.

10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.
Decision			
Deferred			
Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.			
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		(N1H-Z63-UURP, 2025-11-19)	
Detail of Fee Submitted		75000.0, 2025-08-08,	
The proposed proprietary name / brand name		MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen	
Label Claim		Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator’s Specs)	
Reference to Finished product specifications		As per Innovators Specification	
Proposed Pack Size		As per SRO-As per SRO	
Shelf Life (Unit)		2 Year(s)Store at 2-8°c	
For generic drugs (me-too Status)		N/A	
Pharmacotherapeutic Group of (API)		Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16	
Name, address of Manufacturing site:		Self Manufacturing	
Name & address of API manufacturer		Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.	
Detail of stability batches of drug product		Stability was conducted on 3 batches.	
Documents for the procurement of API with approval from DRAP (in case of Import)		A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.	
Pharmaceutical Equivalence and Comparative Dissolution Profile		N/A	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability was conducted on 3 batches.	
The status in reference regulatory authorities		EMA Approved	
GMP status of the firm			
Evidence of approval of manufacturing facility		Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.	
Evaluation Remarks			
After evaluating the dossier, certain queries were raised with the firm. The firm’s responses, along with the evaluator’s remarks, are tabulated below:			
Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4	Revised Certificate of analysis of API including all test attached in	Revised Certificate of analysis of API is not

	does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Annexure-1.	provided by manufacturer, rather provided by weather fold on their letter head. All tests are also not performed in stability studies of drug substance.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated	Raw data and chromatograms of assay performed at 0, 3 and 6months intervals at both real time	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose

	conditions on all applied strengths of Miztide PFP is required along with audit trail.	and accelerated conditions attached in Annexure-4.	strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6month stability, that's why not included. But later on after receiving impurities we performed 9month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.
10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.

Decision

Deferred

Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.

4	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	(NU5-V4N-WZNH, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)		Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16	
Name, address of Manufacturing site:		Self Manufacturing	
Name & address of API manufacturer		Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.	
Detail of stability batches of drug product		Stability was conducted on 3 batches.	
Documents for the procurement of API with approval from DRAP (in case of Import)		A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.	
Pharmaceutical Equivalence and Comparative Dissolution Profile		N/A	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability was conducted on 3 batches.	
The status in reference regulatory authorities		EMA Approved	
GMP status of the firm			
Evidence of approval of manufacturing facility		Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.	
Evaluation Remarks			
After evaluating the dossier, certain queries were raised with the firm. The firm's responses, along with the evaluator's remarks, are tabulated below:			
Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4 does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Revised Certificate of analysis of API including all test attached in Annexure-1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head. All tests are also not performed in stability studies of drug substance.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved.

			Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions on all applied strengths of Miztide PFP is required along with audit trail.	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions attached in Annexure-4.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6 month stability, that's why not included. But later on after receiving impurities we performed 9 month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.

10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.
Decision			
Deferred			
Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.			
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		(Q8Q-PRQ-DZW8, 2025-11-19)	
Detail of Fee Submitted		75000.0, 2025-08-08,	
The proposed proprietary name / brand name		MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen	
Label Claim		Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator’s Specs)	
Reference to Finished product specifications		As per Innovators Specification	
Proposed Pack Size		As per SRO-As per SRO	
Shelf Life (Unit)		2 Year(s)Store at 2-8°c	
For generic drugs (me-too Status)		N/A	
Pharmacotherapeutic Group of (API)		Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16	
Name, address of Manufacturing site:		Self Manufacturing	
Name & address of API manufacturer		Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.	
Detail of stability batches of drug product		Stability was conducted on 3 batches.	
Documents for the procurement of API with approval from DRAP (in case of Import)		A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.	
Pharmaceutical Equivalence and Comparative Dissolution Profile		N/A	
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)		Stability was conducted on 3 batches.	
The status in reference regulatory authorities		EMA Approved	
GMP status of the firm			
Evidence of approval of manufacturing facility		Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.	
Evaluation Remarks			
After evaluating the dossier, certain queries were raised with the firm. The firm’s responses, along with the evaluator’s remarks, are tabulated below:			
Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4	Revised Certificate of analysis of API including all test attached in	Revised Certificate of analysis of API is not

	does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Annexure-1.	provided by manufacturer, rather provided by weather fold on their letter head. All tests are also not performed in stability studies of drug substance.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved. Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated	Raw data and chromatograms of assay performed at 0, 3 and 6months intervals at both real time	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose

	conditions on all applied strengths of Miztide PFP is required along with audit trail.	and accelerated conditions attached in Annexure-4.	strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6month stability, that's why not included. But later on after receiving impurities we performed 9month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.
10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.

Decision

Deferred

Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.

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	(QRS-B2R-BZHB, 2025-11-19)
	Detail of Fee Submitted	75000.0, 2025-08-08,
	The proposed proprietary name / brand name	MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen
	Label Claim	Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 2-8°C
	For generic drugs (me-too Status)	N/A

Pharmacotherapeutic Group of (API)	Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16		
Name, address of Manufacturing site:	Self Manufacturing		
Name & address of API manufacturer	Hangzhou Patience Chemical Co., Ltd. Address: No. 6 Xiyuan 7th Road, Sandun Town, Xihu District, Hangzhou, ZheJiang, China.		
Detail of stability batches of drug product	Stability was conducted on 3 batches.		
Documents for the procurement of API with approval from DRAP (in case of Import)	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A		
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Stability was conducted on 3 batches.		
The status in reference regulatory authorities	EMA Approved		
GMP status of the firm			
Evidence of approval of manufacturing facility	Biological Liquid Injection Vial / PFS and Pen Cartridge Section Letter issued on 14-11-2025.		
Evaluation Remarks			
After evaluating the dossier, certain queries were raised with the firm. The firm's responses, along with the evaluator's remarks, are tabulated below:			
Sr.No.	Queries	Response	Remarks
1	Certificate of analysis of drug substance in module 3.2.S.4.4 does not include; peptide mapping, High molecular weight species, cell based bioassay and individual impurities.	Revised Certificate of analysis of API including all test attached in Annexure-1.	Revised Certificate of analysis of API is not provided by manufacturer, rather provided by weather fold on their letter head. All tests are also not performed in stability studies of drug substance.
2	Complete analytical procedures including above mentioned tests and validation of analytical procedures is required under module 3.2.S.4.2 and 3.2.S.4.3.	Complete analytical procedures including above mentioned tests and validation of analytical procedures attached in Annexure-2.	Analytical procedures of product is attached. The query was to provide analytical procedures of API and its validation.
3	Document/evidence for procurement of API i.e. DRAP attested invoice is required along with the quantity imported.	As Evidence for Import Goods Declaration has been already attached. Also we have intimated DRAP about the Import of said material in Query TVQ-HWDJ1WU. Attached along with.	A letter was submitted by the firm to the In-charge, Evaluation Cell to intimate the import of material for stability studies, informing that 100 g of tirzepatide was imported via FedEx/DHL. Previously, six strengths of tirzepatide have already been approved.

			Therefore, the imported quantity is insufficient to cover the applied products, and a justification with calculations is required.
4	Batch analysis of finished product under module 3.2.p.5.4 does not include; High molecular weight species, dose accuracy, phenol content and particulate matter. These tests should also be a part of stability data.	Revised Certificate of analysis of Finish product including all test attached in Annexure-3.	Batch analysis attached.
5	Stability data of all strengths of Miztide PFP in accelerated conditions is not provided.	Stability data of all strengths attached in Annexure-4.	Accelerated summary is provided but High molecular weight species, dose accuracy, phenol content, particulate matter and impurity testing is not performed in accelerated stability studies.
6	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions on all applied strengths of Miztide PFP is required along with audit trail.	Raw data and chromatograms of assay performed at 0, 3 and 6 months intervals at both real time and accelerated conditions attached in Annexure-4.	Chromatograms of 5mg injection assay is provided. Audit trail is provided of single dose strengths. Chromatograms and Audit trail of multi-dose prefilled pen is still required.
7	Impurity testing is not performed at 0, 3 and 6 months intervals in stability studies of any of the applied strength of Miztide PFP neither at real time nor at accelerated conditions. However, impurity testing at 9 months interval at real time conditions is mentioned in stability data of 10mg and 20mg Miztide PFP only. Complete stability data at both real time and accelerated conditions on all parameters is required.	As impurities was not received at the time of 0, 3 and 6 month stability, that's why not included. But later on after receiving impurities we performed 9 month stability with impurities. Data attached in Annexure-5.	Impurity testing at 9 months' time interval is mentioned in real time stability only. Raw data and chromatograms of all strengths is still required.
9	Comparative testing of all strengths of Miztide PFP with the innovator on all parameters is required along with the raw data and chromatograms.	Comparative testing along with raw data and chromatograms attached in Annexure-7.	Raw data and chromatograms of comparative testing with innovator of all applied strengths is required.

10	Complete BMR of all strengths of Miztide PFP is required.	Complete BMR Attached in Annexure-8.	BMR attached. Summary of product characteristics is not provided.
Decision			
Deferred			
Registration Board deferred the case for fulfillment of above mentioned shortcomings/ deficiencies.			
Case Category		Routine (M. Zubair Masood)	
Name, address of Applicant.		SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, (450)	
Application Form Dy. No / Tracking ID & date of submission		(GDJ-HUH-XVA4, 2024-09-13)	
Detail of Fee Submitted		75000.0, 225000.0 2024-05-27, 2024-07-25	
The proposed proprietary name / brand name		ENTROVAC	
Label Claim		Entrovac Vaccine is indicated for individuals from 06 to 71 months old who are susceptible to Enterovirus Type 71. This vaccine can induce immunity against EV71 to prevent hand, foot and mouth disease (HFMD) caused by infection of EV71.	
Reference to Finished product specifications		Manufacturers Specification	
Proposed Pack Size		Box of 1 Dose x 0.5m-Controlled	
Shelf Life (Unit)		36 Months2 to 8 degree Centigrade	
For generic drugs (me-too Status)		N/A	
Pharmacotherapeutic Group of (API)			
Name, address of Manufacturing site:		Institute of Medical Biology Chinese Academy of Me-No.935, Jiaoling Road, Kunming City, Yunnan Province, The People's Republic of China.-China	
Pharmaceutical Equivalence and Comparative Dissolution Profile			
Name, address of Marketing Authorization Holder:		Institute of Medical Biology Chinese Academy of Me, No.935, Jiaoling Road, Kunming City, Yunnan Province, The People's Republic of 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		N/A	
Evaluation Remarks			
The Registration Board in its 348th meeting deferred the case for the evidence of approval of applied vaccine in Reference Regulatory Authority as approved in 275th Meeting of Registration Board and prevalence of strain. The firm submitted the following response" "The Entro Vac® independently developed by IMBCAMS, is the globally first vaccine for preventing Hand, Foot and Mouth Disease (HFMD) that is mainly circulating in Asia-Pacific region. Currently, there are several EV71 vaccines available over the world, but all of them are from P.R. China. Back to the 2015, we launched our Entro Vac® with the approval from China regulatory authority, and followed by two manufacturers in China for licensing their EV71 vaccines in 2016. Another two manufacturers in Taiwan Province, China also did their R&D works on EV71 vaccines but it was far behind us and finally get registration approval			

in2023. Vaccines are different from drugs, i.e. vaccines mainly target the susceptible individuals in the areas where the diseases are prevalent. Therefore, considering the epidemiological characteristics of HFMD, all manufacturers mainly focus on international registration for EV71 vaccines in the Southeast Asia region. Based on available information, in addition to China, the EV71 vaccines are now available only in Thailand and Indonesia. No EV71 vaccine from any manufacturer has been registered in any SRA countries/regions (e.g., US, EU, Japan)." Moreover, the firm has also submitted an article published in "Asia Pacific Journal of Pediatric and Child Health" of year 2018 which is stating that from winter 2016 to spring 2017, they reported an outbreak of the disease in Lahore and central Punjab which was probably due to Enterovirus 71 infection. The authors are 1- Muhammad Ashraf Sultan, Consultant Pediatrician/ Director, Mid-City Hospital, 3A Shadman, Jail Road, Lahore. 2- Muhammad Faheem Afzal, Associate Professor, Pediatrics, King Edward Medical University, Lahore.

Decision

Rejected

Keeping in view the non-availability of formulation in Reference Regulatory Authorities; Registration Board rejected the application.

8	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	2 World Traders Pakistan Office 55/2, Main Khayaban-e-Hafiz DHA Karachi. (634)
	Application Form Dy. No / Tracking ID & date of submission	(QQX-V7Y-XWMA, 2025-06-26)
	Detail of Fee Submitted	300000.0, 2025-03-22,
	The proposed proprietary name / brand name	Abhay TOX Adsorbed Tetanus Vaccine BP
	Label Claim	Each single dose ampoule (0.5 mL) contains: Tetanus Toxoid (Clostridium Tetani No: 49205 Harvard strain).....≥40 IU (5 to 25 Lf)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	120x0.5mL or 10x0.5m-As per SRO
	Shelf Life (Unit)	36 Year(s) 2-8 °C
	For generic drugs (me-too Status)	Yes
	Pharmaco-therapeutic Group of (API)	Bacterial Vaccine
	Name, address of Manufacturing site:	HUMAN BIOLOGICALS INSTITUTE (A Division of Indian -Rakshapuram, Gachibowli Post, Hyderabad-500032, Telangana-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Name, address of Marketing Authorization Holder:	2 World Traders Pakistan, 55/2 Main Khayaban E Hafiz Phase-V, DHA Karachi Pakistan., Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	Scanned copy of Apostille CoPP No. 4411746/TS/2025 dated 11-09-2025.
	Details of Authorization Letter :	Scanned copy of distribution agreement without any date.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Three Batches: TT/BPTT/001/17, TT/BPTT/002/17 and TT/BPTT/003/17) at Real Time (5± 30C) 36 months and Accelerated (25 + 2oC / 60+ 5%) 6 months
	The status in reference regulatory authorities	None
Evaluation Remarks		

Registration Board in its 352nd meeting deferred the case for submission of following clarifications/ documents by the firm: The Phase-III trial performed by your manufacturer was non-inferiority trial, please provide relevant WHO TRS reference that allows extrapolation of indications for a non-inferior vaccine? WHO is recommending reduction/ removal of Thiomersal from formulations, while you are stating its benefits. Legalized CoPP Response: The firm submitted the following: 1. Tetanus Toxoid has been a part of DTP, Pentavalent (DTwP-Hib-HepB) and DT vaccines of Human Biologicals Institute, as a part of childhood vaccines. The non-inferiority trials conducted with these vaccines have proven safety and immunogenicity for all components of the vaccines including tetanus component. It is also part of Td vaccine of Human Biologicals Institute given to adolescents and adults. The trial conducted with this vaccine has also proven its immunogenicity and safety for both the components of the vaccine including for tetanus. 2. It is to clarify that, thiomersal used in Abhay TOX (Adsorbed Tetanus Vaccine) is within the range of limit i.e. 85 % – 115 % w/v recommended by WHO. Annex 5 of WHO Technical Report Series, No.927 - Recommendations to assure the quality, safety and efficacy of tetanus vaccines (adsorbed) (Annexure 1, Page No. 292). The exact statement from WHO TRS 927 Annex 5 Page No. 292 is as follows. "WHO Guidelines on regulatory expectations related to the elimination, reduction or replacement of thiomersal in vaccines should be followed. Determine the amount of antimicrobial preservative by using a suitable chemical method. The amount should be at least 85% and not more than 115% of the intended amount". 3. Scanned copy of Apostille CoPP again submitted.

Decision

Approved

Approved subject to Import Policy for finished drugs.

9	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	TCBP-FMD UVAS RAVI CAMPUS TCBP-FMD UVAS RAVI CAMPUS PATTOKI (000969)
	Application Form Dy. No / Tracking ID & date of submission	(G9E-URA-UT13, 2025-11-18)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	UVAC-FMD Trivalent FMD Vaccine
	Label Claim	Each dose contains: Serotype "O" not less than 3PD ₅₀ Serotype "A" not less than 3PD ₅₀ Serotype "Asia-1" not less than 3PD ₅₀
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	20 ml ; 10 doses-De-Controlled
	Shelf Life (Unit)	2 Year(s) 2 - 8°C
	For generic drugs (me-too Status)	new product registration
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certification is under process
	Evidence of approval of manufacturing facility	Scanned Copy of Section Approval Letter dated 17-02-2023.
	Evaluation Remarks	
	The firm has submitted evidence of application letter submitted for issuance of GMP Certificate dated 13-02-2025.	
	Decision	

	Approved	
10	Case Category	Routine (M. Zubair Masood)
	Name, address of Applicant.	TCBP-FMD UVAS RAVI CAMPUS TCBP-FMDUVAS RAVI CAMPUS PATTOKI (000969)
	Application Form Dy. No / Tracking ID & date of submission	(YPV-XPZ-V1Q4, 2025-11-18)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	UVAC-FMD Trivalent FMD Vaccine
	Label Claim	Each dose contains: Serotype "O".....not less than 3PD ₅₀ Serotype "A".....not less than 3PD ₅₀ Serotype "Asia-1".....not less than 3PD ₅₀
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ml ; 5 doses-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 - 8°C
	For generic drugs (me-too Status)	new product registration
	Pharmacotherapeutic Group of (API)	Veterinary Vaccine
	Name, address of Manufacturing site:	--
	GMP status of the firm	GMP certification is under process
	Evidence of approval of manufacturing facility	Scanned Copy of Section Approval Letter dated 17-02-2023.
	Evaluation Remarks	
	The firm has submitted evidence of application letter submitted for issuance of GMP Certificate dated 13-02-2025.	
	Decision	
	Approved	

Meeting ended with a vote of thanks to and from the Chair.

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